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NOTIFIKAZZJONIJIET TAL-GVERN

Nru. 1192

ATT DWAR IL-PROFESSJONI NUTARILI U ARKIVJI NUTARILI
(KAP. 55)

Nomina ta' Nutar Konservatur

NGĦARRFU b'din illi bis-saħħa tas-setgħat mogħtija bl-artikolu 20 ta' l-Att dwar il-Professjoni Nutarili u Arkivji Nutarili, il-Qorti tar-Reviżjoni ta' l-Atti Nutarili nnominat lin-Nutar Dott. Nicolette Vella, LL.D., bħala Nutar Konservatur ta' l-Atti tan-Nutar Dott. John Debono, LL.D., sakemm dan ikun nieqes minn dawn il-Gżejjer mid-29 ta' Ottubru, 2004 sat-3 ta' Novembru, 2004.

Carmel Muscat
Għar-Reġistratur
Qorti tar-Reviżjoni ta' l-Atti Nutarili

Id-9 ta' Novembru, 2004

Nru. 1193

ATT DWAR IS-SERVIZZI VETERINARJI
(KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regolamenti li ġej skond l-artikoli 8 u 9 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 li jirregolaw il-Kundizzjonijiet ta' Saħħa ta' l-Annimali Ovini u Kaprini fil-Kummerċ Intra-Komunitarju.

Id-19 ta' Novembru, 2004

GOVERNMENT NOTICES

No. 1192

NOTARIAL PROFESSION AND NOTARIAL ARCHIVES ACT
(CAP. 55)

Appointment of Notary Keeper

IT is hereby notified that, in exercise of the powers conferred by section 20 of the Notarial Profession and Notarial Archives Act, the Court of Revision of Notarial Acts has appointed Notary Dr Nicolette Vella, LL.D., to be Notary Keeper for Notary Dr John Debono, LL.D., during the latter's absence from these Islands from the 29th October, 2004 till the 3rd November, 2004.

Carmel Muscat
F/Registrar
Court of Revision of Notarial Acts

9th November, 2004

No. 1193

VETERINARY SERVICES ACT
(CAP 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with articles 8 and 9 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Animal Health Conditions Governing Intra-Community Trade in Ovine and Caprine Animals Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT
(CAP 437)

Animal Health Conditions Governing Intra-Community Trade in Ovine and Caprine Animals Rules, 2004

BY virtues of the powers conferred by articles 8 and 9 of the Veterinary Services Act, the minister for Rural Affairs and the Environment has made the following rules:-

Title, scope and applicability

1. (1) The title of these rules is the Animal Health Conditions Governing Intra-Community Trade in Ovine and Caprine Animals, Rules, 2004.

(2) The scope of these rules is to implement the provisions found under European Union Council Directive 91/68/EEC regarding animal health conditions governing intra-Community trade in ovine and caprine animals.

(3) These rules define the animal health conditions governing exchanges with Member States of European Union in ovine and caprine animals.

(4) For the purposes of these regulations any reference made under European Union Council Directive 91/68/EEC to Annex E has now been harmonised under Commission Regulation (EC) No 599/2004 of the 30th March 2004 concerning the adoption of a harmonised model certificate and inspection report linked to intra-Community trade in animals and products of animal origin:

Provided that the certificate found under commission decision 599/2004 shall apply to these regulations.

Definitions

2. (1) For the purposes of these rules, the definitions given in Article 2 of Directive 90/425/EEC and in Article 2 of Directive 91/628/EEC of 19 November 1991 on the protection of animals during transport and amending Directives 90/425/EEC and 91/496/EEC (1) shall apply as far as applicable.

(2) In addition, the following definitions shall apply for these purposes of these rules -

"the Act" means the Veterinary Services Act;

"assembly centre" means collection centres and markets, at which under the supervision of the official veterinarian ovine and caprine animals originating from different holdings are grouped together to form consignments of animals for national movement;

"approved assembly centre" means premises on which ovine or caprine animals originating from different holdings are grouped together to form consignments of animals intended for intra- Community trade;

"approved dealer's premises" means premises operated by a dealer as defined in these rules and approved by the competent authorities at which ovine or caprine animals originated from different holdings are grouped together to form consignments of animals intended for intra-Community trade;

"brucellosis-free ovine or caprine holding" means a holding which satisfies the conditions laid down in Chapter 2 of Schedule A;

"the Commission" means the European Commission;

"the Community" means the European Community as established under the Treaty establishing the European Community;

"Competent Authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act.

"compulsorily notifiable disease" means a disease listed under Section I of Schedule B;

"dealer" means any natural or legal person who buys and sells animals commercially either directly or indirectly, who has a turnover of these animals and who within a maximum of 29 days of purchasing animals resells them or relocates them from the first premises to other premises or directly to a slaughterhouse not within his ownership;

"holding of origin" means any holding on which the ovine and caprine animals have been continuously present as required by these Rules and on which records are maintained demonstrating the residence of the animals which may be audited by the competent authorities;

"Member State" means a State which is a Member within the European Community;

"official veterinarian" means a veterinarian designated by the competent central authority of the Member State; for Malta, a veterinarian designated by the Veterinary Services.

"officially brucellosis-free ovine or caprine holding" means a holding which satisfies the conditions laid down in Section I of Chapter 1 of Schedule A;

"ovine or caprine animals for breeding" means ovine and caprine animals other than those for slaughter or for fattening intended to be transported to the place of destination, either directly or via an approved assembly centre, for breeding and production purposes;

"ovine or caprine animals for fattening" means ovine and caprine animals other than those for slaughter or for breeding intended to be

transported to the place of destination, either directly or via an approved assembly centre, in order to be fattened for subsequent slaughter;

"ovine or caprine animals for slaughter" means animals of the ovine or caprine species intended to be taken either directly or via an approved assembly centre to a slaughterhouse in order to be slaughtered;

"region" means that part of a Member State's territory which is at least 2000 km^2 in area and which is subject to inspection by the competent authorities and includes at least one of the following administrative regions:

- Belgium: province/provincie
- Germany: Regierungsbezirk
- Denmark: amt or island
- France: department
- Italy: provincial
- Luxembourg
- Netherlands: RVV-kring
- United Kingdom
  England, Wales and Northern Ireland: county
  Scotland: district or island area
- Ireland: county
- Greece: υομς
- Spain: provincial
- Portugal:
  Continent: distrito
  Other parts of Portugal's territory: região autónoma
- Austria: Bezirk
- Sweden: län
- Finland: lääni/län

"transporter" means any natural or legal person referred to in Article 5 of Directive 91/628/EEC;

"Veterinary Services" means the competent authority within the territory of Malta as established under article 2 of the Veterinary Services Act.

Conditions to trade

3. (1) Ovine and caprine animals for slaughter may be the subject of trade only if they fulfil the conditions laid down in rules 4 to 7 of these rules.

(2) Ovine and caprine animals for fattening may be the subject of trade only if they fulfil the conditions laid down in rules 4 to 8 hereof, without prejudice to any additional guarantees which may be required pursuant to rules 10 and 11.

(3) Ovine and caprine animals for breeding may be the subject of trade only if they fulfil the conditions laid down in rules 4 to 9, without prejudice to any additional guarantees which may be required pursuant to rules 10 and 11.

(4) By way of derogation from the provisions in Sub-rules (2) and (3), the competent authorities of Member States of destination may grant general or limited derogations in respect of movement of ovine and caprine animals for breeding and fattening, intended solely for temporary pasturing near internal borders of the Community.

(5) Ovine and caprine animals covered by these rules must at no time between leaving the holding of origin and arriving at destination come into contact with clovenhoofed animals other than animals that have the same health status.

Powers of the Competent Authority

4. (1) Veterinary Services shall ensure that ovine and caprine animals:

(a) are identified and registered in accordance with European Community legislation;

(b) are inspected by an official veterinarian during the 24 hours preceding the loading of the animals, and show no clinical sign of disease;

(c) do not come from a holding, nor have been in contact with animals from a holding, which is the subject of a prohibition on animal health grounds; the period of such prohibition shall last after the slaughter and, or the disposal of the last animal suffering from or susceptible to anyone of the diseases hereunder referred to, for at least:

(i) 42 days in the case of brucellosis,

(ii) 30 days in the case of rabies,

(iii) 15 days in the case of anthrax;

(d) do not come from a holding, nor have been in contact with animals from a holding, situated in an area which for health reasons is subject to a prohibition or restriction affecting the species involved in accordance with European Community and,or national legislation;

(e) are not the subject of animal health restrictions pursuant to European Community legislation on foot-and-mouth disease nor have they been vaccinated against foot-and-mouth disease.

(2) Veterinary Services shall ensure that the following animals are not the subject of trade:

(a) ovine and caprine animals which may have to be slaughtered under a national programme for the eradication of diseases not referred to in

Annex C to Directive 90/425/EEC or in Chapter I of Schedule B to these rules;

(b) ovine and caprine animals which cannot be marketed on their own territory for health or animal health reasons justified by Article 30 of the Treaty of Rome.

(3) Veterinary Services shall ensure that ovine and caprine animals shall:

(a) either have been born and reared since birth in the European Community, or

(b) have been imported from a third country in accordance with European Community legislation.

Movement of animals

5. (1) Veterinary Services shall ensure that ovine and caprine animals for slaughter, breeding and fattening are not dispatched to another Member State, unless the animals:

(a) have been continuously resident on the holding of origin for at least 30 days, or since birth if the animals are younger than 30 days of age,

(b) do not come from a holding into which ovine or caprine animals have been introduced during the 21 days prior to dispatch,

(c) do not come from a holding into which biungulate animals imported from a third country have been introduced during the 30 days prior to dispatch.

(2) By way of derogation from sub-rules (1)(b) and (c) of this rule, Veterinary Services may authorise the dispatch of ovine and caprine animals to another Member State, if the animals referred to in sub-rules (1)(b) and (c) hereof have been completely isolated from all other animals on the holding.

Application of Rules 2 to 9

6. (1) Veterinary Services shall ensure that the conditions set out in rules 2 to 9 are applied to intra-Community trade in all ovine and caprine animals.

(2) The animals shall not be outside their holding of origin for more than six days before being last certified for trade to the final destination in another Member State as indicated in the health certificate.

Provided that without prejudice to rule 15(1) in the case of transport by sea, the time limit of six days shall be prolonged by the duration of the sea journey.

(3) After leaving the holding of origin the animals shall be consigned directly to the destination in another Member State.

(4) By way of derogation from sub-rule (3) hereof, ovine and caprine animals may, after leaving the holding of origin and before arrival at destination in another Member State, transit through only one approved assembly centre situated in the Member State of origin. In the case of ovine and caprine animals for slaughter, the approved assembly centre may be substituted by approved dealer's premises situated in the Member State of origin.

(5) Animals for slaughter which have been taken on arrival in the Member State of destination to a slaughterhouse, must be slaughtered there as soon as possible but at least within 72 hours of arrival.

(6) Without prejudice to rule 3(5), veterinary services shall ensure that the animals covered by these rules at no time, between leaving the holding of origin and their arrival at destination, compromise the health status of ovine and caprine animals not intended for intra-Community trade.

Derogations form rules 5 and 6

7. (1) By way of derogation from rule 5(1)(a), ovine and caprine animals for slaughter may be subject to trade after they have been continuously resident on the holding of origin for at least 21 days.

(2) By way of derogation from rule 5(1)(b), and without prejudice to sub-rule (1) hereof and rule 6(2), ovine and caprine animals for slaughter may be consigned from a holding of origin into which ovine or caprine animals have been introduced during the 21 days prior to dispatch, if they are transported directly to a slaughterhouse in another Member State for immediate slaughter without passing through an assembly centre or staging point established in accordance with Directive 91/628/EEC.

(3) By way of derogation from rule 6(3) and (4), and without prejudice to the provisions in rule 6(2), ovine and caprine animals for slaughter may, after leaving the holding of origin, pass through one additional assembly centre under the following alternative conditions:

(a) the animals, before passing through the approved assembly centre referred to in rule 6(4) which is situated in the Member State of origin, comply with the following conditions:

(i) after leaving the holding of origin the animals pass through one single assembly centre under official veterinary supervision, which permits at the same time only animals of at least the same health status;

(ii) without prejudice to European Community legislation on identification of sheep and goats, at the latest at that assembly centre the animals are individually identified so as to enable in each case the tracing of the holding of origin; and

(iii) from the assembly centre the animals are, accompanied by an official veterinary document, transported to the approved assembly centre referred to in rule 6(4) to be certified and consigned directly to a slaughterhouse in the Member State of destination;

or

(b) the animals may after dispatch from the Member State of origin transit through one approved assembly centre before being consigned to the slaughterhouse in the Member State of destination under the following conditions:

(i) either the approved assembly centre is situated in the Member State of destination from where the animals must be removed under the responsibility of the official veterinarian directly to a slaughterhouse to be slaughtered within five days of arrival at the approved assembly centre, or

(ii) the approved assembly centre is situated in one Member State of transit from where the animals are consigned directly to the slaughterhouse in the Member State of destination indicated in the animal health certificate issued in accordance with rule 15(6).

Further requirements to be met

8. Without prejudice to the additional guarantees that may be required in accordance with rules 10 and 11, ovine and caprine animals for breeding and fattening shall, in addition to the conditions laid down in rule 4, and — in order to be introduced onto an officially brucellosis-free or brucellosis-free ovine or caprine holding respectively meet the requirements of Chapter I.D or Chapter 2.D of Schedule A.

Further requirements for animals for breeding

9. Without prejudice to the additional guarantees that may be required in accordance with rules 10 and 11, animals for breeding must furthermore meet the following requirements:

(a) they must have been obtained from a holding and must only have been in contact with animals from such a holding:

(i) in which the following diseases have not been clinically diagnosed:

(1) in the previous six months, contagious agalactia of sheep *(Mycoplasma agalactiae)* or contagious agalactia of goats *(Mycoplasma agalactiae, M. capricolum, M. Mycoïdes* var. *mycoïdes* 'large colony'),

(2)in the previous 12 months, paratuberculosis or caseous lymphadenitis,

(3) in the previous three years, pulmonary adenomatosis, Maedi Visna or caprine viral arthritis/encephalitis. However, this period shall be reduced to 12 months if the animals infected with Maedi Visna or caprine viral arthritis/encephalitis have been slaughtered and the remaining animals have reacted negatively to two tests recognized by the European Community, which, without prejudice to compliance with the requirements for other diseases, provides, for one or more of the abovementioned diseases, within the framework of a programme approved in accordance with rules 7 and 8, health guarantees which are equivalent for the said disease or diseases;

(ii) where no facts suggesting that the requirements of point (i) have not been met, have been brought to the attention of the official veterinarian responsible for issuing the health certificate;

(iii) whose owner states that he has no knowledge of any such facts and, moreover, states in writing that the animal or animals intended for intra-Community trade comply with the criteria laid down in point (i);

(b) with regard to contagious epidydimitis *(B. ovis)*, non castrated rams, for breeding, must:

(i) come from a holding where no case of contagious epidydimitis *(B. ovis)* has been diagnosed in the preceding 12 months,

(ii) have been continuously kept on that holding for 60 days prior to dispatch,

(iii) in the 30 days prior to dispatch have undergone, with negative results, a serological test carried out in accordance with Schedule D or satisfy equivalent health guarantees to be recognized by the European Community;

(c) the certificate corresponding to Model III of Schedule E states that these requirements have been met.

Powers of the Minister

10. (1). On the basis of a veterinary services proposal, the Minister in charge of Agriculture may define a compulsory or voluntary national control programme or a national monitoring programme for one of the infectious or contagious diseases referred to in Schedule B, Section III for all or part of the territory of Malta and shall submit the said programme to the European Commission, outlining in particular:

(a) the distribution of the disease in the territory of Malta;

(b) the reasons for the programme, taking into consideration the importance of the disease and the programme's likely benefit in relation to its cost,

(c) the geographical area in which the programme will be implemented,

(d) the various status categories to be applied to the holdings, the standards which must be attained in each category, and the test procedures to be used,

(e) the programme monitoring procedures,

(f) the action to be taken if, for any reason, a holding loses its status,

(g) the measures to be taken if the results of the tests carried out in accordance with the provisions of the programme are positive.

(2) After examination by the European Commission, the programme as referred to in sub-rule (1) may be approved, in compliance with the criteria laid down in sub-rule (1), in accordance with the procedure of the European Community. According to the same procedure, the additional guarantees, general or limited, which may be required in intra-Community trade, shall be defined at the same time or at the latest three months after approval of the programmes. Such guarantees must not exceed those which are implemented nationally on the territory of Malta.

(3) Programmes submitted by Malta may be amended or supplemented in accordance with the procedure laid down in sub-rule 2. Amendments or additions to programmes which have already been approved or to guarantees which have been defined in accordance with sub-rule 2 may be approved under the same procedure.

When territory is free from disease

11. (1) Where Malta considers that its territory or part of its territory is free from one of the diseases listed in Schedule B, sections III to which ovine and caprine animals are susceptible, Veterinary Services shall present to the European Commission appropriate supporting documentation, setting out in particular:

(a) the nature of the disease and the history of its occurrence in the territory of Malta;

(b) the results of surveillance testing based on serological, microbiological, pathological or epidemiological investigation and on the fact that the disease must by law be notified to the Veterinary Services,

(c) the period over which the surveillance was carried out,

(d) where applicable, the period during which vaccination against the disease has been prohibited and the geographical area concerned by such prohibition,

(e) the arrangements for verifying the absence of the disease.

(2) After examination by the European Commission of the supporting documentation submitted by Malta, the additional guarantees, general or limited, which may be required in intra-Community trade shall be defined in accordance with the procedure of the European Community. Such guarantees must not exceed those which Malta implements nationally on its territory.

(3) The Veterinary Services shall notify the European Commission of any change in the supporting documentation specified in sub-rule (1) hereof which relate to the disease. The guarantees defined as laid down in sub-rule (2) may, in the light of such notification, be amended or withdrawn in accordance with the procedure laid down in sub-rule (2).

Assembly centres

12. (1) In order to be approved by the Veterinary Services, assembly centres must at least:

(a) be under the control of an official veterinarian who shall ensure that, in particular, the provisions of rule 3(5) are complied with;

(b) be located in an area which is not subject to prohibition or restrictions in accordance with relevant European Community legislation and,or national legislation;

(c) be cleaned and disinfected before use, as required by the official veterinarian;

(d) have, taking into account the animal capacity of the assembly centre:

(i) a facility dedicated exclusively for this purpose when used as an assembly centre;

(ii) appropriate facilities for loading, unloading and adequate housing of a suitable standard for the animals, for watering and feeding them, and for giving them any necessary treatment; these facilities must be easy to clean and disinfect;

(iii) appropriate inspection facilities;

(iv) appropriate isolation facilities;

(v) appropriate equipment for cleaning and disinfecting rooms and trucks;

(vi) an appropriate storage area for fodder, litter and manure;

(vii) an appropriate system for collecting waste water;

(viii) the use of an office for the official veterinarian.

(e) admit only animals which are identified in accordance with European Community legislation and comply with the animal health conditions set down in these rules for the category of animals concerned. To this end, when animals are admitted, the owner or person in charge of the centre shall ensure they are accompanied by health documents or appropriate certificates for the species and categories involved;

(f) be regularly inspected by the Veterinary Services in order to ascertain that the requirements for approval continue to be fulfilled.

(2) The owner or person in charge of the assembly centre shall be required, on the basis either of the accompanying documents for the animals or of the identification numbers or marks of the animals, to record on a register or a database and retain for a minimum period of three years the following information:

(a) the name of the owner, the origin, date of entry and exit, number and identification of the ovine and caprine animals or the registration number of the holding of origin of the animals entering the centre, where applicable the approval or registration number of the assembly centre through which the animals have passed prior to entering the centre and their proposed destination,

(b) the registration number of the transporter and the licence number of the lorry delivering or collecting animals from the centre.

(3) The Veterinary Services shall issue an approval number to each approved assembly centre. Such approval may be limited to one or the other species covered by these rules or to animals for breeding or fattening or to animals for slaughter. The Veterinary Services shall notify the European Commission of the list of approved assembly centres and of any updates.

(4) The Veterinary Services may suspend or withdraw approval in the event of failure to comply with this rule or other appropriate notices in respect of health restrictions. Approval may be restored when the Veterinary Services is satisfied that that assembly centre is in full compliance with all the appropriate provisions of this rule.

(5) The Veterinary Services shall ensure that, when operating, assembly centres have sufficient approved veterinarians to carry out all duties.

(6) Any detailed rules required for uniform application of this rule shall be adopted in accordance with the requirements of the European Community and under the procedure referred to in article 8 of the Veterinary Services Act.

Registration of dealers

13. (1) All dealers are registered and, for the purpose of intra-Community trade, are approved and issued with an approval number by the Veterinary Services and that approved dealers shall comply with at least the following conditions:

(a) they must deal only in animals which are identified and come from holdings that conform with the conditions set out in rule 3. To this end, the dealer shall ensure that the animals are properly identified and are accompanied by health documents as appropriate in accordance with these rules;

(b) the dealer shall be required, either on the basis of the document accompanying the animals, or on the basis of identification numbers or marks on the animals, to keep a record or database and to store the following data for at least three years:

(i) the name of the owner, origin, date of purchase, categories, number and identification of ovine and caprine animals or registration number of the holding of origin of the animals purchased, where applicable, the approval or registration number of the assembly centre through which the animals have passed prior to purchase and their destination,
(ii) the registration number of the transporter and/or the licence number of the lorry delivering and collecting animals,

(iii) the name and address of the purchaser and the destination of the animal,

(iv) copies of route plans and/or serial number of health certificates as applicable;

(c) when the dealer keeps animals on his premises he shall ensure that:
(i) specific training is given to the staff in charge of the animals in applying the requirements of these rules and in the care and welfare of the animals,

(ii) any necessary controls and tests on the animals are carried out regularly by the official veterinarian and that all necessary steps are taken to prevent the spread of disease.

(2) All premises used by a dealer in connection with his business are registered and issued with an approval number by the Veterinary Services and that they shall comply with at least the following conditions:

(a) they must be under the control of an official veterinarian;

(b) they must be located in an area which is not subject to prohibition or restrictions in accordance with relevant European Community or national legislation;

(c) they must have:

(i) appropriate facilities of sufficient capacity and, in particular, inspection facilities and isolation facilities so that all animals can be isolated in the event of an outbreak of a contagious disease;

(ii) appropriate facilities for unloading and where necessary adequate housing of a suitable standard for the animals, for watering and feeding them, and for giving them any necessary treatment; these facilities must be easy to clean and disinfect;

(iii) an appropriate reception area for litter and manure,

(iv) an appropriate system for collecting waste water;

(d) they must be cleaned and disinfected before use, as required by the official veterinarian.

(3) The Veterinary Services may suspend or withdraw approval in the event of failure to comply with these rules other rules in respect of health restrictions. Approval may be restored when the Veterinary Services is satisfied that the dealer is in full compliance with all the appropriate provisions of these rules.

(4) The Veterinary Services must carry out regular inspections in order to ascertain that the requirements of this rule are fulfilled.

Conditions to be fulfilled by transporters

14. (1) The transporters referred to in Article 5 of Directive 91/628/EEC shall meet the following additional conditions:

(a) for the carriage of animals they must use means of transport which are:

(i) constructed in such a way that the animal faeces, litter or feed cannot leak or fall out of the vehicle,

(ii) cleaned and disinfected immediately after every animal transport or that of any product which could affect animal health and if necessary before any new loading of animals, using disinfectants officially authorised by the Veterinary Services;

(b) they must either have appropriate cleaning and disinfection facilities approved by the Veterinary Services, including facilities for storing litter

and dung, or they must provide documentary evidence that these operations are performed by a third party approved by the Veterinary Services.

(2) The transporter must ensure that for each vehicle used for the transport of animals a register is kept containing at least the following information which shall be kept for a minimum period of three years:

(a) places and dates of pick-up, and the name or business name and address of the holding or assembly centre where the animals are picked up,

(b) places and dates of delivery, and the name or business name and address of any consignee,

(c) species and number of animals carried,

(d) date and place of disinfection,

(e) details of accompanying documentation, number, etc.

(3) Transporters shall ensure that the consignment or animals do not at any time, between leaving the holdings or the assembly centre of origin and arriving at their destination, come into contact with animals of a lower health status.

(4) Transporters shall give a written undertaking stating in particular that:

(a) all the measures necessary to comply with these rules shall be taken and in particular the provisions laid down in this rule and relating to the appropriate documentation that must accompany the animals,

(b) the transport of animals is entrusted to staff who possess the necessary ability, professional competence and knowledge.

(5) Article 18 of the European Union Council Directive 91/628/EEC shall apply in a like manner in case of infringement of this rule.

Documents necessary for transportation

15. (1) Ovine and caprine animals must be accompanied during transportation to destination by a health certificate conforming to either model I, II or III set out in Schedule E, as appropriate. The certificate shall consist of a single sheet or, where more than one page is required, shall be in such a form that any two or more pages are part of an integrated whole and indivisible and shall contain a serial number. It shall be drawn up on the day of the health inspection, in one of the official languages of the country of destination at least. The certificate shall be valid for 10 days from the date of the health inspection.

(2) The health inspection for the issuing of the health certificate, including additional guarantees, for a consignment of animals may be carried out in the holding of origin or in an approved assembly centre or, in the case of animals for slaughter, on approved dealer's premises. For this purpose the Veterinary Services shall ensure that any certificate is drawn up by the official veterinarian after inspections, visits and controls as provided by these rules.

(3) The official veterinarian for the assembly centre shall carry out all necessary checks on animals arriving there.

(4) For ovine and caprine animals for fattening and breeding dispatched to another Member State from an approved assembly centre located in the Member State of origin, the health certificate referred to in sub-rule (1) hereof, conforming to either model II or III set out in Schedule E as appropriate, may only be issued on the basis of the checks provided for in sub-rule (3) and of an official document containing the necessary information completed by the official veterinarian responsible for the holding of origin.

(5) For ovine and caprine animals for slaughter dispatched to another Member State from an approved assembly centre or from an approved dealer's premises located in the Member State of origin, the health certificate referred to in paragraph 1, conforming to model I set out in Schedule E, may only be issued on the basis of the checks provided for in sub-rule (3) and of an official document containing the necessary information completed by the official veterinarian responsible for the holding of origin or the assembly centre referred to in rule 7(3)(a)(i).

(6) For ovine and caprine animals for slaughter passing through an approved assembly centre in accordance with rule 4C(3)(b)(ii), the official veterinarian responsible for the approved assembly centre in the Member State of transit shall provide certification to the Member State of destination by issuing a second health certificate, conforming to model I set out in Schedule E, completing it with the requested data from the original health certificate(s) and attaching to it an officially endorsed copy thereof. In this case, the combined validity of the certificates shall not exceed that provided for in sub-rule1.

(7) The official veterinarian issuing a health certificate for intra-Community trade conforming to either model I, II or III set out in Schedule E as appropriate, shall ensure that the movement is recorded in the ANIMO system on the day the certificate is issued.

Applicability of the European Union Council Directive 90/425/EEC

16. (1) The rules laid down in the European Union Council Directive 90/425/EEC shall apply, in particular to checks at origin, to the organization of, and follow-up to, the checks to be carried out at destination, and to the protective measures to be implemented.

Checks and Inspections

17. Veterinary experts from the Commission may, in cooperation with the Veterinary Services, carry out on-the-spot inspections. The Veterinary Services on whose territory inspections are carried out shall afford all necessary aid to the experts in the accomplishment of their task.

18. Concerning checks at destination, where Malta implements an alternative control system providing guarantees equivalent to those laid down in rule 8 and rule 9 and (c) as regards movements within its territory of ovine and caprine animals, Veterinary Services may grant one another derogations from the inspection provided for under rule 4 (1) (b) and the obligation to produce a certificate provided for under rule 15 on a reciprocal basis for Member States which implement an alternative control system providing guarantees equivalent to those laid down in rules 8 and 9 (a) and (c) as regards movements within their territory of ovine and caprine animals. Veterinary Services shall notify the European Commission thereof.

SCHEDULE A

CHAPTER 1

I. **Officially brucellosis *(B. melitensis)*-free ovine or caprine holding**

A. **Grant of status**

An officially brucellosis *(B. melitensis)*-free ovine or caprine holding means

1. a holding:

(a) in which all the animals which are susceptible to brucellosis *(B. melitensis)* have been free from clinical or any other signs of brucellosis *(B. melitensis)* for at least 12 months;

(b) which contains no ovine or caprine animals which have been vaccinated against brucellosis *(B. melitensis),* save those vaccinated at least two years previously with Rev. 1 vaccine or any other vaccine approved under the relevant procedure of the European Community;

(c) in which two tests separated by an interval of six months or more have been carried out, with negative results, in accordance with Schedule C on all ovine and caprine animals on the holding over six months of age at the time of testing; and

(d) in which, following the tests referred to in point (c), there are only ovine or caprine animals born on the holding or which have come from an officially brucellosis-free or brucellosis-free holding under the conditions laid down in point D, and in which, after qualification, the requirements laid down in point B continue to be fulfilled;

2. a holding situated in an "officially recognized brucellosis-free ovine or caprine holding" in a in terms of the definition in rule 2.

B. **Maintenance of status**

1. In the case of officially brucellosis *(B. melitensis)*-free ovine or caprine holdings which are not situated in a part of the territory which is recognized as officially brucellosis-free, and in which, after qualification, the introduction of animals is carried out in accordance with the requirements of point D, a representative number of the ovine and caprine animals over six months old must be checked annually. The holding may retain its officially brucellosis *(B. melitensis)*-free status if the results of the tests are negative. The representative number of animals to be tested must, for each holding, consist of the following:

— all non-castrated male animals over six months old,

— all animals brought onto the holding since the previous test,

— 25 % of the females which have reached the age of reproduction (i.e. which are sexually mature) or are in milk, with a minimum of 50 per holding except in holdings where there are fewer than 50 such females, in which case all females must be tested.

2. For a region which is not officially brucellosis-free where more than 99 % of the ovine or caprine holdings are declared to be officially brucellosis *(B. melitensis)*-free, the frequency of checks of officially brucellosis-free ovine or caprine holdings may be extended to three years, provided that the holdings which are not officially brucellosis free are placed under official control or undergo an eradication programme.

C. **Suspected or actual cases of brucellosis**

1. Where, on an officially brucellosis-free ovine or caprine holding,

(a) one or more ovine or caprine animals are suspected of having brucellosis *(B. melitensis),* the holding's officially brucellosis-free status must be withdrawn by the Veterinary Services. However, that status may be provisionally suspended if the animal or animals are immediately destroyed or isolated, pending official
confirmation of the disease or an official quashing of the suspicion of that disease;

(b) brucellosis *(B. melitensis)* is confirmed, the provisional suspension may be lifted by the Veterinary Services only if all animals infected or all the animals of species susceptible to infection are slaughtered and two tests, separated by an interval of at least three months or more, and carried out in accordance with Schedule C on all the animals of the holding over six months old, give negative results.

2. If the holding referred to in paragraph 1 hereof is in a region which is recognized as officially free from brucellosis *(B. melitensis),* the Veterinary Services concerned must immediately inform the European Commission and the other Member States.

The Veterinary Services must:
(a) order the slaughtering all infected animals and all animals of species susceptible to infection on the holding concerned. The Veterinary Services concerned must keep the European Commission and the other Member States informed of the development of the situation;
(b) conduct an epidemiological enquiry, and the herds linked epidemiologically to the infected herd must undergo the tests laid down in point 1 (b).

3. Should an outbreak of brucellosis be confirmed in accordance with point 2, after assessing of the circumstances of the renewed outbreak of brucellosis *(B. melitensis)* by the European Commission, if that assessment so justifies, a decision suspending or withdrawing the status of that region may be adopted under the relevant procedure of the European Community. If the status is withdrawn, the conditions for a new qualification shall be specified in accordance with the same procedure.

D. **Introduction of animals onto an officially brucellosis (B. melitensis)-free ovine or caprine holding**
Ovine or caprine animals may not be introduced into an ovine or caprine holding which is officially free from brucellosis unless they either:
1. come from an officially brucellosis-free ovine or caprine holding;
2. or:
— come from a brucellosis-free holding and,
— are identified individually in accordance with rule 4 (1) (a) of these rules,
— have never been vaccinated against brucellosis or if they have been vaccinated, were so vaccinated more than two years previously. However, females over two years old which were vaccinated before the age of seven months may also be brought onto the holding, and
— were isolated under official supervision on the holding of origin and, during such isolation underwent, with negative results, two tests separated by an interval of at least six weeks in accordance with Schedule C.

II. **Officially brucellosis-free Member State or region**
Any Member State or region within the meaning of Article 2 (10) of Directive 91/68/EEC may be recognized, under the relevant procedure of the European Community, as being officially brucellosis-free:
1. (a) in which at least 99,8 % of the ovine or caprine holdings are officially brucellosis-free holdings; or
(b) which fulfils the following conditions:
(i) ovine or caprine brucellosis is a disease that has been compulsorily notifiable for at least five years;
(ii) no case of ovine or caprine brucellosis has been officially confirmed for at least five years;
(iii) vaccination has been prohibited for at least three years; and
(c) for which compliance with these conditions has been established under the relevant procedure of the European Community;
2. in which the conditions set out in point 1 have been satisfied; and
(i) (a)the first year following recognition of a Member State or region as brucellosis-free *(Br. melitensis)*, random checks carried out at either holding or slaughterhouse level show with a confidence rating of 99 % that less than 0,2 % of the holdings were infected, or at least 10 % of the ovine and caprine animals over six months of age have undergone a test carried out in accordance with Schedule C with negative results;
(b) annually, from the second year following recognition of a Member State or region as brucellosis-free *(Br. melitensis)*, random checks carried out at either holding or slaughterhouse level show with a confidence rating of 95 % that less than 0,2 % of the holdings were infected, or at least 5 % of the ovine and caprine animals over six months of age have undergone a test carried out in accordance with Schedule C with negative results;

(c) the provisions laid down in the above two indents may be amended in accordance with the relevant procedure of the European Community.
(ii) the conditions for qualification continue to be fulfilled.

CHAPTER 2
Brucellosis *(B. melitensis)*-free ovine or caprine holding
A. **Grant of status**
A. An ovine or caprine holding is considered to be brucellosis *(B. melitensis)* free:
1. in which:
(a) all the animals susceptible to brucellosis *(B. melitensis)* have been free from clinical or other signs of brucellosis for at least 12 months;
(b) all or some of the ovine or caprine animals have been vaccinated with Rev. 1 vaccine or any other vaccine approved under the relevant procedure of the European Community. The vaccinated animals must have been vaccinated before the age of seven months;
(c) two tests separated by an interval of six months or more have been carried out, with negative results, in accordance with Schedule C, on all vaccinated ovine and caprine animals on the holding which are over 18 months old at the time of testing;
(d) two tests separated by an interval of six months or more have been carried out, with negative results, in accordance with Schedule C, on all non-vaccinated ovine and caprine animals on the holding which are over six months old at the time of testing; and
(e) after the tests referred to under points (c) or (d) have been carried out, all the ovine and caprine animals on the holding were either born there or come from a brucellosis-free holding under the conditions laid down in section D; and
2. in which the requirements laid down under paragraph (b) continue to be fulfilled once it has qualified as brucellosis-free.

B. **Maintenance of status**
An annual test must be carried out on a representative number of the ovine and caprine animals on each holding. The holding may retain its status only if the tests are negative.

The representative number of animals to be tested must, for each holding, consist of:
— all non-castrated male animals over six months old which have not been vaccinated,
— all non-castrated male animals over 18 months which have been vaccinated,
— all animals brought onto the holding since the previous test,
— 25 % of females which are of reproductive age (sexually mature) or in milk, with a minimum of 50 per holding except in holdings where there are fewer than 50 such females, in which case all these females must be tested.

C. **Suspected or actual cases of brucellosis**
1. The brucellosis-free status of an ovine or caprine holding must be withdrawn if the holding contains one or more ovine or caprine animals which are suspected of having brucellosis *(B. melitensis)*. However, that status may be provisionally suspended if the animal or animals are immediately destroyed or isolated pending official confirmation of the disease or an official quashing of the suspicion of that disease.

2. If brucellosis *(B. melitensis)* is confirmed, the provisional suspension may be lifted only if all animals infected or all the animals of the species susceptible to infection are slaughtered and two tests, separated by an interval of three months or more and carried out in accordance with Schedule C on,
— all vaccinated animals over 18 months old,
— all non-vaccinated animals over six months old, and both give negative results.

D. **Introduction of animals into a brucellosis (B. melitensis)-free ovine or caprine holding**
The following animals only may be introduced into an ovine or caprine holding which is free from brucellosis:
1. ovine or caprine animals which come from an ovine or caprine holding which is free from or officially free from brucellosis *(B. melitensis);*

2. until the date laid down for holdings to qualify as brucellosis-free in accordance with the eradication plans adopted under Decision 90/242/EEC ovine or caprine animals from holdings other than those referred
to in point 1, provided that they meet the following conditions:
(a) they must be individually identified in accordance with Article 4 (1)(a) of Directive 91/68/EEC;
(b) they must originate in a holding on which all animals belonging to species which are susceptible to brucellosis *(B. melitensis)* have shown no clinical or other signs of brucellosis *(B. melitensis)* for at least 12 months;
(c) (i) (a)they must not have been vaccinated during the previous two years;

(b) they must have been kept under isolation under veterinary supervision on the holding of origin and, during that period, must have undergone, with negative results, two tests separated by an interval of at least six weeks in accordance with Schedule C; or

(ii) they must have been vaccinated with Rev. 1 vaccine or any other vaccine approved in accordance with the relevant procedure of the European Community before the age of seven months and not less than 15 days before entering the holding of destination.

E. **Change of status**
A brucellosis *(B. melitensis)*-free ovine or caprine holding may qualify as an officially brucellosis *(B. melitensis)*-free herd after a minimum period of two years if:
(a) it contains no animal which has been vaccinated against brucellosis *(B. melitensis)* during the preceding two years at least;
(b) the conditions laid down in point D.2. have been complied with throughout that period;
(c) at the end of the second year, a test carried out, in accordance with Schedule C, on all animals aged over six months has in each case given a negative result.

SCHEDULE B

I[1]
— Foot-and-mouth disease
— Brucellosis *(B. melitensis)*
— Contagious epidydimitis *(B. ovis)*
— Anthrax
— Rabies
III
— Contagious agalactia
— Paratuberculosis
— Caseous lymphadenitis
— Pulmonary adenomatosis
— Maedi Visna
— Caprine viral arthritis/encephalitis.

[1] Compulsorily notifiable diseases

SCHEDULE C

Brucellosis *(B. melitensis)* tests

For a holding to qualify for brucellosis-free status, testing for brucellosis *(B. melitensis)* is performed by means of the Rose Bengal method or by the complement-fixation method described in the Schedule F to these rules or by any other method recognized in accordance with the relevant procedure of the European Community. The complement-fixation method is used for tests on individual animals.

When carrying out the Rose Bengal test, if more than 5 % of the animals on a holding show a positive reaction, a further test is carried out on every animal on the holding by means of the complement-fixation method.

Serum containing 20 or more ICFT units/ml must be regarded as positive in the complement-fixation test.

The antigens used must be approved by the national laboratory and must be standardized against the second international standard anti-brucella abortus serum.

SCHEDULE D

Official contagious epidydimitis *(Brucella ovis)* test
Complement-fixing test*:*
The specific antigen used must be approved by the national laboratory and must be standardized against the international standard anti-brucella ovis serum.

The working serum must be standardized with the international standard antibrucella ovis serum prepared by the Central Veterinary Laboratory, Weybridge, Surrey, United Kingdom.

A serum containing 50 or more International Units per/ml must be regarded as positive.

SCHEDULE E

Where in these regulations reference is made to Schedule E of these regulations or Annex E of the European Union Council Directive 91/68/EEC reference should be made to the European Union Commission Regulation (EC) No 599/2004 concerning the adoption of a harmonised model certificate and inspection report linked to intra-Community trade in animals and products of animal origin

Model III

1. **Consignor** (name and address in full)
……
……
……

2. **Consignee** (name and address in full)
……
……
……

5. **Place of loading** ……
……

6. **Means of transport** ([3])
6.1 Type : ……
6.2 Identification :……

8. **Destination of the animals**
8.1 EU Member state :
8.2 Name address and registration number of :
8.2.1 The slaughterhouse([4]):
8.2.2 The approved assembly centre([4])
8.2.3 The approved assembly centre in the Member state of transit([4]) ([6]):
……
……

9. **Number of animals** ……

HEALTH CERTIFICATE ([1]) FOR TRADE BETWEEN MEMBER STATES OF THE EUROPEAN COMMUNITIES IN OVINE AND CAPRINE ANIMALS FOR BREEDING

No ORIGINAL

3. MEMBER STATE……

4. **Competent authority**
4.1 Ministry :……
4.2 Department : ……
……

7. **Establishment(s) of origin**
7.1 Name and address of the holding of origin([4])
……
……
……
……
……

7.2 Name and address and registration number of the approved assembly centre ([4]) or approved dealer premises ([2]) ([4]) :
……
……
……
……

10. **Identification of the animals** :
10.1 Animal specie(s) …… Breed ……
10.2 Individual identification of the animals included in the consignment :

Official individual identification ([7])	Age (months) and Sex (♂♀,castrated)	Number of animals

11. **Origin of the animals**
The animals where either:
(a) born and have been reared since birth on Community territory ([4])
or
(b) imported from a third country satisfying the animal health conditions laid down in Commission Decision 93/198/EEC in accordance with Article 8 of Directive 72/462/EEC ([4])

12.	**Health information** I, the undersigned, certify that the animals described above meet the following requirements:
12.1	they have been inspected today (within 24 hours prior to loading) and show no clinical sign of disease;
12.2	they are not animals which are to be destroyed under a scheme to eradicate a contagious or infectious disease;
12.3	they were they obtained from a holding which is the subject of a prohibition on animal health grounds and they have not been in contact with animals from such a holding, it being understood that:
12.3.1	such prohibition is connected with the outbreak of one of the following diseases to which the animals are susceptible: - brucellosis, - rabies, - anthrax;
12.3.2	after slaughter and/or destruction of the last animal suffering from or susceptible, the duration of the prohibition must be at least: - 42 days in the case of brucellosis, - 30 days in the case of rabies, - 15 days in the case of anthrax;
12.3.3	they do not come from a holding or have been in contact with animals from a holding in a protection zone which has been set up under community legislation and which animals are prohibited to leave;
12.3.4	they are not the subject of animal health measures pursuant to the community legislation on foot-and-mouth disease nor have they been vaccinated against foot-and-mouth disease;
12.4	they have remained on a single of origin for a period of at least 30 days prior to loading, or since birth in the holding of origin where the animals are less than 30 days old, and no animal of the ovine or caprine species has been introduced into the holding of origin during the last 21 days prior to loading and no biungulate animal imported from a third country has been introduced into the holding of origin, unless those animals were introduced in accordance with Article 4a(2) of Directive 91/68/EEC;
12.5	they comply with additional guarantees provided for in Articles 7 or 8 of council Directive 91/68/EEC and laid down for the Member State of destination or part of its territory ……[insert Member State or part of its territory] in Commission Decision …./…./EC ([4])
12.6	they comply with at least one of the following conditions in 12.6.1, 12.6.2 or 12.6.3 and therefore qualify for admission to an ovine or caprine holding which is officially brucellosis-free *(B. melitensis)* ([4])
12.6.1	the holding of origin is situated in a Member state or part of its territory …… [insert Member State or part of its territory] which is recognised as being officially brucellosis free in accordance with Commission Decision …./…./EC ([4]), or
12.6.2	they come from an officially brucellosis-free *(B. melitensis)* ([4]) holding and
12.6.1	they come from a brucellosis-free *(B. melitensis)* holding and (i) they are identified individually, (ii) they have never been vaccinated against brucellosis or if they have been vaccinated were so vaccinated more than two years previously or they are females over two years old which were vaccinated before the age of seven months and (iii) they were isolated under official supervision on the holding of origin and, during such isolation, underwent, with negative results, two tests for brucellosis in accordance with Annex C to Directive 91/68/EEC, separated by an interval of at least six weeks ([4]);

12.7 they comply with at least one of the following conditions in 12.7.1, 12.7.2 or 12.7.3 and therefore qualify for admission to an ovine or caprine holding which is officially brucellosis-free *(B. melitensis)* ([4])

12.7.1 they come from an officially brucellosis-free *(B. melitensis)* holding ([4]); or

12.7.2 they come from a brucellosis-free *(B. melitensis)* holding ([4]); or

12.7.3 until the qualifying date under eradication plans approved pursuant to Decision 90/242/EEC, they originate from a holding other than that referred to in 12.7.1 and 12.7.2 and satisfy the following conditions:

(i) they are identified individually,
(ii) they originate from a holding in which all the animals of species susceptible to brucellosis (B. melitensis) have been free of clinical symptoms or any other symptoms of brucellosis for at least 12 months;
(iii) either

- they have not been vaccinated against brucellosis (B. melitensis) in the last two years, and
- they were isolated under veterinary supervision on the holding of origin and, during such isolation, underwent, with negative results, two tests for brucellosis in accordance with Annex C to Directive 91/68/EEC, separated by an interval of at least six weeks ([4]),

or

- they were vaccinated with Rev. 1 vaccine before the age of seven months but not later than 15 days before their introduction into the holding of destination ([4]);

12.8 as regards contagious epididymitis of rams (B. ovis), where uncastrated breeding rams are concerned, they must:

(i) come from a holding on which no case of contagious epididymitis of rams (B. ovis) has been recorded in the past 12 months and
(ii) have been kept permanently on that holding for the 60 days preceding consignment, and
(ii) have undergone, within 30 days prior to consignment, with a negative result, a complement fixing test to detect contagious epididymitis of rams (B. ovis) in accordance with Annex D to Directive 91/68/EEC;

12.9 to the best of the knowledge of the undersigned and according to the written declaration made by the owner, they were not obtained from a holding nor have not been in contact with animals from a holding in which the following diseases have been clinically detected:

(i) within the last six months, contagious agalactica of sheep (mycoplasma agalactiae) and contagious agalactica of goats (mycoplasma agalactiae, M. capricolum, M. mycoides subsp. mycoides large colony),
(ii) within the last 12 months, paratuberculosis or caseous lymphadenitis,
(iii) within the last three years, pulmonary adenomatosis, maedi/visna or caprine viral arthritis/ ecephalitis. However, this time limit is reduced to 12 months if animals affected by maedi/visna or caprine viral arthritis/ecephalitis have been slaughtered and the remaining animals have reacted negatively to two tests.

12.10 As regards scrapie, the animals:

12.10.1 either have been kept continuously since birth or for the last three years on a holding or holdings which have satisfied the following requirements for at least three years ([4])

(i) it is/they are subject to regular official veterinary checks,
(ii) the animals are marked,
(iii) no case of scrapie has been confirmed,
(iv) checking by sampling of old female animals intended for culling is carried out on the holding(s)
(v) females are introduced into the holding(s) only if they come from a holding which complies with the same requirements; or

12.10.2 are sheep for the ARR/ARR prion protein genotype, as define in Annex I to Commission Decision 2002/1003/EC ([4]),

12.10.3 if they are destined for a Member State which benefit for all or part of its territory, from the provisions laid down in point (b) or (c) of Part I in Chapter A in Annex VIII to Rule (EC) No 999/2001 they comply with the additional guarantees laid down for the Member State of destination or part of its territory …… [insert Member State or part of its territory] in Commission Rule (EC) No …./…. ([4]).

13.1 The animals were transported using means of transport and containment which had, beforehand, been cleaned and disinfected using an officially approved disinfectant, and in such a way as to provide effective protection of the animals' health status.

13.2 Based on the official documentation accompanying the animals the consignment covered by this health certificate started the journey on ……..(insert date) ([5])

13.3 At the time of inspection the animals were fit to be transported on the intended journey in accordance with the provisions of Directive 91/628/EEC ([6])

14. This certificate is valid for 10 days from the date of inspection	
14.1 **Official stamp and signature** Stamp	14.2 **Done at**: …….. (insert place of inspection) 14.3 **Done on**: …….. (insert date of inspection) 14.4 **Signature of official veterinarian** …… ……. (insert name and capacity in block capitals)

([1]) health certificates may be drawn up only for animals which are to be transported in the same railway wagon, truck/lorry, aircraft or boat/ship, which originate from the same holding/assembly centre and which are being sent to the same consignee.
([2]) Give the registration number in the case of railway wagons and lorries/trucks, the flight number in the case of aircraft and the name in case of boats and ships.
([3]) State number and location
([4]) Delete where not applicable.
([5]) In the case where a consignment is grouped in an assembly centre and comprises animals that where loaded on different date, the date at which the journey commenced for the whole consignments is considered to be the earliest date when any part of the consignment left the holding of origin.
([6]) This statement does not exempt transporters from their obligations in accordance with Community provisions in force in particular regarding the fitness of animals to be transported.

Nru. 1194

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regolamenti li ġej skond l-artikoli 8 u 9 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti ma jistabbilixxux biżżejjed l-eżami għal *trichinae (trichinella spiralis)* fuq l-importazzjoni minn pajjiżi terzi ta' laħam frisk derivat minn qżieqeż domestiċi, jew kif ikunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regolameti ta' l-2004 dwar l-Eżami għal *Trichinae (trichinella spiralis)* ma' l-importazzjoni minn Pajjiżi Terzi ta' Laħam Frisk Derivat minn Qżieqeż Domestiċi.

Id-19 ta' Novembru, 2004

No. 1194

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 12 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules do not sufficiently establish the examination for trichinae (*trichinella spiralis*) upon importation from third countries of fresh meat derived from domestic swine, or how they are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

The Examination for Trichinae (*trichinella spiralis*) upon Importation from Third Countries of Fresh Meat Derived from Domestic Swine Rules, 2004

19th November, 2004

VETERINARY SERVICES ACT, 2001 (CAP. 437)

The Examination for Trichinae (*Trichinella Spiralis*) upon Importation from Third Countries of Fresh Meat Derived from Domestic Swine Rules, 2004

IN exercise of the powers conferred under article 12 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, in agreement with the Minister of Health, the Elderly and the Community Care, has made the following rules:-

Title and scope

1. (1) The title of these rules is The Examination for Trichinae (*Trichinella Spiralis*) upon Importation from Third Countries of Fresh Meat Derived from Domestic Swine Rules, 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 77/96/EEC on the Examination for Trichinae (*trichinella spiralis*) upon Importation from Third Countries of Fresh Meat Derived from Domestic Swine.

Definitions

2. For the purposes of these rules, and unless context otherwise requires -

(a) "Competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

(b) "examination" refers to the examination to detect the presence of *trichinae* in fresh meat;

(c) "fresh meat" means fresh meat of domestic swine;

(d) "Member State" means a State which is a Member within the European Community;

(e) "the Commission" means the European Commission;

(f) "the Community" means the European Community as established under the Treaty establishing the European Community;

(g) "Third country" means a State which is not a Member within the European Community;

(h) "Veterinary Services" means the competent authority within the territory of Malta as established under article 2 of the Veterinary Services Act.

Examination of fresh meat originating from Third Countries

3. (1) In order to be admitted to intra-community trade, fresh meat originating in third countries which contains skeletal muscles (striated muscles) shall be examined under the supervision and responsibility of an official veterinarian.

(2) The examination shall be carried out in accordance with one of the methods provided for in Schedule I, on the whole carcass or, failing this, on each half carcass, quarter carcass or piece to be imported into the community.

(3) The examination shall take place in a slaughterhouse approved in the exporting country in accordance with Article 4 of Council Directive 72/462/EEC and authorised to carry out this examination in accordance with rule 4 hereof.

(4) The examination shall take place before the health marking provided for in Article 17(2)(e) of Council Directive 72/462/EEC.

(5) If it is not possible to carry out the examination in the exporting country, the Veterinary Services of Malta for which the fresh meat is intended may authorise its importation provided that the examination is carried out within the European Community territory at the time of the public health inspection provided for in Article 5 of Council Directive 97/78/EEC, at a border inspection post within the meaning of that Directive.

(6) (a) If the outcome of the examination is negative, the fresh meat shall be marked immediately after the examination, in accordance with Schedule III.

(b) In the case of ink stamping, use shall be made of an authorised colorant within the meaning of European Community requirements.

Exemptions from examination

4. (1) By way of derogation from rule 3, the Veterinary Services of Malta for which it is intended may authorise the exemption from examination of fresh meat from certain third countries or parts of such countries, provided it is frozen in accordance with the provisions of Schedule IV.

(2) This treatment shall be carried out in an establishment situated in the exporting third country, and described in rule 5(1) hereof. Freezing in the exporting third country must be the subject of certification by the official veterinarian on the health certificate accompanying the meat, as referred to in Article 22 (1) of Council Directive 72/462/EEC.

(3) If the treatment has not been carried out in the exporting third country, it must be carried out at an inspection post as described in rule 3 (5) hereof. Freezing in the Republic of Malta or in a Member State must be the subject of certification by the official veterinarian on the certificates accompanying the meat, as referred to in Article 5 of Council Directive 77/99/EEC.

Procedure for the authorisation of examination and freezing

5. (1) The authorisation for a slaughterhouse to carry out the examination and of a cutting plant to cut up or bone meat which has undergone such examination, or the authorisation for an establishment to carry out the freezing treatment referred to in rule 4, shall be decided according to the relevant procedure by the European Commission. In addition to the requirements of Article 4 of Council Directive 72/462/EEC, account shall be taken of the guarantees given in respect of compliance with the Council Directive 77/96/EEC and, in the case of slaughterhouses, of -

(a) the presence of the rooms and apparatus necessary for carrying out the examination;

(b) the qualifications of the personnel responsible for carrying out the examination.

Authorisation shall be granted to a slaughterhouse and cutting plant only where the competent authorities of the third country concerned have officially recognised that the slaughterhouse and cutting plant are in a position to satisfy the conditions laid down in Regulation 6 and in Schedule III; also, in the case of a slaughterhouse, that it has a laboratory which complies with the conditions laid down in Schedule II, Chapter I, and which is in a position to satisfy the requirements of the other chapters of Schedule II and those of Schedule I.

Authorisation shall be granted to an establishment to carry out the freezing treatment only if the competent authorities of the third country concerned have officially recognised that the establishment is in a position to satisfy the conditions laid down in Schedule IV.

(2) On any of the lists referred to in Article 4 (4) of Council Directive 72/462/EEC, a special indication shall be inserted against the names of the establishments which have been granted an authorisation within the meaning of sub-rule (1) hereof.

When authorisation is given

6. (1) In slaughterhouses which have been granted an authorisation in accordance with rule 5, swine the meat of which is intended for the community must be slaughtered in different rooms or in the absence thereof at different times from swine the meat of which is not intended for the European Community, unless the meat of such swine is examined in accordance with the same procedure.

(2) The cutting and boning of meat which has undergone an examination with negative results and is intended for the community must be carried out in cutting plants, in accordance with rule 5 hereof. In these cutting plants, the cutting and boning of such meat must be carried out in different rooms or in the absence thereof, at different times from meat which is not intended for the community, unless the meat is examined in accordance with the same procedure.

Application of Council Directive 77/96/EEC

7. The inspections in third countries provided for in Article 5 of Council Directive 72/462/EEC must also verify whether the Council Directive 77/96/EEC is being applied.

List to be Prepared by the Veterinary Services of the Republic of Malta

8. The Veterinary Services of Malta shall draw up and communicate to the European Commission the list of the inspection posts referred to in rule 3 (5) at which:

(a) the examination;

(b) the freezing referred to in rule 4, may be carried out.

They shall ensure that these posts have the equipment necessary for carrying out the operations in question.

Adaptation of the Schedule

9. In the light of technological developments the Schedule to these rules will be adapted according to the European Community requirements; such adaptation must ensure that health guarantees are maintained at their present standard.

SCHEDULE I

Methods of examination for trichinae

1. TRICHINOSCOPIC EXAMINATION

(a) Apparatus
An incandescent lamp trichinoscope with 50 by and 80 to 100 by magnification.

A pressure glass consisting of two glass plates one of which is divided into equal fields small curved scissors, small forceps, a knife for cutting specimens, small numbered containers for storing the specimens separately, a dropping pipette, a glass of acetic acid and a glass of potassium hydroxide solution for brightening any calcifications or softening dried meat.

(b) Taking of Specimens
In the case of whole carcasses, at least one specimen of the size of a hazelnut is to be taken from both diaphragm pillars at the transition of the sinewy part.

If there is only one diaphragm pillar, one specimen the size of two hazelnuts is to be taken. In the absence of both diaphragm pillars, two specimens approximately the size of a hazelnut are to be taken from the rib part or the breastbone part of the diaphragm or, as the case may be, from the lingual muscle or the jaw muscle or from the abdominal muscles.

For pieces of meat, from each piece take three samples of skeletal muscle, containing little fat, if possible the size of a hazelnut, and taken from different points, where possible near to bones or tendons.

(c) Method
If both diaphragm pillars are present the trichinae inspector must cut, from each of the above specimens taken from a whole carcass, seven pieces the size of an oat-kernel making 14 in all; if only one diaphragm pillar is present, 14 pieces, from different places and if possible from the transition to the sinewy part; he must then compress them between the glass plates in such a way that normal print can be clearly read through the slide preparation. If the flesh of the specimens to be examined is dry and old, the preparations must be softened in a mixture of one part potassium hydroxide solution to about two parts water for 10 to 20 minutes before pressing.

If, in the case of whole carcasses, specimens have to be taken from the rib part or the breastbone part of the diaphragm, the lingual muscle or jaw muscle or the abdominal muscles, then 14 pieces the size of an oat-kernal are to be cut from each specimen, i.e. a total of 28.

From each of the samples taken from pieces of meat, the trichinae inspector must cut four pieces the size of an oat-kernal, making 12 pieces in all.

The trichinoscopic examination must be carried out in such a manner that each preparation is scanned slowly and carefully. If the trichinoscopic examination reveals suspect areas, the nature of which cannot be definitely ascertained even with the most powerful magnification of the trichinoscope, these must be checked by microscope.

The microscopic examination should be carried out in such a manner that each preparation is scanned slowly and carefully at a magnification of 30 to 40 X.

In the case of an uncertain result, the examination must be continued on a further number of specimens and slide preparations, if necessary with the aid of higher magnifications, until the information required is obtained.

The trichinoscopic examination must be carried out for at least three minutes.

The trichinoscopic examination must be carried out for at least six minutes in the case of substitute specimens taken from the rib part or breastbone part of the diaphragm pillars, the lingual muscle or the jaw muscle or the abdominal muscles.

The minimum time fixed for the examination does not include the time necessary for sample-taking and for making the preparations. As a general rule, the trichinoscopic examiner should not inspect more than 840 pieces a day, though by way of exception he may inspect up to 1 050.

2. THE ARTIFICIAL DIGESTION METHOD

(a) Apparatus and Material

- knife for taking samples;

- small numbered containers, with closures, for storing samples, if necessary until repetition of the examinations;

- incubator, 2 to 3 litre glass funnel with stand, a connecting hose in rubber, clamps for fastening the connecting hose, a plastic sieve (approximately 18 cm in diameter, and approximately 1 mm mesh);

- gauze;

- a small tapering tube with a sealed end;

- a glass block dish;

- a meat mincer;

- a stereomicroscope (magnification 14 to 40 X) with a suitable light source;

- digestive liquid made up as follows: 10 g of pepsin (80 E/g FIP: Fédération internationale de pharmacie), ml HCl (at least 37%) made up to a litre with tap water.

(b) Taking of Specimens

1. In the case of whole carcasses a sample of at least 20 g to be taken from a diaphragm pillar at the transition to the sinewy part. In the absence of diaphragm pillars a specimen of at least 20 g to be taken from the rib part or the breastbone part of the diaphragm or from the lingual muscle or the jaw muscle or the abdominal muscles;

2. For pieces of meat, a sample of at least 20 g of skeletal muscle to be taken, containing little fat and where possible near to bones or tendons.

(c) Method

For the examination of a collective specimen from 10 pigs, a 10g specimen shall be prepared from each individual 20 g sample. The remaining 10g shall be kept for additional single-specimen examination should this be necessary.

10 specimens, each weighing 10g, shall be combined into a collective specimen; it shall be minced in a meat mincer (with 2 mm perforations) and placed loosely in a sieve lined with a layer of gauze. The sieve shall then be placed in a funnel connected by a length of rubber hose to a small tapered tube with a sealed end; the funnel shall be filled from the edge with digestive liquid until the matter for analysis is completely covered. The proportion of matter for analysis to digestive liquid must be approximately 1:20 to 1:30.

After 18 to 20 hours of incubation at 37 to 39 * C, the small tapered tube shall be disconnected and removed. After carefully drawing off the supernatant liquid, the sediment present in the tip of the

tube is to be carefully rinsed in a dish. Then to be examined for the presence of trichinae with a stereo microscope at 20 to 40 by magnification.

In the case of a positive or doubtful result from the examination of a collective specimen, the remaining single specimens to be examined individually after addition of a further 20 g from each pig, or in the case of pieces of meat, the addition of 20 g taken from each piece, according to (b) above.

3. METHOD USING THE ARTIFICIAL DIGESTION OF COLLECTIVE SAMPLES

(a) Apparatus and reagents

- knife and tweezers for collecting specimens;

- meat mincer with 2 to 3 mm diameter perforations;

- a 3 litre erlenmeyer flask with a rubber or cottonwool plug;

- a conical separation funnel of 2 000 ml capacity;

- an ordinary Abase stand of approximately 28 cm length with an 80 cm stem;

- a ring, diameter approximately 10 to 11 cm which can be fixed to the stand;

- a clamp with a flat vice (23 x 40 mm) which can be attached to the stand by means of a double coupling;

- a sieve (mesh size 177 microns) with an external diameter of 11 cm fitted with brass or stainless steel mesh;

- a funnel with an internal diameter of not less than 12 cm;

- 100 ml glass measuring cylinders;

- a stereomicroscope (magnification 15 to 40x) with a suitable light source, or a trichinoscope with horizontal table for the compressor with suitable light source;

- when using the trichinoscope: a larval counting basin is used which may be described as follows: the larval counting basin is made from 3 mm thick acrylic plates, as follows:

  (i) the bottom of the basin to be 180 x 40 mm, marked off into squares;

  (ii) the sides to be 230 x 20 mm,

  (iii) the end to be 40 x 20 mm. The bottom and the ends should be inserted between the sides, thus forming a basin with two small handles in both ends. The upper side of the bottom should be raised 7 to 9 mm from the base of the frame formed by the sides and the ends. The parts should be fixed by using glue appropriate for the material,

- a number of 9 cm diameter petri dishes (when using stereo microscope) marked on their undersides into 10 x 10 mm square examination areas using a pointed instrument;

- a number of 10 litre bins to be used when applying decontamination, such as formal treatment, to the apparatus and for the remaining digestive juice in the case of positive results;

- concentrated (37 %) hydrochloric acid;

- pepsin strength: 1:10 000NF (US national formulary) corresponding to 1:12 500BP (British Pharmacopoea) corresponding to 2 000FIP (Fédération Internationale de Pharmacie);

- a number of trays which can hold 50 samples of approximately 2g each;

- a balance accurate to 0,1 g.

(b) Collection of specimens

1. In the case of whole carcasses, a specimen to be taken of approximately 2g from a pillar of the diaphragm at the transition to the sinewy part.

In the absence of diaphragm pillars, a specimen of the same size to be taken from the rib part of the breastbone part of the diaphragm, from the lingual muscle or the jaw muscle or the abdominal muscles.

2. For cuts of meat, a sample of approximately 2 g of skeletal muscle to be taken, containing little fat and, where possible, near to bones or tendons.

(c) Method

1. (i) Complete pools (100 samples at a time)
Approximately 1 g of sample shall be taken from each of the 100 individual samples from the pigs. The pooled sample is put once through the mincer.

The minced meat shall be placed in the 3 litre erlenmeyer flask together with 7 g of pepsin, approximately 2 litres of tapwater heated to about 40 to 41 °C and 25 ml of concentrated hydrochloric acid. The mixture shall be shaken to dissolve the pepsin.

The pH of the solution will be about 1, 5 to 2.

- For digestion, the Erlenmeyer flask shall be incubated at 40 to 41 °C for approximately four hours. The flask shall be regularly shaken during the time of incubation, at least twice every hour.

- The digested solution shall be filtered through the sieve into the conical 2 litre separation funnel and left undisturbed on the stand for at least one hour.

- A total volume of approximately 45 ml should be run off into a measuring cylinder and divided between three petri dishes, the bottoms of which should be marked off into squares, with 15 ml in each dish.

- Each petri dish shall be minutely examined for larval trichinae under the stereomicroscope.
- Where larval counting basins are employed, the 45 ml shall be distributed between two larval counting basins and examined under the trichinoscope.

The larvae appear as identifiable organisms in the deposit and often, when the water is lukewarm, rolling and unrolling movements of the "spiral" may be observed.

- Digests should be examined as soon as they are ready. Under no circumstances should examination be postponed until the following day.

If the digests are unclear or not examined within 30 minutes of their preparation, they should be clarified as follows. The final sample of 45 ml is poured into a measuring cylinder and allowed to stand for 10 minutes. At the end of this time, 30 ml of supernatant fluid is removed by suction and the remaining 15 ml is made up to 45 ml with tap-water. After a further settling period of 10 minutes, 30 ml of supernatant fluid is removed by suction and the remaining 15 ml is poured into a

petri dish or larval counting basin for examination. The measuring cylinder should be washed with 10 ml of tapwater and these washings should be added to the sample in the petri dish or larval counting basin for examination.

(ii) Pools of less than 100 samples

Up to 15 single samples could be added to a total pool of 100 samples and be examined together with these samples. If more than 15 samples and less than 100 samples are examined, the digestion fluid should be reduced proportionately.

2. In the case of a positive or doubtful result following the examination of a collective sample, a further 20 g sample should be taken from each pig in accordance with (b) above. The 20 g samples from five pigs should be pooled and examined by the method described above. In this way samples from 20 groups of five pigs will be examined. When trichinellae are detected in a pooled sample from five pigs, further 20 g samples should be collected from the individual pigs in the group and each should separately be examined using the method described above.

4. THE MECHANICALLY ASSISTED POOLED SAMPLE DIGESTION METHOD/SEDIMENTATION TECHNIQUE

(a) Apparatus and reagents

- knife or scissors for cutting specimens;

- trays marked off with 50 squares each of which can hold samples of approximately 2 g of meat;

- a stomacher lab-blender 3 500 thermo model;
- plastic bags suitable for the stomacher lab-blender;

- conical separation funnels of 2 litre capacity, preferably fitted with teflon safety plugs;

- stands, rings and clamps, sieves, mesh size 177 microns, external diameter 11 cm with stainless steel mesh;

- funnels with an internal diameter not less than 12 cm, to support the sieves;

- 100 ml glass measuring cylinders;

- a 25 ml dispenser;

- beakers of 3 litre capacity;

- spoon or glass rod for stirring the digestion fluid in the beaker;

- a plastic syringe and tube for suction;

- a measuring spoon for 6 g;

- a thermometer accurate to C 0, 5 °c within the range 1 to 100 °C;

- a vibrator, e.g. an electric shaver with the head removed;

- a relay which will switch on and off at one minute interval;

- a trichinoscope with a horizontal table or a stereomicroscope, with a suitable light source;

- larval counting basin (when using trichinoscope) : the larval counting basin is made from 3 mm thick acrylic plates as follows:

(i) the bottom of the basin to be 180 x 40 mm, marked off into squares;

(ii) the sides to be 230 x 20 mm;

(iii) the end to be 40 x 20 mm. The bottom and the ends should be inserted between the sides, thus forming two small handles in both ends. The upper side of the bottom should be raised 7 to 9 mm from the base of the frame formed by the sides and the ends. The parts should be fixed by using glue appropriate for the material,

- a number of 9 cm diameter petri dishes (when using stereo microscope) marked on their undersides into 10 x 10 mm square examination areas using a pointed instrument;
- 17, 5 % hydrochloric acid solution,. pepsin strength 1:10 000NF (US national formulary) corresponding to 1:12 500BP (British Pharmacopoea) corresponding to 2 000FIP (Fédération Internationale de Pharmacie);

- a number of 10 litre bins to be used when applying decontamination, such as formal treatment, to the apparatus and for the remaining digestive juice in the case of positive results,

- a balance accurate to 0, 1G.

(b) Collection of specimens

1. In the case of whole carcasses, a specimen to be taken of approximately 2g from a pillar of the diaphragm at the transition to the sinewy part. In the absence of diaphragm pillars, a specimen of the same size to be taken from the rib part or the breastbone part of the diaphragm, from the jaw muscle or the abdominal m
muscle.

2. For cuts of meat, a sample of approximately 2 g of skeletal muscle to be taken, containing little fat and, where possible, near to bones or tendons.

(c) Method

1. Digestion procedure

(i) Complete pools (100 samples at a time)

- the stomacher lab-blender 3 500 should be fitted with a double plastic bag and the temperature control set at 40 to 41 °C;

- one and a half litres of water preheated to about 32 to 35 °C is poured into the inner plastic bag and the water heated to 40 to 41 °C;

- 25 ml of 17, 5 % hydrochloric acid is then added to the water in the stomacher;

- 100 samples of approximately 1 g each (at 25 to 30 °C) taken from each of the individual samples, in accordance with (b), are then added;

- 6 g pepsin is finally added. This order of addition should be strictly adhered to in order to avoid decomposition of the pepsin. The stomacher is then allowed to pound the content of the bag for 25 minutes;

- the plastic bag is then removed from the stomacher and the digestion fluid is filtered through the sieve into a 3 litre beaker;
- the plastic bag is washed with approximately 100 ml of water, which is then used to rinse the sieve and finally added to the filtrate in the beaker;

Up to 15 single samples could be added to a total pool of 100 samples and be examined together with these samples;

(ii) Smaller pools less than 100 samples
- the stomacher lab-blender 3 500 should be fitted with a double plastic bag and the temperature control set at 40 to 41 °C;

- a digestion fluid is prepared by mixing about one and a half litres of water and 25 ml of 17, 5 % hydrochloric acid. 6 g of pepsin is added and the whole mixed at a temperature of 40 to 41 °C. This order of addition should be strictly adhered to in order to avoid decomposition of the pepsin;

- of the digestion fluid, a volume corresponding to 15 ml per gram of sample is measured (e.g. for 30 samples the volume required is 30 x 15 ml or 450 ml) and transferred to the inner of the two plastic bags together with the meat samples of approximately 1 g (at 25 to 3?°C) taken from each of the individual samples in accordance with (b);

- water at a temperature of approximately 41 °C is poured into the outer bag to a total volume in the two bags of one and a half litres;

- the stomacher is then allowed to pound the content of the bag for 25 minutes;

- the plastic bag is then removed from the stomacher and the digestion fluid is filtered through the sieve into a 3 litre beaker;

- the plastic bag is washed with approximately 100 ml of water, which is then used to rinse the sieve and finally added to the filtrate in the beaker.

2. Recovery of larvae by sedimentation

- ice (300 to 400 g of ice flakes, scaly ice or crushed ice) is added to the digestion fluid, bringing its volume up to about 2 litres. The digestion fluid is then stirred until the ice has melted. In the case of smaller pools, the amount of ice should be reduced correspondingly;

- the chilled digestion fluid is transferred to a 2 litre separation funnel, equipped with a vibrator in an extra clamp;

- sedimentation for 30 minutes, during which time the sedimentation funnel is vibrated intermittently, i.e. one minute vibration followed by one minute pause;

- after 30 minutes, a 60 ml sample of the sediment is quickly run off into a 100 ml measuring cylinder, the funnel is rinsed with detergent solution after use;

- the 60 ml sample is allowed to stand for at least 10 minutes, after which time the supernatant should be withdrawn by suction, leaving a volume of 15 ml to be examined for the presence of larvae;

- for suction, a disposable syringe can be used, equipped with a plastic tube. The length of the tube should be such that 15 ml will remain in the measuring cylinder when the flanges of the syringe rest on the cylinder's rim;

- the remaining 15 ml is poured into a larval counting basin or two petri dishes and examined using a trichinoscope or stereo microscope respectively;

- digests should be examined as soon as they are ready. Under no circumstances should examination be postponed until the following day.

If the digests are unclear, or are not examined within 30 minutes of their preparation, they should be clarified as follows. The final sample of 60 ml is poured into a measuring cylinder and allowed to stand for 10 minutes. At the end of.this time, 45 ml of supernatant fluid is removed by suction and the remaining 15 ml is made up to 45 ml with tapwater. After a further settling period of 10 minutes, 30 ml of supernatant fluid is removed by suction and the remaining 15 ml is poured into a petri dish or larval counting basin for examination. The measuring cylinder should be washed with 10 ml of tapwater and these washings should be added to the sample in the petri dish or the larval counting basin for examination.

3. In the case of a positive or doubtful result, following the examination of a collective sample, a further 20 g sample should be taken from each pig in accordance with (b) above. The 20 g samples from five pigs should be pooled and examined by the method described above. In this way, samples from 20 groups of five pigs will be examined. When trichinellae are detected in a pooled sample from five pigs, further 20 g samples should be collected from the individual pigs in the group and each should separately be examined using the method described above.

5. THE MECHANICALLY ASSISTED POOLED SAMPLE DIGESTION METHOD "ON FILTER ISOLATION" TECHNIQUE

(a) Apparatus and reagents

Those indicated in method 4 (a). Supplementary equipment to the above mentioned:

- 1 litre Gelman funnel, complete with filter holder (diameter 45 mm);

- filter discs; the filter discs consist of:
a circular stainless steel mesh with an aperture of 35 microns (the diameter of the disc should be 45 mm), two rubber rings made of 1 mm thick rubber (the external diameter should be 45 mm and the internal diameter 38 mm), the circular mesh is placed between the two rubber rings and bonded to them using a twocomponent glue suitable for the two materials;

- an Erlenmeyer flask with a capacity of 3 litres and fitted with a side tube for suction;

- a filter pump, plastic bags with a capacity of at least 80 ml;

- equipment for sealing the plastic bags;

- rennilase, strength 1:150 000 soxhlet units per gram.

(b) Collection of specimens

See method 4(b).

(c) Method

1. Digestion procedure

(i) Complete pools (100 samples at a time)
See method 4 c (1) (i).

(ii) Smaller pools less than 100 samples
See method 4 c (1) (ii).

2. Recovery of larvae by filtration

- ice (300 to 400 g of ice flakes, scaly ice or crushed ice) is added to the digestion fluid, bringing its volume up to about 2 litres. In the case of smaller pools, the amount of ice should be reduced correspondingly;

- the digestion fluid is then stirred until the ice has melted. The chilled digestion fluid is then left for at least three minutes to let the larvae coil.

- the Gelman funnel, fitted with a filter holder and filter disc, is mounted on the Erlenymeyer flask connected to a filter pump.
- the digestion fluid is poured into the gelman funnel and filtered. Towards the end of filtration, the passage of the digestion fluid through the filter can be assisted by applying suction with the filter pump. Suction should cease before the filter becomes dry, i.e. when 2 to 5 ml of fluid are left in the funnel.

- when all the digestion fluid has been filtered, the filter disc is removed and placed in an 80 ml capacity plastic bag, together with 15 to 20 ml of rennilase solution. The solution of.rennilase is made by adding 2g of rennilase to 100 ml of tapwater.

- the plastic bag is sealed twice and placed in the stomacher between the inner and outer bag.

- the stomacher is allowed to pound for three minutes, e.g. while it is working on a complete or incomplete pool.

- after three minutes, the plastic bag, complete with filter disc and rennilase solution, is removed from the stomacher and opened with scissors. The liquid contents are poured into a larval counting basin or petri dish. The bag is washed out with 5 to 10 ml of water which is then added to the larval counting basin for examination by trichinoscope or to the petri dish for examination by stereomicroscope.

- digests should be examined as soon as they are ready. Under no circumstances should examination be postponed until the following day.

Note
Filter discs should never be used when not completely clean. Unclean discs should never be allowed to dry out. Filter discs can be cleaned by leaving them in rennilase solution overnight. Before use, they should be washed in fresh rennilase solution using the stomacher.

3. In the case of a positive or doubtful result, following the examination of a collective sample, a further 20 g sample should be taken from each pig in accordance with (b) above. The 20 g samples from five pigs should be pooled and examined by the method described above. In this way, samples from 20 groups of five pigs will be examined. When trichinellae are detected in a pooled sample from five pigs, further 20 g samples should be collected from the individual pigs in the group and each should separately be examined using the method described above.

6. THE MAGNETIC STIRRER METHOD FOR POOLED SAMPLE DIGESTION

(a) Apparatus and reagents

- knife and tweezers for cutting specimens;
- trays marked off into 50 squares each of which can hold samples of approximately 2 g of meat;

- a Moulinette blender;

- magnetic stirrers, with thermostatically controlled heating plate and teflon coated stirring rods, approximately 5 cm long;

- conical separation funnels of 2 litre capacity;

- stands, rings and clamps;

- sieves, mesh size 177 microns, external diameter 11 cm with stainless steel mesh;

- funnels with an internal diameter not less than 12 cm, to support the sieves;

- beaker of 3 litre capacity;

- measuring cylinders of approximately 50 ml capacity, or centrifuge tubes;

- a trichinoscope with horizontal table or a stereomicroscope, with a suitable light source;

- larval counting basin (when using trichinoscope): the larval counting basin is made from 3 mm thick acrylic plates as follows:

(i) the bottom of the basin to be 180 x 40 mm, marked off into squares,

(ii) the sides to be 230 x 20 mm,

(iii) the end to be 40 x 20 mm. The bottom and the ends should be inserted between the sides, thus forming two small handles in both ends. The upper side of the bottom should be raised 7 to 9 mm from the base of the frame formed by the sides and the ends. The parts should be fixed by using glue appropriate for the material;

- a number of 9 cm diameter petri dishes (when using stereo microscope) marked on their undersides into 10 x 10 mm square examination areas using a pointed instrument;

- aluminium foil;

- 25 % hydrochloric acid;
- pepsin strength:1:10 000NF (US National Formulary) corresponding to 1:12 500BP (British Pharmacopoea) corresponding to 2 000FIP (Fédération Internationale de Pharmacie);

- tapwater heated to 46 to 48 °C;

- a number of 10 litre bins to be used when applying decontamination, such as formal treatment, to the apparatus and for the remaining digestive juice in the case of positive results;

- a balance accurate to 0, 1G.

(b) Collection of specimens

1. In the case of whole carcasses, a specimen to be taken of approximately 2g from a pillar of the diaphragm at the transition to the sinewy part.
In the absence of diaphragm pillars, a specimen of the same size to be taken from the rib part or the breastbone part of the diaphragm, from the jaw muscle or the abdominal muscles.

2. For cuts of meat, a sample of approximately 2 g of skeletal muscle to be taken, containing little fat and, where possible, near to bones or tendons.

(c) Method

1. (i) Complete pools (100 samples at a time)

- 100 samples of approximately 1 g each, taken from each of the individual samples in accordance with (b), are chopped in the moulinette blender. The blender should be operated three to four times for approximately one second each time.

- the chopped meat is transferred to a 3 litre beaker and sprinkled with 10 g of pepsin. 2 litres of tapwater, preheated to 46 to 48 °C, is poured into the beaker, together with 16 ml of hydrochloric acid.

- the mincing insert of the Moulinette blender is immersed repeatedly in the digestion fluid in the beaker to remove any meat still adhering.

- the stirring rod is placed in the beaker and the beaker is covered with aluminium foil.

- the beaker is placed on the preheated heating plate of the magnetic stirrer and the stirring process started. Before starting the stirring process, the magnetic stirrer should be adjusted so that it maintains a constant temperature of 44 to 46 °C throughout the period of operation. During the stirring process, the digestion fluid should rotate at a sufficiently high speed to create a deep whirl without splashing.
- the digestion fluid is stirred for 30 minutes, at the end of which the stirrer is switched off and the digestion fluid is poured through the sieve into the sedimentation funnel.

- the digestion fluid is allowed to stand in the funnel for 30 minutes.

- after 30 minutes, a 40 ml sample of digestion fluid is quickly run off into the measuring cylinder or centrifuge tube.

- the 40 ml sample is allowed to stand for 10 minutes, at the end of which time 30 ml of supernatant is withdrawn by suction, leaving a volume of 10ml.

- the remaining 10 ml sample of sediment is poured into a larval counting basin or petri dish.

- then the cylinder or centrifuge tube is rinsed with about 10 ml of tap-water which has to be added to the sample in the larval counting basin or petri dish. Subsequently, the sample is examined by trichinoscope or stereomicroscope respectively.

- digests should be examined as soon as they are ready. Under no circumstances should examination be postponed until the following day.

If the digests are not examined within 30 minutes of their preparation, they should be clarified as follows. The final sample of about 40 ml is poured into a measuring cylinder and allowed to stand for 10 minutes, after which time 30 ml of the supernatant fluid is removed leaving a volume of 10 ml. This volume is made up to 40 ml with tap-water. After a further settling period of 10 minutes, 30 ml of the supernatant fluid is withdrawn by suction leaving a volume of 10 ml for examination in a petri dish or larval counting basin. The measuring cylinder should be washed with 10 ml of tap-water and these washings should be added to the sample in the petri dish or the larval counting basin for examination.

If the sediment is found to be unclear on examination, the sample should be poured into a measuring cylinder and made up to 40 ml with tap-water and then the above procedure should be followed.

(ii) Pools of less than 100 samples

When needed, up to 15 samples of 1 g each May be added to a total pool of100 samples and examined together with these samples according to (c) (1) (i). More than 15 samples should be examined as a complete pool. For pools up to 50 samples, the digestion fluid may be reduced to 1 litre.

2. In the case of a positive or doubtful result following the examination of a collective sample, a further 20 g sample should be taken from each pig in accordance with (b) above. The 20 g samples from five pigs should be pooled and examined by the method described above. In this way samples from 20 groups of five pigs will be examined. when trichinellae are detected in a pooled sample from five pigs, further 20 g samples should be collected from the individual pigs in the group and each should separately be examined using the method described above.

7. THE AUTOMATIC DIGESTION METHOD FOR POOLED SAMPLES OF UP TO 35g

(a) Apparatus and reagents

- knife or scissors for cutting specimens,

- trays marked off into 50 squares each of which can hold samples of approximately 2 g of meat,

- a Trichomatic 35 blender with filtration insert,

- hydrochloric acid solution 8.5% ± 0.5 weight,

- transparent polycarbonate membrane filters with a diameter of 50mm and a pore size of 14 microns,

- pepsin strength:1:10 000NF (US National Formulary) corresponding to 1:12 500BP (British Pharmacopoea) corresponding to 2 000FIP (Fédération Internationale de Pharmacie),

- a balance accurate to 0.1g,

- tweezers with a flat tip,

- a number of microscope slides with a side length of at least 5cm or a number of at least 6 cm diameter petri dishes marked on their undersides into 10 x 10 mm large areas using a pointed instrument,

- a stereomicroscope, with a transmitted light (magnification 15 to 60 times) or a trichinoscope with a horizontal table,

- a bin for collection of waste liquids,

- a number of 10 litre bins to be used when applying decontamination, such as formal treatment, to the apparatus and for the remaining digestive juice in the case of positive results,

(b) Collection of specimens

1. In the case of a whole carcass a specimen to be taken of approximately 2g from a pillar of the diaphragm at the transition to the sinewy part. In the absence of diaphragm pillars, a specimen of the same size to be taken from the rib part of the breastbone, part of the diaphragm, from the jaw muscle or the abdominal muscles.

2. For cuts of meat, a sample of approximately 2 g of skeletal muscle to be taken, containing little fat and, where possible, near to bones or tendons.

(c) Method

1. Digestion procedure

- place the blender with filtration insert, connect the waste tube and lead the tube to the waste bi;

- when the blender is switched on, the heatup will start;

- before start, the bottom valve, located below the reaction chamber, should be opened and closed;

- up to 35 samples of approximately 1 g each (at 25 to 30 o C), taken from each of the individual samples in accordance with (b), are then added. Make sure that larger pieces of tendons are removed as this may clot the membrane filter;

- pour water to the edge of a liquid chamber connected to the blender (approximately 400ml);

- pour about 30ml hydrochloric acid (8.5%) t the edge of the smaller, connected liquid chamber;

- place a membrane filter under the coarse filter in the filter holder in the filter insert;

- 7 g of pepsin is added last. The order of addition should be strictly adhered to in order to avoid decomposition of the pepsin;

- close the lids to the reaction and liquid chambers;

- select the period of digestion. Short digestion period (5 minutes) for pigs at normal age of slaughtering and extended digestion time (8 minutes) for other samples;

- the automatic dispensing starts when the start button on the blender is activated and digestion with following filtration will proceed automatically. After 10 to 13 minutes, the process is completed and stops automatically;
- the lid to the reaction chamber is opened once it is checked that the chamber is emptied. If there is foam or remains of digestion liquid in the chamber, repeat the procedure according to point 4;

2. Recovery of larvae
- dismount the filter holder;
- the membrane filter is examined by means of a microscope or a trichinoscope.

3. Cleansing of equipment
- in the case of a positive result, fill the reaction chamber in the blender two thirds with boiling water. Ordinary tap water is poured into the connecting liquid chamber until the lower level sensor is covered. The automatic cleaning program is then carried out. Decontaminate the filter holder together with the remaining equipment, for example by means of formal treatment.

- after the day's work, fill the liquid chamber in the blender with water and carry out a standard program.

4. Use of membrane filters.
Each poly-carbonate membrane filter may be used no more than five times. The filter should be turned between each use. In addition, the filter should be checked after each use for any damage which would make it unsuitable for further use.

5. Method to be used when digestion is incomplete and filtration cannot therefore be carried out.

When the automatic process in the blender is carried out according to point 1, open the lid to the reaction chamber and check whether there is foam or liquid remaining in the chamber. If this is the case, carry out the following procedure:

- close the bottom valve below the reaction chamber;

- dismount the filter holder and transfer the membrane filter to a slide or Petri dish;

- put a new membrane filter in the filter holder and mount the filter holder;

- fill water into the liquid chamber in the blender until the lower level sensor is covered;

- carry out the automatic cleaning program;

- after the cleaning program has been completed open the lid to the reaction chamber and check for liquid remains;
- if the chamber is empty, dismount the filter holder and transfer the membrane filter with a tweezer to a slide or Petri dish

- the two membrane filters are examined according to point 2. If the filters cannot be examined repeat the entire digestion process with extended digestion time, according to point 1.

6. In the case of a positive or doubtful result following the result of a collective sample, a further 20 g sample should be taken from each pig in accordance with point (b) above. These samples shall be investigated individually according to the above mentioned method.

SCHEDULE II

Chapter 1
Conditions for the authorisation of trichinae (trichinella spiralis) laboratories

1. Trichinae laboratories must be situated next to the swine slaughterhouses and, if the establishment does not already possess such facilities to fulfil the other requirements of the Council Directive 77/96/EEC on third countries, have at least the following facilities available:

(a) a lockable room adequately equipped for the preparation of specimens; its walls must be smooth and must be lined with a washable light-coloured covering or paint up to a height of 2 m. A preparation room must be provided for each method of examination used;

(b) an adequately equipped lockable examination room which can be darkened when examination is performed by trichinoscope;

(c) equipment providing adequate ventilation and, if necessary, air conditioning equipment which ensures that the room temperature does not exceed + 25°C;

(d) adequate natural or artificial lighting which does not alter colours; direct sunlight must be avoided;

(e) in the preparation room, adequate equipment for cleaning and disinfecting hands;

(f) possibly, refrigerators in which to store meat samples;

(g) a washroom for cleansing and disinfecting examination equipment (e.g. containers for samples, compressors, knives and scissors), with:

- a waterproof floor-covering which is rot-proof and easy to clean and disinfect,

- smooth walls which, up to a height of at least 2 m, are lined by a washable and light-coloured covering or paint.
This provision need not be applied when using the methods indicated under points ii, iii, iv, v, vi of Schedule I provided the laboratories are equipped with a large suitably plumbed sink.

(h) changing rooms, wash basins and rest rooms and flush lavatories;. (i) wash basins with hot and cold running water, provided with cleansing and disinfecting materials and disposable towels;
(j) watertight corrosion-resistant containers, with hermetically sealed lids, for collecting the samples after examination, and so designed as to prevent unauthorised removal of the contents;

(k) adequate supplies of hot and cold drinking water;

(l) equipment for removing waste water which fulfils the conditions for the authorisation of slaughterhouses;
(m) proper equipment for protection against pests (insects, rodents, etc.).

Chapter 2

Requirements applicable to staff, premises, equipment and instruments in trichinae laboratories

2. Absolute cleanliness is required at all times of laboratory staff, premises, equipment and instruments:

(a) staff must wear clean working clothes and wash their hands several times during working hours and after each break;

(b) no animal may enter trichinae laboratories;

(c) equipment and instruments used must be kept clean and in good repair. They must be carefully cleansed and disinfected several times during and at the end of the day's work.

3. Drinking water must be used for all purposes.

4. As regards health, staff taking meat samples for examination must comply with the European Community rules

5. The meat samples required for examination must be taken immediately after slaughter and examined without delay in the trichinae laboratory of the slaughterhouse. These examinations are forbidden away from the slaughterhouse in which the animals were slaughtered.

6. To avoid fatigue and its consequences, inspection staff should be given short breaks during the working day.

Chapter 3

Requirements in respect of trichinoscopes

The construction and design of trichinoscopes must meet the following minimum criteria:

1. Simple operation.

2. High light intensity:

- accurate results must be obtainable even in a room which is not completely dark,

- a projector bulb of 100 w (12 v) must be used as the light source.

3. Adequate magnification:

- normal working magnification:50 by,

- 80 to 100 by magnification for more precise assessment of objects not clearly identifiable under normal working magnification.

4. Resolving power:

- a clear sharp picture of welldefined colour must be obtainable at each magnification.

5. Switch mechanism:

- each change of magnification must be accompanied by automatic adjustment of the brightness of the image.

6. Increase of contrast:

- the condensor must be provided with an iris diaphragm enabling the contrast to be increased for the closer inspection of difficult cases,

- the iris diaphragm must be easy to operate (e.g. Control lever on the platform of the trichinoscope).

7. Easy focusing:

- rapid focusing by means of an adjusting ring,

- precise focusing by means of a control lever.

8. Voltage regulation:

- so that brightness may be adjusted as required.

9. One-way movement of the compressor:

- an automatic blocking mechanism must ensure that the compressor moves in only one direction, to prevent unintentional displacement.

10. Free view of the projector screen.

11. Projector screen :
- at least 54 cm in diameter,

- high reflecting capability,

- durable,

- can be dismantled,

- easy to clean.

SCHEDULE III

Marking of meat, which has been examined for trichinae

1. Marking of the meat must be carried out under the responsibility of the official veterinarian. For this purpose, he shall keep and maintain:

- the instruments intended for marking which he may hand over to the assistant staff only at the time of marking and for the length of time required for this purpose,

- the tags mentioned in paragraph 5. These tags shall be given to the assistant staff at the time when they must be used and in the required number.

2. The mark must be round with a diameter of 2,5 cm. The following information must appear on the mark in perfectly legible characters:

- towards the centre the capital letter " T " with arms 1 cm long and 0,2 cm wide,

- under the letter " T " one of the following sets of initials: **EEK**. The letters must be 0,4 cm high.

3. Carcasses must be marked in ink or hot-branded on the inside of the thighs, in accordance with paragraph 2.

4. Heads must be marked in ink or hot-branded, with a mark meeting the requirements of paragraph 2.

With the exception of cuts exempt from health marking by virtue of European Community requirements, those taken in cutting plants from carcasses marked in accordance with the rules must, where they bear no stamp, be marked in accordance with paragraph 2 before the health mark is affixed.

The label provided for in the second subparagraph of the above mentioned paragraph 43 must comply with the conditions of paragraph 6 below.

5. Marking may also be effected by means of a round tag. This tag, to be affixed to each piece or to each carcass must not be reusable, must be made of strong materials and must meet all hygiene requirements. The following information must appear on the stamp seals in perfectly legible characters:

- towards the centre the capital letter " T ",

- under the letter " T " one of the following sets of initials: **EEK**. The letters must be 0, 2 cm high.

6. The label affixed to the packages of meat must, in addition to the health mark, bear a clearly legible mark identical to that provided for in paragraph 2.

SCHEDULE IV

The freezing of meat

I. Method I

1. Meat brought in already frozen must be kept in this condition.

2. The technical equipment and energy supply of the refrigerating room, must be such as to ensure that the temperature referred to under paragraph 6 is reached very rapidly and maintained in all parts of the room and of the meat.

3. Insulated packaging should be removed before freezing, except for meat which has already reached throughout the temperature referred to under paragraph 6 when it is brought into the refrigeration room.

4. Consignments in the refrigeration room must be kept separately and under lock.

5. The date and time when each consignment is brought into the refrigeration room must be recorded.

6. The temperature in the refrigeration room must be at least -25 °C. It should be measured with calibrated thermoelectric instruments and continuously recorded. It may not be measured directly in the cold airflow. The instruments must be kept under lock. The charts must include the relevant numbers from the meat inspection register on importation and the date and time of the commencement and completion of freezing, and must be retained for one year after compilation.

7. Meat with a diameter or thickness of up to 25 cm must be frozen for at least 240 consecutive hours, and meat with a diameter or thickness of between 25 and 50 cm must be frozen for at least 480 consecutive hours. This freezing process may not be applied to meat, which has a larger diameter or is thicker. The freezing time shall be calculated from the point when the temperature referred to in paragraph 6 is reached in the freezing room.

II. METHOD 2

The general provisions of paragraphs 1 to 5 of method 1 shall be complied with, and the following time-temperature combinations applied:

1. Meat with a diameter or thickness of up to 15 cm must be frozen according to one of the following time-temperature combinations:

- 20 days at -15 °C,

- 10 days at -23 °C,

- 6 days at -29 °C.

2. Meat with a diameter or thickness of between 15 cm and 50 cm must be frozen according to one of the following time-temperature combinations:

- 30 days at -15 °C,
- 20 days at -25 °C,
- 12 days at -29 °C.

The temperature in the refrigeration room must be no higher than the level of the selected inactivation temperature. It should be measured with calibrated thermoelectric instruments and continuously recorded. It may not be measured directly in the cold air flow. The instruments must be kept under lock. The charts must include the relevant numbers from the meat inspection register

on importation and the date and time of the commencement and completion of freezing, and must be retained for one year after compilation.

III. METHOD 3

Control of the temperature at the centre of the meat pieces.

1. The following time-temperature combinations shall be applied where the temperature is controlled at the centre of the meat pieces and the conditions in paragraphs 2 to 6 are fulfilled:

- 106 hours at -18 °C,

- 82 hours at -21 °C,

- 63 hours at -23, 5 °C,

- 48 hours at -26 °C,

- 35 hours at -29 °C,
- 22 hours at -32 °C,

- 8 hours at -35 °C,

- 1/2 hour at -37 °C.

2. Meat brought in already frozen must be kept in this condition.

3. Consignments in the refrigeration room must be kept separately and under lock.

4. The date and time when each consignment is brought into the refrigeration room must be recorded.

5. The technical equipment and energy supply of the refrigeration room must be such as to ensure that the temperature referred to under paragraph 1 is reached very rapidly and maintained in all parts of the meat.

6. The temperature should be measured with calibrated thermoelectric instruments and continuously recorded. The probe of the thermometer has to be placed at the centre of a calibrated piece of meat of a size no smaller than the thickest piece of meat to be frozen. This calibrated piece of meat should be placed at the least favourable site in the freezing room, not close to the cooling equipment or directly in the cold air flow. The instruments must be kept under lock. The charts must include the relevant numbers from the meat inspection register on importation and the date and time of the commencement and completion of freezing, and must be retained for one year after compilation.

SCHEDULE V

Inspection and freezing of horsemeat

1. Inspection the inspection of horsemeat has to be performed according to a digestion method mentioned in Annex I with the following modifications:

- specimens of at least 10 g to be taken from the lingual muscle or the jaw muscle. In the absence of lingual muscle or jaw muscle a specimen of the same size to be taken from a pillar of the diaphragm at the transition to the sinewy part. The muscle should be clean of connective tissue and fat.

- a 5 g sample is digested for inspection if the artificial digestion of collective samples according to Schedule I, No. III to VII is applied. For each digest, the total weight of muscle under examination must not exceed 100 g for methods III, IV, V and VI in Schedule I or 35 g for method VII in Schedule I.

- in the case of a positive result a further 10 g specimen must be taken for a subsequent independent examination.

2. Freezing of horse meat to kill trichinae by freezing, horse meat must undergo cold treatment in accordance with one of the methods described in Schedule IV.

Nru. 1195

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni mas-Servizzi Veterinarji, qiegħed b'din jippubblika r-regoli skond l-artikolu 5(1) ta' l-Att dwar is-Servizzi Veterinarji:-

Regoli ta' l-2004 dwar il-Kundizzjonijiet biex irendu u jżommu t-Territorju ta' Malta ħieles mill-Marda Magħrufa tal-Qżieqeż.

Id-19 ta' Novembru, 2004

No. 1195

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Veterinary Services, is hereby publishing the following rules in accordance with article 5(1) of the Veterinary Services Act:-

Conditions to Render and Keep the Territory of Malta Free from Classical Swine Fever Rules, 2004

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Conditions to Render and Keep the Territory of Malta Free from Classical Swine Fever Rules, 2004

IN exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, after consultation with Veterinary Services, has made the following Rules:-

Title and Scope

1. (1) The title of these rules is the Conditions to Render and Keep the Territory of Malta free from Classical Swine Fever Rules, 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 80/1095/EEC laying down the conditions to render and keep the territory of Malta free from classical swine fever, and in accordance with articles 5(1) and 23(b) of the Veterinary Services Act.

Definitions

2. For the purposes of these rules, the following definitions shall apply:

"officially swine fever-free holding" means a holding in which:

(i) no swine fever has been detected for at least the preceding 12 months,

(ii) there are no pigs which have been vaccinated against swine fever in the preceding 12 months,

(iii) vaccination against swine fever has not been authorized for at least the preceding 12 months,

In addition, no swine fever must have been detected for at least the preceding 12 months at least within a radius of two kilometers around the holding;

"officially swine fever-free Member State" means a European Union Member State in which:

(i) no swine fever has been detected for at least the preceding 12 months,

(ii) vaccination against swine fever has not been authorized for at least the preceding 12 months, in which the holdings contain no pigs which have been vaccinated against swine fever in the preceding 12 months and which has been so recognized under rule 3 (2) or 7 (1),

"officially swine fever-free region" means a region in which:

(i) no swine fever has been detected for at least the preceding 12 months,

(ii) vaccination against swine fever has not been authorized for at least the preceding 12 months, in which the holdings contain no pigs which have been vaccinated against swine fever in the preceding 12 months and which has been so recognized under rule 7 (2);

"swine fever-free Member State or region" means a European Union Member State or region in which no swine fever has been detected for at least the preceding 12 months.

Plan for eradication of swine fever

3. (1) The territory of Malta shall prepare a plan for the accelerated eradication of swine fever.

(2) Not later than six months after the date of notification of this Government Notice, the status of the territory of Malta shall be established under the European Community procedure for the purpose of determining those required to submit a plan in accordance with sub-rule (1) hereof.

(3) This plan, which must be carried out over a period of not more than six years, must meet the requirements of rule 4 hereof and be approved in accordance with Article 5 (3) of Council Decision 80/1096/EEC introducing Community financial measures for the eradication of classical swine fever.

(4) If the territory of Malta is not officially swine fever-free upon completion of the measure specified in sub-rules (1), (2), and (3) hereof, it shall prepare a new plan for completing the eradication of the disease.

(5) The period for implementing the new plan shall be such that the total period for implementing the measures specified in the provisions of the sub-

rules hereof is of 10 years. The new plan must meet the requirements laid down in Rule 4a and be approved in accordance with Article 5 (3) of Decision 80/1096/EEC.

Specifications of plan of eradication of disease

4. (1) The plan referred to in rule 3 hereof must be designed to ensure that the territory of Malta will be officially free from swine fever after six years at most.

(2) Such plan must specify as appropriate:

(i) the date of prohibition of vaccination of breeding pigs,
(ii) the date of prohibition or, in the first two years of implementing the plan, of restriction of vaccination of fattening pigs,
(iii) the date of commencement of the swine fever detection campaign, where such has proved necessary;
(iv) the measures, resources and timetable proposed by the territory of Malta in order to attain the objective fixed in sub-rule (1) hereof.

(3) The plan may be implemented on a regional basis if the territory of Malta is able to guarantee that the status of the regions concerned will be protected and maintained. In that event, the details required under sub-rule (2) hereof must relate to each of the regions defined in the plan.

(4) The territory of Malta shall notify the European Commission of:

(a) the annual expenditure in connection with swine fever in each of the past three years, with a breakdown of such expenditure;
(b) forecast annual expenditure on the six-year plan.

Further specifications of plan

5. (1)The new plan referred to in sub-rules 3(4) and 3(5) hereof, must be designed to ensure that, upon expiry of the period specified, the territory of Malta will be officially free from classical swine fever.

(2) The new plan must specify as appropriate:

(a) in the case of regions where vaccination has been performed for upwards of one year:

(i) the number of holdings selected for the purpose of obtaining samples which are representative of the region concerned, and the number of pigs in each holding,

(ii) the number of piglets which have been produced by vaccinated sows on those holdings and which will not be vaccinated,

(iii) the number and type of the tests which those piglets will undergo over a six-month period

with a view to detecting whether or not the classical swine-fever virus is present,

(iv) that vaccination must be discontinued if the tests referred to in paragraph (iii) hereof reveal that the classical swine-fever virus is not present, and the date on which the prohibition is likely to take effect;

(b) in the case of regions where vaccination has been performed for less than 12 months:

(i) the date of commencement of vaccination,

(ii) the likely date on which the measures referred to in subparagraph (a) will be implemented;

(c) if vaccination has been suspended, but the region is not yet officially swine fever free:

(i) the number of herds (breeding, multiplier, mixed and fattening herds) in which spot checks will be carried out,

(ii) the total number and description of the tests carried out on those herds each year,

(iii) the number of spot serological tests which will be carried out each year on slaughter pigs at the time of slaughter.

Spot-Checks by European Commission.

6. (a) The European Commission shall make regular on-the-spot checks to verify from a veterinary viewpoint whether the plans are being applied.

(b) The territory of Malta shall take the necessary steps to facilitate these checks and shall in particular ensure that the experts are supplied at their request with all information and documentation needed for assessing the execution of the plans.

(c) The general provisions for implementing this rule, especially as regards the frequency and method of carrying out the checks referred to in paragraph (a) hereof, the rules governing the appointment of veterinary experts and the procedure which they must follow when drawing up their report, shall be laid down in accordance with European Community procedure.

Plans to be forwarded to the Commission

7. (1) The territory of Malta shall, in accordance with Article 5 (1) of Decision 80/1096/EEC, forward to the Commission the plans

provided for in sub-rules 3 (1), (2), and (3) or, in accordance with Article 5 (1) (a) of that Decision, the new plans provided for in sub-rules 3 (4) and (5).

(2) Such plans shall be approved in accordance with the procedure set out in Article 5 (3) of that Decision. The new plans shall be approved in accordance with the procedure set out in Article 5 (3) of Decision 80/1096/EEC.

(3) Should swine fever spread alarmingly in its territory or in any other part of the European Community territory during the implementation of a plan approved under sub-rule (2), the territory of Malta may review the situation and take the precautionary measures they deem appropriate, including the reintroduction of organized preventive vaccination. The European Commission shall be informed accordingly.

(4) Plans approved under sub-rule (2) may be modified or supplemented by the same procedure in order to keep pace with developments in the situation with regard to swine fever in the territory of Malta, and in particular to take account of possible implementation of the measures provided for in sub-rule (3).

Conditions for a territory to be recognized swine fever-free

8. (1) The territory of Malta shall be recognized as officially swine fever-free territory once the following conditions have been fulfilled in the territory of Malta for at least 12 months:

(a) no swine fever has been detected;

(b) vaccination against swine fever has been discontinued.

(2) Under European Community procedure, a part of the territory of Malta to which sub-rule 4 (3) applies may be recognized as officially swine fever-free, though not earlier than three months after it has fulfilled the conditions of sub-rule (1) of this rule, provided the territory of Malta in question can supply adequate guarantees that the status of that part of its territory will be maintained, in particular by showing evidence of the existence of measures:

(i) either to prohibit the introduction into the part of its territory concerned of pigs from holdings which are not officially swine fever-free;

(ii) or to prohibit vaccinated pigs from leaving holdings situated in a part of its territory which is not officially swine fever-free or which is not swine fever-free except for immediate slaughter or for introduction into another holding of the same status.

Loss of status as officially swine fever free

9. (1) If the territory of Malta, during the period laid down in Article 2 (1) of Decision 80/1096/EEC loses its status as officially swine fever free, it may avail itself of sub-rule 3(1) provided its plan does not extend beyond that period. Similarly, if the territory of Malta, during the whole period laid down in Article 2 (1) of Decision 80/1096/EEC, loses its status as officially

swine fever-free, it may avail itself of sub-rule 3(4) provided the execution of its plan does not extend beyond the duration of the supplementary measures.

(2) (a) However, if an outbreak or a number of epizootiologically interrelated outbreaks of swine fever occur within a geographically limited area in the territory of Malta which is officially swine fever-free, the status of the territory of Malta shall not be withdrawn for a period of 15 days if the territory of Malta takes measures to isolate the area in question.

(b)Within the said 15-day period, however a decision may be taken under the procedure in Article 9 of European Union Council Directive 80/1095/EEC to withdraw the status or if the measures taken by the territory of Malta are deemed satisfactory to maintain it for a maximum of three months.

Nru. 1196

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni mas-Servizzi Veterinarji, qiegħed b'din jippubblika l-abbozz tar-regoli li ġejjin skond l-artikolu 20 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni dwar Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni.

Regolamenti ta' l-2004 dwar l-Iffinanzjar ta' Spezzjonijiet Veterinarji u Kontrolli ta' Prodotti ta' Annimali koperti bil-Leġislazzjoni Veterinarja.

Id-19 ta' Novembru, 2004

No. 1196

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Veterinary Services, is hereby publishing the following draft rules in accordance with article 20 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft.

The Financing of Veterinary Inspections and Controls of Animal Products covered by Veterinary Legislation Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

The Financing of Veterinary Inspections and Controls of Animal Products covered by Veterinary Legislation Rules, 2004

IN exercise of the powers conferred by article 20 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has, with the concurrence of the Prime Minister and Minister of Finance, made the following Rules:-

Title and scope.

1. (1) The title of these rules is The Financing of Veterinary Inspections and Controls of Animal Products covered by Veterinary Legislation Rules, 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 85/73/EEC on the Financing of Veterinary Inspections and Controls of Animal Products covered by Veterinary Legislation and in accordance with article 20 of the Veterinary Services Act.

Collection of fees for inspections and controls.

2. In accordance with the arrangements laid down in Schedule A of these rules, a fee is to be collected to cover the costs occasioned by inspections of and controls on the products listed in that Schedule, including those aimed

at ensuring animal production in slaughterhouses, in accordance with the requirements of European Union Council Directive 93/119/EEC.

Fee to be Collected.

3. In accordance with the arrangements laid down in Schedule B to these rules, a fee is to be collected to cover the costs occasioned by the inspections and controls provided for by European Union Council Directive 96/23/EC.

4. In accordance with the arrangements laid down in Schedule C to these rules, a fee is to be collected to cover the costs occasioned by inspections of, and controls on, the live animals listed in the said Schedule.

Government financing of inspections and controls.

5. (1) Pending the adoption of other provisions governing fees, the Government budget shall ensure the financing of inspections and controls not covered by rules 2, 3 and 4.

(2) For the purposes of rule 5 (1), national fees may be charged in accordance with the principles adopted for Community fees in European Union Council Directive 85/73/EEC.

Level of fees.

6. (1) The fees shall be set at a level which covers the costs borne by the Veterinary Services in respect of -

(a) salary costs and social-security costs involved in the inspection service;
(b) administrative costs incurred in carrying out controls and inspections, which may include the expenditure required for in-service training of inspectors, and for the controls and inspections referred to in rules 2, 3 and 4.

No refunds permitted.

(2) No direct or indirect refund of the fees provided for in these regulations shall be permitted. However the possible application of the standard average provided for in Schedules A, B and C shall not be considered an indirect refund in the assessment of individual cases.

(3) It shall be authorized to charge an amount exceeding the levels of fees, provided that the total fees charged do not exceed the actual cost of inspection.

Existing fees replaced.

(4) These fees shall replace all other health-inspection charges or fees levied by the national, regional or local authorities in the territory of Malta for the inspections and controls referred to in rules 2, 3 and 4 and the certification thereof. These regulations shall not prevent the State from charging fees for combating epizootic and enzootic diseases.

Scrutiny by the European Commission.

7. (1) Veterinary Services shall regularly communicate to the European Commission:

(a) data concerning the distribution and use of fees; they must be able to justify their methods of calculation;
(b) the conversion rates adopted each year in accordance with Article 7 of the European Union Council Directive 85/73/EEC;
(c) the place or places where fees are charged, giving any explanations necessary.

(2) As part of the on-the-spot checks to be carried out by the European Commission, the Commission may, in collaboration with the Veterinary Services, verify whether the provisions of European Union Council Directive 85/73/EEC are being applied.

SCHEDULE A

CHAPTER I

Fees applicable to Meat covered by European Union Council Directives 64/433/EEC, 71/118/EEC, 91/495/EEC and 92/45/EEC

The fee referred to in rule 2 is fixed in accordance with rule 6 (1), as follows:

1. Without prejudice to Sections 4 and 5 of this Schedule, the fees for inspection costs relating to slaughter shall be according to the following standard amounts:

(a) beef and veal:
- (i) adult bovine animals: Lm.1.92.0 per animal,
- (ii) young bovine animals: Lm.1.07.0 per animal;

(b) solipeds / equidae: Lm.1.88.0 per animal;

(c) pig-meat: animals of a carcase weight
- (i) of less than 25 kg: Lm.0.21.0 per animal,
- (ii) equal to or greater than 25 kg: Lm.0.56.0 per animal;

(d) sheep-meat and goat-meat: animals of a carcase weight
- (i) of less than 12 kg: Lm.0.08.0 per animal,
- (ii) of between 12 kg and 18 kg: Lm.0.15.0 per animal,
- (iii) of more than 18 kg: Lm.0.21.0 per animal;

(e) poultry meat:
1) either at a standard rate as follows:
   - (i) for broilers, other young poultry for fattening weighing less than 2 kg and for cast hens: Lm.0.00.4 per animal,
   - (ii) other young poultry for fattening of a carcase weight equal to or greater than 2 kg: Lm.0.00.9 per animal,
   - (iii) other heavy adult poultry weighing 5 kg or more: Lm.0.02.0 per animal;

2) or, if it is decided not to make the distinction between categories of poultry as in (i), at Lm.0.01.3 per bird;

(f) rabbit meat and meat of small game birds or ground game:
- (i) for rabbits and small game birds and ground game, the standard rates laid down in (e);
- (ii) for the following land mammals:
  - wild boar: the rates laid down in (c), increased if the levels are insufficient to cover this cost, the cost of the trichinioscopic exam provided for in European Union Council Directive 92/45/EEC,
  - ruminants: the rates laid down in (d).

2. The controls and inspections connected with the cutting operations referred to in, *inter alia*, Article 3 (1) (B) of European Union Council Directive 64/433/EEC and Article 3 (1) (B) of European Union Council Directive 71/118/EEC must be covered

(a) either at a standard rate by the addition of a standard amount of Lm.1.28.0 per tonne on meat entering a cutting plant. That amount is added to the amounts referred to in 1 above; or

(b) by charging the actual costs of inspection per hour worked. Where the cutting operations are carried out in the establishment where the meat is obtained, the amounts laid down in the first subparagraph shall be reduced by up to 55 %.

Where it is opted to levy fees by the hour worked, Veterinary Services must be able to demonstrate to the European Commission that the actual costs cannot be covered by charging fees in accordance with (a).

3. An amount shall be charged corresponding to the actual expenditure necessary for controls or inspections of meat being stored pursuant to, *inter alia*, Article 3 (1) (D) of European Union Council Directive 64/433/EEC and Article 3 (1) (C) of European Union Council Directive 71/118/EEC.

The detailed rules for applying this paragraph may be laid down according to the requirements of the European Community and under the procedure provided for in Article 20 of the Veterinary Services Act with a view in particular to settling the cases of intervention meat and meat subject to short-term storage in successive cold stores.

4. In order to cover increased costs, the State may:

(a) either increase the standard amounts of fees as laid down in Sections 1 and 2(a) of this Schedule for individual establishments.
Apart from that laid down in Section 5 (a) of this Schedule, the conditions to be met might be the following:

(i) higher inspection costs due to a particular lack of uniformity in the animals for slaughter from the point of view of age, size, weight and state of health;
(ii) longer waiting and otherwise non-productive periods for inspection staff owing to inadequate advance planning by the establishment of animal deliveries or technical inadequacies or failures, for example in older establishments;
(iii) frequent delays in the slaughtering process, e.g. as a result of insufficient slaughter staff and hence under-employment of inspection staff;
(iv) higher costs due to special travelling times;
(v) more time taken up on inspections due to frequently changing slaughter periods beyond the control of inspection staff;
(vi) frequent interruptions in the slaughtering process to meet cleaning and disinfecting requirements;
(vii) inspections of animals which, at the request of the owner, are slaughtered outside normal slaughtering hours.

The amount of the increases in the central standard rate for fees depends on the level of the costs to be covered; or

(b) charge a special fee covering actual costs.

5. Where salary costs, the structure of establishments and the relationship between veterinarians and inspectors diverge from the European Community average taken as a basis for calculation of the standard amounts fixed in Sections1 and 2 (a) of this Schedule, may exceptionally reduce them to meet the real costs of inspection:

(a) in general, where there are substantial differences in the cost of living and salary costs;

(b) for individual establishments, where the following conditions are met:

(i) a minimum daily slaughter rate enabling the deployment of the relevant inspection staff to be planned in advance;

(ii) the number of slaughtered animals is constant, so that animal deliveries may be planned in advance, thus enabling rational use to be made of the inspection staff;
(iii) strict organization and planning within the establishment together with a rapid slaughter rate, permitting optimum use of inspection staff;
(iv) no waiting or otherwise non-productive periods for inspection staff;
(v) the animals for slaughter are as far as possible uniform in age, size, weight and state of health.

In no case should the application of these exemptions result in reductions of more than 55 % of the levels indicated in Sections 1 and 2 (a) of this Schedule.

6. (a) The fees referred to in Sections1, 2 and 3 of this Schedule must be collected, as appropriate, at the slaughterhouse, cutting plant or cold store. They shall be payable by the operator or the owner carrying out the aforementioned operations, who may, however, pass on the fee charged for the operation concerned to the natural or legal person on whose behalf the operation is carried out. Where the health inspection of live poultry is carried out at the farm of origin, in accordance with European Union Council Directive 71/118/EEC, an amount of up to 20 % of the standard rates laid down in Section 1 (e) of this Schedule may be charged at the farm of origin.

(b) By way of derogation from the concept of the place of charge referred to in the first sentence of (a), in the case of establishments carrying out more than one operation and of chains of production covering more than one operation, a total aggregate fee may be charged, including the various amounts simultaneously and at a single location.

(c) If the fee charged at a slaughterhouse covers the whole of the inspection costs referred to in (a), no fee shall be charged at the cutting plant or the cold store.

CHAPTER II

Fees applicable to Meat covered by European Union Council Directive 72/462/EEC, Chapter III of European Union Council Directive 71/118/EEC, Chapter III of European Union Council Directive 92/45/EEC, and Chapter II of Schedule I to European Union Council Directive 92/118/EEC

1. The fee referred to in rule 2 is fixed at the minimum standard level of Lm.2.14.0 per tonne (on the bone), with a minimum amount of Lm.12.82.0 per consignment. This amount may however be exceptionally increased to meet actual costs.

2. When the decisions provided for in Article 8 (3) of European Union Council Directive 90/675/EEC are adopted and in accordance with the same procedure the amounts referred to in Section 1 of this Chapter of this Schedule shall be adjusted in the light of the reduced frequency of checks decided on.

3. The fee referred to in Section 1 of this Chapter of this Schedule is payable by the importer or his customs agent and charged at the customs office responsible for the border inspection post or directly at the inspection post.

4. Part of the yield of the fees provided for in this Chapter may be allocated to a health solidarity fund designed to strengthen the veterinary services to allow them to react more effectively to any appearance of an exotic disease.

CHAPTER III

Fees applicable to fishery products covered by European Union Council Directive 91/493/EEC

Section I

Fishery products falling under Chapter I of European Union Council Directive 91/493/EEC.

The fee referred to in rule 2 shall be fixed in accordance with rule 6 (1) as follows:

1. (a) A fee shall be collected for inspection costs relating to the official checks provided for in Chapter V (II) of the Annex to European Union Council Directive 91/493/EEC;

(b) the fee provided for in (a) shall be fixed at Lm.0.43.0 per tonne of fishery products for the first 50 tonnes and at Lm.0.21.0 per tonne thereafter. It shall be collected at the time of first placing on the market, unless already collected on landing, and shall, in any event, be charged to the first purchaser. A system may be provided which allows aggregation of quantities of fishery products over a given period and arrangements may be made for centralized collection at the time of first sale;

(c) by way of derogation to (b), the fees collected on herrings and mackerel must not exceed Lm.21.40.0 per consignment unloaded if the actual costs do not exceed that amount;

(d) the collection of the fee provided for in (a) shall be without prejudice to the collection of that provided for in Section 2 of this Chapter of this Schedule in the event of subsequent processing of fisheries products, without prejudice to Section 7 (b) of this Chapter of this Schedule.

2. (a) A fee shall be collected for inspection costs relating in particular to the official checks carried out in accordance with point I of Chapter V of the Annex to European Union Council Directive 91/493/EEC and to the official checks provided for in point II of the said Chapter V.

(b) The fee provided for in (a) shall be fixed at Lm.0.43.0 and shall be charged on every tonne of fishery products entering a preparation and/or processing establishment or coming from a factory ship.

Furthermore, in the case of inspection of a factory ship abroad, the actual cost of the said inspection shall be charged.

(c) A lower level of fees may be fixed for the species referred to in Section 1 (c) of this Chapter of this Schedule in accordance with the relevant procedure of European Community.

3. (a) Where, following a detailed examination of the costs of the checks referred to in Section 1 (a) of this Chapter of this Schedule for a given product in its territory, the territory of Malta considers that the actual costs cannot be covered by collecting fees in accordance with Section 1 (b) of this Chapter of this Schedule, Veterinary Services shall be authorized to lay down arrangements for levying fees by the hour worked for that product.

(b) Where, following a detailed examination of the costs of the checks referred to in Section 2 (a) of this Chapter of this Schedule for a given product in its territory, the territory of Malta considers that the actual costs cannot be covered by collecting fees in accordance with Section 2

(b) of this Chapter of this Schedule in a given establishment, Veterinary Services shall be authorized to lay down arrangements for levying fees by the hour worked for establishments handling that product.

Where it is opted to levy fees by the hour worked, Veterinary Services must be able to demonstrate to the European Commission that the actual costs cannot be covered by collecting fees in accordance with Sections1 (b) and 2 (b) of this Chapter of this Schedule.

4. (a) It shall be authorized to reduce the amount of the fee provided for in Section 1 (b) of this Chapter of this Schedule when the checks provided for in Section 1 of this Chapter of this Schedule are facilitated by the fact that:

(i) the fish are graded for freshness and/or size in accordance with Rules (EEC) No 103/76 and No 104/76, or recognized in accordance with national rules, and/or
(ii) first sale transactions are grouped together, in particular in a fish auction or wholesale market.

Under no circumstances may application of the above provisions lead to reductions of more than 55 %.

However, an additional reduction may be decided on in accordance with the relevant procedure of the European Community.

(b) The amount of the fee provided for in Section 2 of this Chapter of this Schedule may be reduced when:

(i) preparation or processing is carried out on the same site as the first sale or processing, and / or
(ii) in a given establishment, operating conditions and guarantees as to the establishment's own checks are such that inspection staff requirements can be reduced.

Under no circumstances may application of the above provisions lead to reductions of more than 55 %.

However, an additional reduction may be decided on in accordance with the relevant procedure of the European Community.

5. An amount shall be collected corresponding to the actual cost of checks on fishery products in establishments only chilling, freezing, packaging or storing. However, if the fee collected in accordance with Sections 1 and 2 of this Chapter of this Schedule covers all the inspection costs relating to the checks provided for in Chapter V of the Annex to European Union Council Directive 91/493/EEC, the fee referred to in this Section shall not be collected.

6. (a) The fees provided for in Sections 2 and 5 of this Chapter of this Schedule shall be payable by the operator or the owner of the establishment carrying out the aforementioned operations, who may, however, pass on the fee charged for the operation concerned to the natural or legal person on whose behalf the operation is carried out.

(b) In the case of fishery products intended for subsequent preparation and/or processing within the territory of Malta, a total fee may be collected covering the different amounts on a single occasion and in a single location.

In order for this possibility to be availed of, however, Veterinary Services must first inform the European Commission.

7. Systems shall be set up to check that the fees provided for in this Chapter have been paid by the operators concerned.

In particular, operators shall receive written attestations or some other proof of individual or global payment or order for payment of the fees provided for in Section 1 (a) of this Chapter of this Schedule, unless the fishery products concerned are intended for preparation or processing within the territory of Malta where they were landed, and provided that the full amount of the fee is paid at the processing establishment or preparation establishment.

If necessary, detailed implementing rules shall be adopted in accordance with the requirements of the European Community and under the procedure laid down in Article 20 of the Veterinary Services Act.

The European Commission shall be informed accordingly by Veterinary Services.

Section II

Fishery products falling under Chapter II of European Union Council Directive 91/493/EEC.

1. In the case of the fishery products referred to in the second paragraph of Article 10 of European Union Council Directive 91/493/EEC, the provisions laid down in Section 1 of Section I of this Schedule shall apply.

An additional amount shall also be collected to cover inspection costs inherent in this type of vessel and unloading, with a minimum of Lm.0.43.0 per tonne unloaded.

2. For fishery products other than those referred to in Section 1, that is to say all fishery products which have to go through border inspection posts, the fee provided for in Regulation 1 shall be fixed in accordance with Regulation 5 (1) at the minimum standard level of Lm.2.14.0 per tonne, with a minimum of Lm.12.82.0 per consignment, although, above 100 tonnes, the minimum standard amount of Lm.2.14.0 shall be reduced to:

(i) Lm.0.64.0 per additional tonne for fishery products which have undergone no preparation other than gutting;
(ii) Lm.1.07.0 per additional tonne for the other fishery products.

3. When decisions concerning the reducing of frequencies of checks are adopted by the European Community and in accordance with the requirements of European Community and under the procedure laid down in Article 16 (5) of the Veterinary Services Act, the amounts referred to in Section 2 of this Section of this Chapter of this Schedule shall be adjusted in the light of the reduced frequency of checks decided on.

When those decisions are taken, the guarantees given by third countries as regards acceptance of the principles of regionalization, equivalence, reciprocity and other European Community principles, shall be taken into account, in particular where these third countries are covered by a

comprehensive agreement with the European Community on the equivalence of veterinary guarantees (animal and public health).

Under no circumstances may application of this variation lead to fees of less than the amounts charged in accordance with Section I (1) (b) and (2) (b) for products landed from vessels flying Community flags.

Collection of this fee shall be without prejudice to collection of the fee provided for in Section 2 (b) of Chapter I of this Schedule in the event of further processing.

For the purposes of implementing this Chapter, the fees provided for under Section I shall be applied to imports landed by vessels flying the flag of Greenland.

4. Section 2 of this Section of this Chapter of this Schedule may be derogated by raising fees to the level of actual costs.

5. The fee provided for in Section 2 of this Section of this Chapter of this Schedule shall be payable by the importer, or his customs agent, and collected at the customs office responsible for the border inspection post or directly at the border inspection post.

SCHEDULE B

FEES INTENDED TO ENSURE THAT THE CONTROLS ON LIVE ANIMALS AND PRODUCTS OF ANIMAL ORIGIN PROVIDED FOR IN EUROPEAN UNION COUNCIL DIRECTIVE 96/23/EEC ARE CARRIED OUT

1. The fee referred to in rule 2 shall be fixed as follows:

(a) for live animals for slaughter and meat covered by Chapter I of Schedule A: Lm.0.58.0 per tonne of slaughtered meat;

(b) for aquaculture products covered by Chapter III of Schedule A: Lm.0.04.0 per tonne of marketed product;

(c) for milk and milk products: Lm.0.00.9 per 1000 litres of raw milk;

(d) for egg products: the amount corresponding to the actual cost of the control;

(e) for honey: an amount covering the actual cost of the inspection or control may be charged.

2. In compliance with the levels fixed in Section 1 of this Schedule, one of the following schemes may be opted for:

(a) the fee referred to in Section 1 of this Schedule is collected in full in an establishment forming part of the chain of production:
   (i) slaughterhouse in the case of the fee provided for in Section 1 (a) of this Schedule,
   (ii) establishment carrying out preparation and / or processing in the case of the fee provided for in Section 1 (b) of this Schedule,
   (iii) raw milk collection establishment in the case of the fee provided for in Section 1 (c) of this Schedule;

(b) a proportion of the fee referred to in Section 1 of this Schedule is collected at every stage in the chain of production, including the rearing stage, in accordance with criteria to be defined according to those defined by the European Community.

3. The fee referred to in Section 1 of this Schedule shall be payable by the operator or the owner of the establishment or establishments concerned, who may, however, pass on the fee charged to the natural or legal person on whose behalf the operations concerned are carried out.

SCHEDULE C

FEES TO BE CHARGED FOR LIVE ANIMALS

CHAPTER I

Live Animals and Products of Animal Origin covered by European Union Council Directive 90/425/EEC

1. To finance controls at origin a fee must be charged.

2. The scope and the level of the fee, the detailed rules for its application, including in particular the determination of those liable for payment, and any exceptions shall be laid down in accordance with European Community procedure.

CHAPTER II

Live Animals intended for Importation covered by European Union Council Directive 90/425/EEC

1. The fee referred to in Regulation 4 is fixed:

(a) for animals of the species referred to in Chapter I of Schedule A at the standard rate of Lm.2.14.0 per tonne live weight with a minimum amount of Lm.12.82.0 per consignment;

(b) for animals of other species at the actual cost of inspection expressed either per animal or per tonne imported, with a minimum of Lm.12.82.0 per consignment it being understood that this minimum does not apply to imports of species referred to in European Commission Decision 97/794/EEC.

These amounts may however, by derogation, be increased to the level of actual costs.

2. When reducing of frequencies are adopted to some third countries in a similar way than reducing of frequencies adopted by the European Community, the amount of the fee to be charged on imports from these third countries shall be fixed in the comprehensive equivalence agreement with the said third countries taking into account the following principles:

(i) the frequency of checks,
(ii) the level of the fee applied by the said third country to imports originating in the territory of Malta,
(iii) abolition of other charges levied by the third country, such as compulsory lodging or collection of a health bond.

3. The fee referred to in Section 1 of this Schedule is payable by the importer or his customs agent and collected at the customs office responsible for the border inspection post, or directly to the border inspection post.

4. A lower level of fees may be applied to imports from certain third countries in accordance with the rules fixed by the European Community.

5. Part of the yield of the fees provided for in this Chapter may be allocated to a health solidarity fund designed to strengthen the veterinary services to allow them to react more effectively to any appearance of an exotic disease.

Nru. 1197

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni mas-Servizzi Veterinarji, qiegħed b'din jippubblika l-abbozz tar-regoli li ġejjin skond l-artikoli 8 u 9 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni dwar Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti ma jistabbilixxux biżżejjed il-kundizzjonijiet ta' saħħa ta' annimali li jirregolaw il-moviment u importazzjoni minn pajjiżi terzi ta' ekwidi, jew kif dawn ikunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz.

Regolamenti ta' l-2004 dwar il-Kundizzjonijiet ta' Saħħa ta' l-Annimali li jirregolaw il-Moviment u Importazzjoni minn Pajjiżi Terzi ta' Ekwidi.

Id-19 ta' Novembru, 2004

No. 1197

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with articles 8 and 9 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules do not sufficiently establish animal health conditions governing the movement of and import from third countries of equidae, or how they are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Animal Health Conditions governing the Movement and Import from Third Countries of Equidae Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT, 2001 (CAP. 437)

Animal Health Conditions governing the Movement and Import from Third Countries of Equidae Rules, 2004

IN exercise of the powers conferred under articles 8 and 9 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Chapter 1: GENERAL PROVISIONS

Title and scope and applicability

1. (1) The title of these rules is the Animal Health Conditions governing the Movement and Import from Third Countries of Equidae Rules, 2004

(2) The scope of these rules is to implement the rules found under European Union Council Directive 90/426/EEC of the 26th. June 1990 on animal health conditions governing the movement and import from third countries of equidae.

(3) These rules lay down animal health conditions for the movement between Malta and Member States and import from third countries of live equidae.

Definitions

2. For the purposes of these rules –

(a) "compulsorily notifiable diseases" means the diseases listed in Schedule A;

(b) "equidae" means wild or domesticated animals of the equine (including zebras) or asinine species or the offspring of crossings of those species;

(c) "equidae for breeding and production" means equidae other than equidae for slaughter and registered equidae;

(d) "equidae for slaughter" means equidae intended to be transported either directly or after transit through a market or an approved marshalling centre to the slaughterhouse for slaughter;

(e) "holding" means an agricultural or training establishment, a stable or, generally speaking, any premises or facilities in which equidae are habitually kept or bred, for whatever use;

(f) "Member State" means a State which is a Member within the European Community;

(g) "Member State or Third Country free from African horse sickness" means any Member State or third country in which there has been no clinical, serological (in unvaccinated equidae) or epidemiological evidence of African horse sickness on the territory concerned in the previous two years and in which there have been no vaccinations against the disease during the previous 12 months;

(h) "official veterinarian" means the veterinarian designated by the competent central authority of a Member State or of a Third Country;

(i) "registered equidae" means any equidae registered as defined in Directive 90/427/EEC, identified by means of an identification document issued by the breeding authority or any other competent authority of the country where the animal originated which manages the studbook or register for that breed of animal or any international association or organisation which manages horses for competition or racing;

(j) "temporary admission" means the status of a registered animal originating in a third country and admitted into Community territory for a period of less than 90 days to be fixed by the Commission in accordance with the procedure of the Community, depending on the health situation in the country of origin;

(k) "the Commission" means the European Commission;

(l) "the Community" means the European Community as established under the Treaty establishing the European Community;

(m) "the Competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

(n) "Third country" means a State which is not a Member within the European Community;

(o) "Veterinary Services" means the competent authority within the territory of Malta as established under article 2 of the Veterinary Services Act.

Chapter 2: RULES FOR THE MOVEMENT OF EQUIDAE

Authorisations of movement of equidae and exemptions

3. Veterinary Services shall authorise the movement of equidae registered in the territory of Malta or send equidae to another Member State only where they satisfy the conditions laid down in rules 4 and 5. However, the Veterinary Services at destination may grant general or limited exemption in respect of movement of equidae which -

(a) are being ridden or taken, for sporting or recreational purposes, along roads situated near internal borders of the Community;

(b) are taking part in cultural or similar events or in activities organised by authorised local bodies situated near internal borders of the Community;

(c) are intended solely for temporary pasturing or work near internal borders of the Community. When making use of such authorisation, Veterinary Services shall inform the Commission of the content of the exemptions granted.

Rules for inspection of equidae

4. (1) Equidae must show no clinical sign of disease at inspection. Inspection must be carried out in the 48 hours prior to their embarkation or loading. In the case of registered equidae, however, this inspection shall, without prejudice to regulation 6, be required for intra-Community trade only.

(2) Without prejudice to the requirements of sub-rule (5) regarding compulsorily notifiable diseases, the official veterinarian must, at the time of inspection, be satisfied that there are no grounds in particular on the basis of declarations by the owner or breeder for concluding that the equidae have been in contact with equidae suffering from an infectious or contagious disease during the 15 days immediately preceding inspection.

(3) The equidae must not be intended for slaughter under a national programme of contagious or infectious disease eradication.

(4) The equidae must be identified in the following manner:

(i) in the case of registered horses, by means of an identification document, as provided for in Directive 90/427/EEC, which must certify in particular that Article 5 (5) and (6) have been complied with. The official veterinarian will have to suspend the validity of this document for the period of the prohibitions provided for in Article 5(5). The document should, following the slaughter of the registered horse, be returned to the authority which issued it;

(ii) for equidae for breeding and production, identification by a method to be established by the Commission in accordance with the relevant procedure of the Community. Until such time as this method is in use, the officially approved national identification methods shall remain applicable, provided that they are notified by the Veterinary Services to the Commission and the other Member States within three months of the date on which these regulations are adopted.

(5) In addition to the requirements laid down in rule 5, the equidae must not come from a holding which has been the subject of one of the following prohibition orders -

(i) if all the animals of species susceptible to the disease located on the holding have not been slaughtered, the period of prohibition concerning the holding of origin must be at least -

(a) six months in the case of equidae suspected of having contracted dourine, beginning on the date of the last actual or possible contact with a sick animal. However, in the case of a stallion, the prohibition shall apply until the animal is castrated,

(b) six months in the case of glanders or equine encephalomyelitis, beginning on the day on which the equidae suffering from the disease in question are slaughtered,

(c) in the case of infectious anaemia, until the date on which, the infected animals having been slaughtered, the remaining animals have shown a negative reaction to two Coggins tests carried out three months apart,

(d) six months in the case of vesicular stomatitis,

(e) one month from the last recorded case, in the case of rabies,

(f)15 days from the last recorded case, in the case of anthrax;

(ii) if all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises disinfected, the period of prohibition shall be 30 days, beginning on the day on which the animals were destroyed and the premises disinfected, except in the case of anthrax, where the period of prohibition is 15 days.

The Veterinary Services may derogate from these prohibition measures for hippodromes and racecourses, and shall notify the Commission of the nature of any derogation granted.

(6) Where Veterinary Services draws up or has drawn up a voluntary or compulsory control programme for a disease to which equidae are susceptible, they may present the programme to the Commission outlining in particular –

(a) the distribution of the disease on its territory;

(b) the reasons for the programme, taking into consideration the significance of the disease and its cost/benefit advantages;

(c) the geographical area in which the programme will be implemented;

(d) the status categories to be applied to establishments, the standards which must be attained for each species and the test procedures to be used, the programme monitoring procedures;

(e) the action to be taken if, for any reason, a holding loses its status;

(f) the measures to be taken if the results of the tests carried out in accordance with the provisions of the programme are positive;

(g) the non-discriminatory nature of trade in the territory of Malta with respect to intra-Community trade. The programmes presented by the Veterinary Services shall be examined by the Commission. Where appropriate it shall approve them in accordance with the relevant procedure of the Community. Any additional guarantees, general or specific, which may be required in intra-Community trade may be defined in accordance with the same procedure. Such guarantees must not exceed those required by Malta in its own territory. Programmes submitted by Veterinary Services may be amended or supplemented in accordance with the same procedure.

Dispatch of equidae when not free from African horse sickness

5. (1) When the territory of Malta is not free of African horse sickness within the meaning of a Member State or Third Country free from African horse sickness in rule 2 hereof, Veterinary Services may authorise to dispatch equidae from that part of the territory of Malta which is considered to be infected within the meaning of sub-rule (2) of this rule only under the conditions set out in sub-rule (3) hereof.

(2) (i) A part of the territory of Malta shall be considered to be infected with African horse sickness if:

(a) clinical, serological (in unvaccinated animals) and, or epidemiological evidence has revealed the presence of African horse sickness in the past two years, or

(b) vaccination against African horse sickness has been carried out in the past 12 months.

(ii) The part of the territory considered to be infected with African horse sickness must comprise as a minimum:

(a) a protection zone with a radius of at least 100 km around any centre of infection;

(b) a surveillance zone at least 50 km extending beyond the protection zone, in which no vaccination has been carried out in the last 12 months.

(iii) The rules controlling the combat measures relating to the territories and zones referred to in paragraphs (a) and (b) and the relevant derogation are specified in Directive 92/35/EEC.

(iv) All vaccinated equidae found in the protection zone must be registered and identified in accordance with Article 6 (1) of Directive 92/35/EEC. The identification document and/or health certificate shall carry a clear reference to such vaccination.

(3) Malta may dispatch from its territory referred to in sub-rule 2 (b) only equidae which meet the following requirements:

(i) they must be dispatched only during certain periods of the year, having regard to the activity of vector insects as has been determined by the Community;

(ii) they must show no clinical symptom of African horse sickness on the day of the inspection referred to in rule 4 (1);

(iii) (a) if they have not been vaccinated against African horse sickness, they must have undergone and reacted negatively to a complement fixation test for African horse sickness as described in Schedule D, on two occasions, with an interval of between 21 and 30 days between the two tests, the second of which must have been carried out during the 10 days prior to dispatch,

(b) if they have been vaccinated, they must not have undergone vaccination during the previous two months and must have undergone the fixation test described in Schedule D at the aforementioned intervals without having recorded an increase in the antibody count. Other monitoring methods recognised by the Commission may be used

(iv) they must have been kept in a quarantine station for a minimum period of 40 days prior to dispatch;

(v) they must have been protected from vector insects during the period of quarantine and during transportation from the quarantine station to the place of dispatch.

Derogation in case of inspection

6. Veterinary Services may grant, to equidae coming from Member States which implement an alternative control system providing guarantees equivalent to those laid down in rule 4(5) as regards movements within their territory of equidae and registered equidae, in particular by means of the identification document, one other derogation from the provisions of the second sentence of rule 4(1) and the second indent of rule 8(1) on a reciprocal basis. The Veterinary Services shall notify the Commission thereof.

Transportation of equidae

7. (1) The equidae must be transported, as soon as possible, from the holding of origin either directly or via an approved market or marshalling centre as defined in Article 2 (2) (o) of Directive 64/432/EEC to the place of destination by means of transport or containers which have been regularly cleansed and disinfected with a disinfectant at intervals to be fixed by the Veterinary Services. The means of transport must be designed in such a way that equidae droppings, litter or fodder cannot escape from such means during transportation. Transportation must be effected in such a way that the health and wellbeing of the equidae can be protected effectively.

(2) The Veterinary Services may, at destination, on a general or restricted basis, grant a derogation from some of the requirements of rule 4 (5) for any animal bearing a special mark indicating that it is scheduled for slaughter, provided that

the health certificate mentions such derogation. In the case of granting such a derogation, equidae for slaughter must be transported directly to the designated slaughterhouse and be slaughtered within five days of arrival at the slaughterhouse.

(3) The official veterinarian must record the identification number or identification document number of the slaughtered animal and forward to the competent authority of the place of dispatch, at the latter's request, an attestation to the effect that the animal has been slaughtered.

Identification document and certificates

8. (1) The Veterinary Services shall verify that:

(i) registered equidae which leave their holdings are accompanied by the identification document laid down in rule 4 (4) together if they are intended for intra-Community trade with the attestation provided for in Schedule B;

(ii) equidae for breeding, production and slaughter are, during their transportation to a Member State, accompanied by a health certificate complying with Schedule C to these rules. Equidae for breeding, production and slaughter at destination of Malta are accompanied by a health certificate complying with Annex C to Directive 90/426/EEC. The certificate, or in the case of an identification document, the form containing the health particulars, must, without prejudice to rule 6, be drawn up during the 48 hours preceding their embarkation or else no later than the last working day prior to it, in at least one of the official languages of Malta and of the Member State of destination. The duration of validity of the certificate is 10 days. The certificate must consist of a single sheet.

(2) Imports of equidae other than registered equidae may be covered by a single health certificate per consignment rather than by the individual certificate referred to in sub-rule paragraph (1)(ii) hereof.

Application of Veterinary Framework Act and Council Directive 90/425/EEC

9. The rules laid down in Article 15 of the Veterinary Framework Act and in Council Directive 90/425/EE concerning veterinary and zootechnical checks in intra-Community trade in certain live animals and products with a view to the completion of the internal market, shall apply in particular to checks at origin, to the organisation of, and follow-up to, the checks to be carried out at destination, and to the safeguard measures to be implemented.

On-the-spot inspections

10. Veterinary experts from the Commission may, to the extent necessary to ensure uniform application of Directive 90/426/EEC and in co-operation with the

Veterinary Services, carry out on-the-spot inspections. Veterinary Services shall give the experts all the assistance necessary to carry out their task.

Chapter 3: RULES FOR IMPORTS FROM THIRD COUNTRIES

Conditions for imported equidae from Third Country

11. Equidae imported from a third country into the Community through the territory of Malta must satisfy the conditions laid down in rules 12 to 16.

When equidae are Imported

12. In order to be imported, the equidae must come from a third country or part of a third country appearing on a list drawn up by the Commission

Conditions for the importation of equidae

13. (1) The equidae must come from third countries:

(i) free from African horse sickness;

(ii) which have been free for two years from Venezuelan equine encephalomyelitis (VEE);

(iii) which have been free for six months from dourine and glanders.

(2) Veterinary Services shall apply decision of the Commission that may:

(i) decide that the provisions of paragraph 1 shall apply to only a part of the territory of a third country. In the event that the African horse sickness requirements apply on a regional basis, at the very least the measures laid down in rules 5 (2) and (3) must be complied with;

(ii) require additional guarantees for diseases alien to the Community.

Other conditions for transportation

14. Before the day of loading for transportation to Malta, the equidae must have remained without interruption in the territory or part of the territory of a third country or, in the event of regionalisation, in the part of the territory defined pursuant to rule 13 (2) (i) for a period determined in regulation 15. They must come from a holding placed under veterinary supervision.

Other qualifications for importation of equidae from Third Countries

15. (1) Importation of equidae from the territory of a third country or part thereof as defined in accordance with rule 13 (2) (i) on the list drawn up in

accordance with rule 12 shall be authorised only if the equidae, over and above the requirements of rule 13 -

(i) comply with the animal health requirements adopted, with reference to the species in question and the categories of equidae, by the Community for imports of equidae from that country. The reference basis for fixing animal health conditions in accordance with sub-rule (1) shall be the standards laid down in rules 4 and 5; and

(ii) in the case of a third country not free of vesicular stomatitis or viral arteritis for at least six months, the equidae must meet the following requirements:

(a) they must come from a holding which has been free of vesicular stomatitis for at least six months and they must have reacted negatively to a serological test prior to dispatch;

(b) in the case of viral arteritis, male equidae must notwithstanding regulation 18 have reacted negatively to a serological test or to a virus isolation test or to any other test recognised by the Community.

The requirement relating to equine viral arteritis shall apply to male equidae with the exception of:

(a) equidae vaccinated against equine viral arteritis under official supervision with a vaccine approved by the competent authority and which have reacted with a negative result at 1 in 4 to a serum neutralisation test for that disease. The equidae shall be vaccinated on the date on which the blood specimen is taken or within the following 15 days on condition that they have been isolated during that period. The test shall be carried out and certified, and the result and vaccination certified, under official veterinary supervision. Vaccination shall be repeated at regular intervals. In the case of registered equidae, vaccinations and the results of serological tests shall be entered in the identification document (passport),

(b) equidae vaccinated against equine viral arteritis under official supervision with a vaccine approved by the competent authority and which have undergone two serum neutralisation tests for that disease at an interval of at least 10 days between the age of 180 and 270 days without an increase in antibodies being established. The equidae shall be isolated under official supervision from the time the first blood specimen is taken up to vaccination. The tests shall be carried out and certified, and the results and vaccinations certified, under official veterinary supervision. Vaccination shall be repeated at regular intervals. In the case of registered equidae, vaccinations and the results of serological tests shall be entered in the identification document (passport),

(c) equidae less than 180 days old,

(d) equidae for slaughter sent directly to a slaughterhouse accompanied by a certificate as provided for in Annex I to Commission Decision 93/196/EEC animal health conditions and veterinary certification for imports of equidae for slaughter

(2) Without prejudice to Decision 92/160/EEC, the territory of Malta shall authorise imports of equidae for slaughter from a third country appearing in Part I of the Annex to Decision 79/542/EEC and which are clearly and indelibly marked by a hot-branded 'S' of not less than 3 cm size on the hoof of the left front leg and:

(i) which, if sent directly to a slaughterhouse to be slaughtered within five days after arrival at the slaughterhouse and not more than five days after arrival in the Community, meet the requirements of Annex I to the Decision 93/196/EEC on animal health conditions and veterinary certification for imports of equidae for slaughter. However, where equidae are subjected to a sea-voyage of more than eight days, the Veterinary Services of Malta may decide that such equidae may be slaughtered within 21 days of arrival at the slaughterhouse, provided they remain at the slaughterhouse under the daily supervision of the official veterinarian. Malta Veterinary Services shall notify the Commission of such cases;

or

(ii) which, if they are passing through a market or a marshalling centre before being slaughtered, meet the requirements of Annex II to the European Commission Decision 93/196/EC.

(3) Without prejudice to Decision 92/160/EEC, Malta shall authorise imports of registered equidae and equidae for breeding –

(i) coming from a third country appearing in Annex I to Commission decision 93/197/EC on animal health conditions and veterinary certification for imports of registered equidae and equidae for breeding and production, and

(ii) conforming to the requirements laid down in the appropriate specimen animal health certificate set out in Annex II to Commission decision 93/197/EC.

Identification of equidae

16. (1) The equidae must be identified in accordance with rule 4 (4) and accompanied by a certificate drawn up by an official veterinarian of the exporting third country. This certificate must:

(i) be issued on the day of loading of the animals for dispatch to the Member State of destination or, in the case of registered horses, on the last working day before embarkation;

(ii) be drawn up in at least one of the official languages of Malta or the Member State of destination and one of those of the Member State in which the import inspection is carried out;

(iii) accompany the animals in the original;

(iv) attest to the fact that the animals satisfy the requirements of Directive 90/426/EEC and those laid down pursuant to that Directive with regard to importation of equidae from third countries;

(v) consist of a single sheet;

(vi) be made out for a single consignee or, in the case of animals for slaughter, for a consignment, provided the animals are properly marked and identified. Veterinary Service shall inform the Commission if they make use of this option.

(2) The certificate must be drawn up on a form complying with a model established by the Community.

Equidae on Arrival in Malta

17. (1) Immediately upon arrival in Malta as Member State of destination, equidae for slaughter shall be taken to a slaughterhouse, either directly or after transition through a market or a marshalling centre, and, in accordance with animal health requirements, be slaughtered within a period of time specified in rule 15.

(2) Without prejudice to any special conditions which may be adopted by the Community, Malta Veterinary Services may, on animal health grounds, designate the slaughterhouse to which such equidae must be taken.

Re-entry of registered horse for racing

18. Without prejudice to Decision 92/160/EEC, Veterinary Service shall authorise the re-entry of registered horses for racing, competition and cultural events after temporary export where such horses:

(a) return from third countries appearing in Parts I and II of the special column for equidae in the Annex to Decision 79/542/EEC to which they have been temporarily exported either directly of after transit through other countries of the same group in Annex I to the Decision 93/195/EEC on animal health conditions and veterinary certification of the re-entry of registered horses for racing, competition and cultural events after temporary export

(b) comply with the requirements laid down in the specimen animal health certificate set out in Annex II to the Decision 93/195/EEC.

SCHEDULE A

Compulsorily notifiable diseases

The following diseases are compulsorily notifiable:

- Dourine
- Glanders
- Equine encephalomyelitis (of all types, including VEE)
- Infectious anaemia
- Rabies
- Anthrax
- African horse sickness
- Vesicular stomatitis.

SCHEDULE B

HEALTH INFORMATION ([a])

Passport No. ……..

I, the undersigned, certify ([b]) that the equine animal described above meets the following requirements:

(a) it has been examined today and shows no clinical sign of disease;

(b) it is not intended for slaughter under a national programme of contagious or infectious disease eradication;

(c) it does not come from the territory or part of the territory of a Member State/third country which is the subject of restrictions for reasons of African horse sickness ([c]), or

- it comes from the territory or part of the territory of a Member State which was subject to prohibition for animal health reasons and has undergone, with satisfactory results, the tests provided for in Article 5 (3) of Directive 90/426/EEC in the quarantine station of ……

between ……. and ……..([c]) ;

- it is not vaccinated against African horse sickness, or it was vaccinated against African horse sickness on …… ([c]) ([d]) ;

(d) it has not come from a holding which was subject to prohibition for animal health reasons nor had contact with equidae from a holding which was subject to prohibition for animal health reasons:

- during six months in the case of equidae suspected of having contracted dourine, beginning on the date of the last actual or possible contact with a sick animal. However, in the case of a stallion, the prohibition shall apply until the animal is castrated,

- during six months in the case of glanders or equine encephalomyelitis, beginning on the day on which the equidae suffering from the disease in question are slaughtered,

- in the case of infectious anaemia, until the date on which, the infected animals having been slaughtered, the remaining animals have shown a negative reaction to two Coggins tests carried out three months apart,

- during six months from the last case, in the case of vesicular stomatitis,

- during one month from the last case, in the case of rabies,

- during 15 days from the last case, in the case of anthrax,

- if all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises disinfected during 30 days, beginning on the day on which the animals were destroyed and the premises disinfected, except in the case of anthrax, where the period of prohibition is 15 days;

(e) to the best of my knowledge, it has not been in contact with equidae suffering from an infectious or contagious disease in the 15 days prior to this declaration.

Date	Place	Stamp and signature of the official veterinarian ([1])

([1]) Name in block capitals and capacity.

(f) at the time of inspection it was fit to be transported on the intended journey in accordance with the provisions of Directive 91/628/EEC(4)

_____

([a]) This information is not required where there is a bilateral agreement in accordance with Article 6 of Directive 90/426/EEC.
([b]) Valid for 10 days.
([c]) Delete whichever does not apply.
([d]) The vaccination date must be entered in the passport.

SCHEDULE C

MODEL
Health certificate for trade between Member States of the EEC

EQUIDAE

No:.....

Member State of dispatch :
.....

Ministry responsible:
.....

Territorial Department responsible:
.....

I. Number of equidae:

II. Identification of equidae:

Number of equidae (1)	Species : horse, ass, mule, hinny	Breed, Age, Sex	Method of identification and identification(2)

(1) In the case of animals for slaughter, nature of the special mark.
(2) A passport identifying the equine animal may be attached to this certificate provided that its number is stated.

III. Origin and destination of animal/s:
The animal/s is/are to be sent from:
.....

(Place of export)
to:
.....

(Member State and place of destination)
Name and address of consignor:
.....
.....

Name and address of consignee:
.....
.....

IV. Health information (a)
I, the undersigned, certify that the animal/s described above meet/s the following requirements:

1. it/they has/have been examined today and show/s no clinical sign of disease;

2. it/they is/are not intended for slaughter under a national programme of contagious or infectious disease eradication;

3. - it/they does/do not come from the territory or part of the territory of a Member State/third country which is the subject of restrictions for reasons of African horse sickness,
or
- it/they come/s from the territory or part of the territory of a Member State which was the subject of restrictions for reasons of African horse sickness and has/have undergone, with satisfactory results, the tests provided for in Article 5 (3) of Directive 90/426/EEC in the quarantine station of between and ([b]);

- it/they is/are not vaccinated against African horse sickness,

or

- it/they was/were vaccinated against African horse sickness on ([b]);

4. it/they has/have not come from a holding which was subject to prohibition for animal health reasons nor had contact with equidae from a holding which was subject to prohibition for animal health reasons:

- during six months in the case of equidae suspected of having contracted dourine, beginning on the date of the last actual or possible contact with a sick animal. However, in the case of a stallion, the prohibition shall apply until the animal is castrated,

- during six months in the case of glanders or equine encephalomyelitis, beginning on the day on which the equidae suffering from the disease in question are slaughtered,

- in the case of infectious anaemia, until the date on which, the infected animals having been slaughtered, the remaining animals have shown a negative reaction to two Coggins tests carried out three months apart,

- during six months from the last case, in the case of vesicular stomatitis,

- during one month from the last case, in the case of rabies,

- during 15 days from the last case, in the case of anthrax,

- if all the animals of species susceptible to the disease located on the holding have been slaughtered and the premises desinfected during 30 days, beginning on the day on which the animals were destroyed and the premises desinfected, except in the case of anthrax, where the period of prohibition is 15 days;

5. to the best of my knowledge, it/they has/have not been in contact with equidae suffering from an infectious or contagious disease in the 15 days prior to this declaration.

6. at the time of inspection it/they was/were fit to be transported on the intended journey in accordance with the provisions of Directive 91/628/EEC ([d]).

V. This certificate is valid for 10 days.

Done at ....., date.....

Stamp

.....

(signature of the official veterinarian) ([3])

.....

(Signature)
(Name in capital letters and capacity of signing veterinarian) ([c])

([a]) This information is not required where there is a bilateral agreement in accordance with Article 6 of Directive 90/426/EEC.

([b]) Delete whichever does not apply.

([c]) In Germany 'Beamteter Tierarzt'; in Belgium 'Inspecteur vétérinaire' or 'Inspecteur Dierenarts'; in France 'Vétérinaire officiel'; in Italy 'Veterinario ufficiale'; in Luxembourg 'Inspecteur vétérinaire'; in the Netherlands 'Officieel Dierenarts'; in Denmark 'Embeds Dyrlaege'; in Ireland 'Veterinary Inspector'; in the United Kingdom 'Veterinary Inspector'; in Greece 'Episimos ktiniatros'; in Spain 'Inspector Veterinario'; and in Portugal 'Inspector Veterinÿrio'. ".Auriche.- "Amtstierarzt"; Finlande: "kutmanelâinliiakàri ou kaupungînetiintâakâri ou laâninelainlaâkari/kommunaheierinâr ou stadavetcrinàr ou tinsveterinar "; Suède: "lansveterinàr, distriklsveleriniir ou gràrmvetetinar "

([d]) This statement does not exempt transporters from their obligations in accordance with Community provisions in force in particular regarding the fitness of animals to be transported.

5) This statement does not exempt transporters from their obligations in accordance with Community provisions in force in particular regarding the fitness of animals to be transported.

SCHEDULE D

African horse sickness diagnosis

Reagents for the enzyme-linked immunosorbent assays (ELISA) described below may be obtained from the European Community Reference Laboratory or the OIE Reference Laboratories for African horse sickness.

1. Competitive elisa for the detection of antibodies to african horse sickness virus (AHSV) (prescribed test)

Competitive ELISA is used to detect specific AHSV antibodies in sera from any species of equidae. The broad spectrum, polyclonal, immune anti-AHSV guinea-pig serum (hereinafter "guinea-pig antiserum") is serogroup specific and is able to detect all known serotypes of AHS virus.

The principle of the test is the interruption of the reaction between AHSV antigen and a guinea-pig antiserum by a test serum sample. AHSV antibodies in the test serum sample will compete with those in the guinea-pig antiserum resulting in a reduction in the expected colour (following the addition of enzyme labelled anti-guinea-pig antibody and substrate). Sera can be tested at a single dilution of 1 in 5 (spot test method) or may be titrated (serum titration method) to give dilution end-points. Inhibition values higher than 50 % may be regarded as positive.

The test protocol described hereinafter is used in the Regional Reference Laboratory for African horse sickness in Pirbright, United Kingdom.

1.1. Test procedure

1.1.1. *Preparation of plates*

1.1.1.1. Coat ELISA plates with AHSV antigen extracted from infected cell cultures and diluted in carbonate/bicarbonate buffer, pH 9,6. Incubate the ELISA plates overnight at 4 °C.

1.1.1.2. Wash plates three times by flooding and emptying the wells with phosphate buffered saline (PBS), pH 7,2 to 7,4 pH, and blot dry on adsorbent paper.

1.1.2. *Control wells*

1.1.2.1. Titrate the positive control sera in a twofold dilution series, from 1 in 5 to 1 in 640, across column 1 in blocking buffer (PBS containing 0,05 % (v/v) Tween-20, 5,0 % (w/v) skimmed-milk powder (Cadbury's Marvel™) and 1 % (v/v) adult bovine serum) to give a final volume of 50 µl/well

1.1.2.2. Add 50 µl of the negative control serum at a dilution of 1 in 5 (10 µl serum + 40 µl blocking buffer) to wells A and B of column 2.

1.1.2.3. Add 100 µl/well of blocking buffer to wells C and D of column 2 (blank).

1.1.2.4. Add 50 µl of blocking buffer to wells E, F, G and H of column 2 (guinea pig control).

1.1.3. *Spot test method*

1.1.3.1. Add a 1 in 5 dilution of each test serum in blocking buffer to duplicate wells of columns 3 to 12 (10 µl sera + 40 µl blocking buffer).

or

1.1.4. *Serum titration method*

1.1.4.1. Prepare a twofold dilution series of each test sample (1 in 5 to 1 in 640) in blocking buffer across eight wells of single columns (3 to 12).

then

1.1.5. Add 50 µl of guinea pig antisera, pre-diluted in blocking buffer, to all wells except the blank wells of the ELISA plate (all wells now contain a final volume of 100 µl).

1.1.5.1. Incubate for 1 hour at 37 °C on an orbital shaker.

1.1.5.2. Wash plates three times and blot dry as before.

1.1.5.3. Add 50 µl of rabbit anti-guinea-pig horseradish peroxidase (HRP) conjugate pre-diluted in blocking buffer to each well.

1.1.5.4. Incubate for 1 hour at 37 °C on an orbital shaker.

1.1.5.5. Wash plates three times and blot dry as before.

1.1.6. *Chromogen*

Prepare the chromogen OPD (OPD = ortho-phenyldiamine) solution according to the manufacturers instructions (0,4 mg/ml in sterile distilled water) just before use. Add substrate (hydrogen peroxide = H2O2) to give a final concentration of 0,05 % (v/v) (1 in 2000 of a 30 % solution of H2O2). Add 50 µl of the OPD solution to each well and leave plates on the bench for 10 minutes at ambient temperature. Stop the reaction by the addition of 50 µl/well of 1M sulphuric acid (H2SO4).

1.1.7. *Reading*

Read spectrophotometrically at 492 nm.

1.2. Expression of results

1.2.1. Using a software package print out the optical density (OD) values, and the percentage inhibition (PI) for test and control sera based on the mean value recorded in the four guinea pig control wells. The data expressed as OD and PI values are used to determine whether the test has performed within acceptable limits. The upper control limits (UCL) and lower control limits (LCL) for the guinea pig control are between OD values 1,4 and 0,4 respectively. The end-point titre for the positive control based on 50 % PI should be 1 in 240 (within a range from 1 in 120 to 1 in 480). Any plate that fails to conform to the above criteria must be rejected. However, if the positive control serum titre is greater than 1 in 480 and the test samples are still negative then the negative test samples can be accepted.

The duplicate negative control serum wells and the duplicate blank wells should record PI values between + 25 % and - 25 %, and between + 95 % and + 105 %, respectively. Failure to be within these limits does not invalidate the plate but does suggest that background colour is developing.

1.2.2. The diagnostic threshold (cut-off value) for test sera is 50 % (PI 50 %). Samples recording PI values greater than 50 % are recorded as positive. Samples recording PI values lower than 50 % are recorded as negative.

Samples that record PI values above and below the threshold for the duplicate wells are considered doubtful. Such samples may be re-tested in the spot test and by titration. Positive samples may also be titrated to provide an indication of the degree of positivity.

Spot test layout

	1	2	3	4	5	6	7	8	9	10	11	12
	+ve cont	Test sera										
A	1:5	-ve cont	31	32	33	34	35	36	37	38	39	40
B	1:10	-ve cont	31	32	33	34	35	36	37	38	39	40
C	1:20	Blank										
D	1:40	Blank										
E	1:80	GP cont.										
F	1:160	GP cont.										
G	1:320	GP cont.	1	2	3	4	5	6	7	8	9	10
H	1:640	GP cont.	1	2	3	4	5	6	7	8	9	10
-ve cont= negative control. +ve cont= positive control. GP cont= guinea pig control												

Test sera

	1	2	3	4	5	6	7	8	9	10	11	12
	+ve cont	Test sera										
A	1:5	-ve cont	1:5									1:5
B	1:10	-ve cont	1:10									1:10
C	1:20	Blank	1:20									1:20
D	1:40	Blank	1:40									1:40
E	1:80	GP cont.	1:80									1:80
F	1:160	GP cont.	1:160									1:160
G	1:320	GP cont.	1:320									1:320
H	1:640	GP cont.	1:640									1:640
-ve cont= negative control. +ve cont= positive control. GP cont= guinea pig control												

2. Indirect elisa for the detection of antibodies to african horse sickness virus (AHSV) (prescribed test)

The test described hereinafter is in accordance with the test description in Chapter 2.1.11 of the *OIE Manual of Standards for Diagnostic Tests and Vaccines, fourth edition, 2000*.

The recombinant VP7 protein has been used as antigen for AHS virus antibody determination with a high index of sensitivity and specificity. Other advantages are that it is stable and not infective.

2.1. Test procedure

2.1.1. *Solid phase*

2.1.1.1. ELISA plates are coated with recombinant AHSV-4 VP7 diluted in carbonate/bicarbonate buffer, pH 9,6. Incubate plates overnight at 4 °C.

2.1.1.2. Wash the plates five times with distilled water containing 0,01 % (v/v) Tween 20 (washing solution). Gently tap the plates onto absorbent material to remove any residual wash.

2.1.1.3. Block the plates with phosphate buffered saline (PBS) + 5 % (w/v) skimmed milk (Nestlé Dry Skim Milk™), 200 µl /well, for 1 hour at 37 °C.

2.1.1.4. Remove the blocking solution and gently tap the plates onto absorbent material.

2.1.2. *Test samples*

2.1.2.1. Serum samples to be tested, and positive and negative control sera, are diluted 1 in 25 in PBS + 5 % (w/v) skimmed milk + 0,05 % (v/v) Tween 20, 100 µl per well. Incubate for 1 hour at 37 °C.

For titration, make a twofold dilution series from 1 in 25 (100 µl /well), one serum per plate column, and do the same with positive and negative controls. Incubate for 1 hour at 37 °C.

2.1.2.2. Wash the plates as described in step 2.1.1.2.

2.1.3. *Conjugate*

2.1.3.1. Dispense 100 µl /well of horseradish-peroxidase (HRP) -conjugated anti-horse gamma-globulin diluted in PBS + 5 % milk + 0,05 % Tween 20, pH 7,2. Incubate for 1 hour at 37 °C.

2.1.3.2. Wash the plates as described in step 2.1.1.2.

2.1.4. *Cromogen/Substrate*

2.1.4.1. Add 200 µl /well of chromogen/substrate solution (10 ml of 80,6 mM DMAB (dimethyl aminobenzaldehyde) + 10 ml of 1,56 mM MBTH (3-methyl-2-benzo-thiazoline hydrazone hydrochlorid) + 5 µl H2O2)

Colour development is stopped by adding 50 µl of 3N H2SO4 after approximately 5 to 10 minutes (before the negative control begins to be coloured).

Other chromogens such as ABTS (2,2'-Azino-bis-[3-ethylbenzothiazoline-6-sulphonic acid]), TMB (tetramethyl benzidine), or OPD (ortho-phenyldiamine) can also be used.

2.1.4.2. Read the plates at 600 nm (or 620 nm).

2.2. Interpretation of the results

2.2.1. Calculate the cut-off value by adding 0,6 to the value of the negative control (0,6 is the standard deviation derived with a group of 30 negative sera).

2.2.2. Test samples giving absorbance values lower than the cut-off are regarded as negative.

2.2.3. Test samples giving absorbance values greater than the cut-off + 0,15 are regarded as positive.

2.2.4. Test samples giving intermediate absorbance values are doubtful and a second technique must be employed to confirm the result.

3. Blocking elisa for the detection of antibodies to african horse sickness virus (AHSV) (prescribed test)

The blocking ELISA is designed to detect specific AHSV antibodies in sera from any susceptible species. VP7 is the major, antigenic, viral protein of AHSV, and is conserved within the nine serotypes. Because the monoclonal antibody (Mab) is also directed against the VP7, the assay will give a high level of sensitivity and specificity. Further, the recombinant VP7 antigen is completely innocuous and therefore guarantees a high degree of safety.

The principal of the test is the interruption of the reaction between the recombinant VP7, as the antigen bound to the ELISA plate and the conjugated Mab specific for the VP7. Antibody in the test sera will block the reaction between the antigen and the Mab resulting in a reduction in colour.
The test described hereinafter is carried out in the European Community Reference Laboratory for African horse sickness in Algete, Spain.

3.1. Test procedure

3.1.1. *ELISA plates*

3.1.1.1. Coat ELISA plates with recombinant AHSV-4 VP7 diluted in carbonate/bicarbonate buffer, pH 9,6. Incubate overnight at 4 °C.

3.1.1.2. Wash the plates five times with phosphate buffered saline (PBS) containing 0,05 % (v/v) Tween 20 (PBST).

3.1.1.3. Stabilise the plate by treatment with a stabilising solution (in order to allow long term storage at 4 °C without loss of activity) and blot dry onto adsorbent material.

3.1.2. *Test samples and controls*

3.1.2.1. For screening:
dilute test sera and controls 1 in 10 directly on the plate in PBST to give a final volume 100 µl/well. Incubate for 1 hour at 37 °C.

3.1.2.2. For titration:
prepare a twofold dilution series of test sera and positive controls (100 µl/well) from 1 in 10 to 1 in 1 280 across eight wells. Negative control is tested at 1 in 10 dilution.

3.1.3. *Conjugate*
Add 50 µl /well of pre-diluted horseradish-peroxidase (HRP) -conjugated Mab (monoclonal antibodies specific for VP7) to each well and mix gently to ensure homogeneity. Incubate for 30 minutes at 37 °C.

3.1.4. Wash the plates five times with PBST and blot dry as above.

3.1.5. *Chromogen/Substrate*
Add 100 µl /well of chromogen/substrate solution (1 ml of ABTS (2,2'-Azino-bis-[3-ethylbenzothiazoline-6-sulphonic acid]) 5 mg/ml + 9 ml of substrate buffer (0,1 M Phosphate-Citrate buffer of pH 4 containing 0,03 % H2O2] and incubate for 10 minutes at room temperature. Colour development is stopped by adding 100 µl /well of 2 % (w/v) SDS (sodium dodecyl sulphate).

3.1.6. *Reading*
Read at 405 nm in an ELISA reader.

3.2. Interpretation of the results

3.2.1. *Assay validation*

The test is valid when the optical density (OD) of negative control (NC) is higher than 1,0 and the OD of positive control (PC) is lower than 0,2.

3.2.2. *Cut-off calculation*
Positive cut-off = NC – ((NC – PC)x 0,3)
Negative cut-off = NC – ((NC – PC)x 0,2)
Where, NC is the OD of the negative control and PC the OD of positive control.

3.2.3. *Interpretation of results*
Samples with OD lower than positive cut-off should be considered as positives to AHSV antibodies.
Samples with OD higher than negative cut-off should be considered negatives for AHSV antibodies.
Samples with OD between these two values should be considered doubtful and the animals re-sampled after two to three weeks.

Nru. 1198

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regolamenti li ġej skond l-artikolu 10 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni dwar Ikel u Regolamenti Veterinarji, fejn tiddikara kif fil-fehma tagħha r-regolamenti proposti jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regolamenti ta' l-2004 dwar il-Kundizzjonijiet ta' Saħħa ta' l-Annimali li jirregolaw it-Tqegħid fis-Suq ta' Annimali u Prodotti ta' l-Akwakultura.

Id-19 ta' Novembru, 2004

No. 1198

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 10 of the Veterinary Services Act to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Animal Health Conditions governing the Placing on the Market of Aquaculture Animals and Products Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Animal Health Conditions governing the Placing on the Market of Aquaculture Animals and Products Rules, 2004

IN exercise of the powers conferred under Article 10 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, in agreement with the Minister of Health, the Elderly and Community Care has made the following Rules:-

Title, scope and applicability.

1. (1) The title of these Rules is the Animal Health Conditions governing the Placing on the Market of Aquaculture Animals and Products, Rules, 2004.

(2) The scope of these Rules is to implement the provisions found under European Union Council Rule 91/67/EEC concerning animal health conditions governing the placing on the market of aquaculture animals and products.

(3) This Rule shall apply without prejudice to Community or national provisions on the conservation of species.

Definitions.

2. For the purposes of these Rules and unless the context otherwise requires:

'aquaculture animals' means live fish, crustaceans or molluscs coming from a farm, including those from the wild intended for a farm;

'aquaculture products' means products derived from aquaculture animals, whether intended for farming, such as eggs and gametes, or for human consumption;

'fish, crustaceans or molluscs' means any fish, crustacean or mollusc at any stage of development;

'farm' means any establishment or, in general, any geographically defined installation in which aquaculture animals are reared or kept with a view to their being placed on the market;

'approved farm' meansa farm complying, as the case may be, with the requirements of Schedule C I, II or III, and approved as such in accordance with Rule 6;

'approved zone' meansa zone complying, as the case may be, with the provisions of Scegule B I, II or III, and approved as such in accordance with Rrule 5;

'approved laboratory' means a laboratory located in the territory of Malta, designated by the competent authority, under its responsibility, to carry out the diagnostic tests provided for in this Rule;

'official service' means the veterinary service or any other service of equivalent level designated by the Veterinary Services of Malta or third country and responsible for carrying out the controls provided for in this Rule;

'health inspection' means a visit by an official service or services for the purpose of conducting health checks on a farm or zone;

'placing on the market' means holding or displaying for sale, offering for sale, selling, delivering, transferring or any other form of placing on the market in the Community, with the exception of retail sale.

Placing on the market of Community aquaculture animals and products

3. (1) The placing on the market of aquaculture animals shall be subject to the following general requirements:

(a) they must show no clinical signs of disease on the day of loading;

(b) they must not be intended for destruction or slaughter under a scheme for the eradication of a disease listed in Scedule A hereto; and

(c) they must not come from a farm which is subject to a prohibition for animal health reasons and must not have been in contact with animals from such a farm, and in particular from a farm which is subject to control measures in the context of Commission Directive 93/53/EEC of the 24th June 1993 introducing minimum Community measures for the control of certain fish diseases.[1]

(2) Aquaculture products being placed on the market for breeding purposes (eggs and gametes) must originate from animals which satisfy the requirements laid down in sub-rule (1).

(3) Aquaculture products being placed on the market for human consumption must originate from animals which satisfy the requirements laid own in sub-rule 3(1).

(4) This Rule shall apply without prejudice to the provisions of Directive 93/53/EEC with regard to the control of certain fish diseases, in particular the diseases in list I.

Transport and dispatch of acquaculture animals

3. (1) Aquaculture animals must be dispatched in the shortest possible period to the place of destination, using means of transport that have been cleaned and, if necessary, disinfected in advance with a disinfectant that is officially authorized in Malta if it is the territory of dispatch.

(2) If water is used in overland transport, the vehicles shall be designed in such a way that water cannot escape from the vehicle during transport.Transport shall be carried out in such a way as to safeguard effectively the health of the animals, in particular by changing the water. Changes of water must be carried out in places complying with the requirements of Schedule D. A list of these places and any subsequent amendments thereto must be notified by Malta to the Commission, which shall forward that information to the other Member States.

Approval of zones

4. (1) In order to obtain, for one or more of the diseases referred to in

[1] OJ No L 175, 19. 7. 1993, p. 23.

Shcedule A, column 1, list II, the status of approved zone, Malta shall submit to the Commission:

(a) all appropriate justifications concerning the conditions laid down, as the case may be, in Schedule B under I B, II B or III B,

(b) the national rulesens uring compliance with the conditions laid down, as the case may be, in Schedule B under I C, II C or III C.

(2) The Commission shall scrutinize the information referred to in sub-rule (1). The Commission shall use such information as a basis for approving zones in accordance with the procedure laid down in Article 26 of Directive 91/67/EEC. If, in accordance with Schedule B under I.D.5, II.D or III.D.5, the approval of a zone is withdrawn by the official service, the Commission shall revoke the decision concerning its approval.

Approval and reapproval of farms in a non-approved zone

5. (1) In order to obtain, for one or more of the diseases referred to in Schedule A, column 1, list II, the status of approved farm situated in a non-approved zone, Malta shall submit to the Commission:

(a) all appropriate justifications concerning the conditions set out, as the case may be, in Schedule C under I A, II A or III A,

(b) the national rules ensuring compliance with the conditions set out in
Schedule C under I B, II B or III B.

(2) On receipt of the file relating to the request for approval or reapproval of a farm in a non-approved zone, the Commission shall have a month within which to examine that file. That examination shall be carried out in the light of the information mentioned in sub-rule (1) and, where appropriate, of on-site inspections undertaken in accordance with the provisions set out in Article 17 of Directive 91/67/EEC .

(3) Should that examination lead to favorable conclusions, the Commission shall forward such conclusions to Malta. Malta hall have a period of two weeks within which to make known their remarks.

(4) After expiry of that period, if no remarkshave been made or if Malta's remarks are not contrary to the Commission's conclusions, the Commission shall approve or re-approve the farm.

(5) Should there exist major differences between the Commission's conclusions and Maltas' remarks, or should the Commission, after examining the file, consider that the approval or re-approval ought not be granted, the Commission shall have two months within which to refer the matter to the Standing Veterinary Committee and obtain its opinion.

(6) If in accordance with Schedule C under I C, II C or III C, the approval of a farm is withdrawn by the official service, the Commission shall revoke the approval decision.

(7) The Commission shall draw up the list of approved farms. It shall amend that list in order to take account of new approvals or withdrawal of approvals. The Commission shall forward the list and any amendments thereto to Malta.

Placing of live fish on the market

6. The placing on the market of live fish belonging to the susceptible species referred to in Schedule A, column 2, list II, their eggs or gametes, shall be subject to the following additional guarantees:

(a) where they are to be introduced into an approved zone, they must, in accordance with Rule 10, be accompanied by a movement document corresponding to the model set out in Schedule E, Chapter 1 or 2, certifying that they come from an approved zone or an approved farm.

(b) where they are to be introduced into a farm which, although not situated in an approved zone, fulfils the conditions set out in Schedule C I, they must in accordance with Rule 10, be accompanied by a movement document corresponding to the model set out in Schedule E, Chapter 1 or 2, certifying that they come respectively from an approved zone or from a farm of the same health status as the farm of destination.

Placing of molluscs on the market

7. The placing on the market of live molluscs referred to in Scehdule A, column 2, list II, shall be subject to the following additional guarantees:

(a) if they are to be relaid in an approved coastal zone, they must, in accordance with Rule 10, be accompanied by a movement document corresponding to the model set out in Schedule E, Chapter 3 or 4, certifying that they come from an approved coastal zone or from an approved farm in a non-approved coastal zone, as the case may be;

(b) if they are to be relaid in a farm which although not situated in an approved coastal zone fulfils the conditions set out in Schedule C III, they must, in accordance with Rule 10, be accompanied by a movement document corresponding to the model set out in Schedule E, Chapter 3 or 4, certifying that they come from an approved coastal zone or from a farm of the same health status as the farm of destination.

Placing of acquaculture animals and products for human consumption on the market in an approved zone originating in a non-approved zone

8. The placing on the market in an approved zone of aquaculture animals and productsfor human consumption originating in a non-approved zone shall be subject to the following requirements:

(a) fish susceptible to the diseases referred to in Schedule A, column 1, list II, must be slaughtered and eviscerated prior to dispatch.

(b) live molluscs susceptible to the diseases referred to in Scedule A, column 1, list II, must be delivered either for direct human consumption or to the preserving industry; they shall not be relaid unless they originate in an approved farm in a non-approved coastal zone, or they are temporarily immersed in storage ponds or purification centreswhich are specially equipped and approved for that purpose by the competent authority and include in particular a system for the treatment and disinfection of residual water.

Rule to ensure the carrying out of the programme

9. (1) Where Malta has drawn up a programme specifying in particular:

(a) the geographical zone and farm or farms concerned,

(b) the measures to be taken by the official services to ensure that the programme is properly carried out,

(c) the procedures followed by the approved laboratories, their number and location,

(d) the prevalence of the disease or diseases listed in Schedule A, column 1 of lists I and II,

(e) the measures laid down to combat these diseases where detected, the introduction of aquaculture animals and products coming from a Member State into zones or farms covered by the programme shall be subject to the rules set out in Rules 6 and 7.

(2) Where Malta has drawn up a programme specifying in particular:

(a) the geographical zone and farm or farms concerned,

(b) the measures to be taken by the official services to ensure that the programme is properly carried out,

(c) the procedures followed by the approved laboratories, their number and location,

(d) the prevalence of the disease or diseases listed in Schedule A, column 1 of lists I and II,

(e) the measures laid down to combat these diseases where detected,

the introduction of aquaculture animals and products coming from Malta into zones or farms covered by the programme shall be subject to the rules set out in Rules 6 and 7.

Movement documents

11. (1) The movement documents referred to in Rules 6 and 7 must be drawn up by the official service at the place of origin within 48 hours before loading, in the official language or languages of the place of destination. They must be drawn up on a single sheet of paper, be made out for a single consignee. They shall be valid for 10 days.

(2) Each consignment of aquaculture animals and products must be clearly identified in order to be able to trace back to the farm of origin, and to verify where appropriate the correlation of the animals or products with the information contained in the accompanying movement document. This information may figure directly on the container or on a label fixed to it or on the movement document.

Control programmes

11. (1) According to the procedure laid down in Rule 6 (1) (c), Malta may draws up a voluntary or compulsory control programme for one of the diseases referred to in Schedule A, column 1 of list III, it shall submit the programme to the Commission, outlining in particular:

(a) the distribution of the disease in Malta,

(b) the justification of the programme, taking into account, the importance of the disease and the programme's likely benefit in relation to its cost,

(c) the geographical area in which the programme will be implemented,

(d) the status of farms to be established, and the standards which must be achieved by the farms in each category, including test procedures,

(e) the rules applicable for entry of animals of a lower health status into the farm,

(f) the action to be taken if, for any reason, a farm loses its status,

(g) the procedures under which the programme is to be monitored.

(2) The additional guarantees, general or specific, which may be required for the introduction of aquaculture animals and products into officially

checked zones or farms shall be defined in accordance with the same procedure.

(3) Programmes may be amended or supplemented in accordance with the procedure laid down in sub-rule (1). Under the same procedure, it may be approved an amendment or addition to a programme which has been approved or to guarantees which have been defined in accordance with sub-rule (2).

Guarantees to be accompanied by movement document

12. Where Malta considers that its territory or part of its territory is free from one of the diseases listed in Schedule A, column 1, of List III, and has defined the zones that are to be regarded as free from, and the species that are susceptible to, the disease in question, and the additional guarantees, general or specific, which may be required for the introduction of aquaculture animals and products into those areas, live fish, shellfish or crustaceans and if appropriate, their eggs and gametes, coming from Malta and introduced into such zones must be accompanied by a movement document, corresponding to a model to be published by the official service of Malta, certifying that they comply with such additional guarantees.

Requirements for the placing on the market of certain live farmed fish

13. (1) Without prejudice to the requirements for diseases referred to in Schedule A, column 1, list III, established in accordance with Rules 11 and 12, the placing on the market of live farmed fish not belonging to the susceptible species referred to in Schedule A, column 2, list II, as well as their eggs and gametes shall be subject to the following additional requirements:

(a) where they are to be introduced into an approved zone, they must, in accordance with Rule 10, be accompanied by a movement document corresponding to the model to be drawn up in accordance with the procedure laid down in Article 7 (1) (d) of the Veterinary Framework Act, certifying that they come from a zone of the same health status, from an approved farm in a non-approved zone or from a farm which may be situated in a non-approved zone on condition that such a farm contains no fish belonging to the susceptible species referred to in Schedule A, column 2, list II, and is not connected with a watercourse or with coastal or estuarial waters.

(b) where they are to be introduced into a farm which, although situated in a non-approved zone, fulfils the conditions of Schedule C, they must, in accordance with Rule 10, be accompanied by a movement document, corresponding to the model to be drawn up in accordance with the procedure laid down in Article 7 (1) (d) of the Veterinary Framework Act, certifying that they come from an

approved zone, from a farm of the same health status or from a farm which may be situated in a non-approved zone on condition that such a farm contains no fish belonging to the susceptible species referred to in Schedule A, column 2, list II, and is not connected with a watercourse or with coastal or estuarial waters.

(2) The requirements laid down in sub-rule 1 shall apply to the placing on the market of farmed molluscs not belonging to the susceptible species referred to in Schedule A, column 2, list II.

(3) Without prejudice to the requirements for diseases referred to in Schedule A, column 1, list III established in accordance with Rules 11 and 12, the placing on the market of wild fish, molluscs or crustaceans, their eggs or gametes, shall be subject to the following additional requirements:

(a) where they are to be introduced into an approved zone, they must, in accordance with Rule 10, be accompanied by a movement document, corresponding to the model to be drawn up in accordance with the procedure laid down in Article 7 (1) (d) of the Veterinary Framework Act, certifying that they come from a zone of the same health status;

(b) where they are to be introduced into a farm which, although situated in a non-approved zone, fulfils the conditions of Schedule C, they must, in accordance with Rule 10, be accompanied by a movement document, corresponding to the model to be drawn up in accordance with the procedure laid down in Article 7 (1) (d) of the Veterinary Framework Act, certifying that they come from an approved zone;

(c) where such animals are fished in the deep sea and are to be used for breeding in approved zones and approved farms, they must be placed in quarantine under the supervision of the official service in suitable facilities and under appropriate conditions to be determined in accordance with Article 7 (1) (b) and (c) of the Veterinary Framework Act.

(4) The requirements laid down in sub-rules (1), (2) and (3) shall not apply where practical experience and/or scientific evidence has shown that there is no passive transmission of the disease when aquaculture animals, their eggs and gametes, not belonging to the susceptible species referred to in Schedule A, column 2, list II, are moved from a non-approved zone to an approved zone.

(5) This Rule shall not apply to ornamental tropical fish kept permanently in aquariums.

Detection and confirmation of viral haemorrhagic septcaemia (VHS)

14. Sampling plansand diagnostic methodsto be applied for the detection and confirmation of the presence of the diseases referred to in Scedule A, column 1, shall be established in accordance with the procedure laid down in Article 26 of Directive 91/67/EEC. These sampling plans must take account of the presence of wild fish, crustaceans and molluscs in the aquatic environment.

Veterinary checks

15. (1) The rules laid down in Article 16 of the Veterinary Framework Act concerning veterinary checks in trade with Malta as regards aquaculture products for human consumption and as regards aquaculture animals and products placed on the market shall apply, in particular as regards the organisation of and the action to be taken following the inspections to be carried out at destination, and the protective safeguard measures to be implemented. In addition:

(a) consignments of live farmed fish, their eggs or gametes in trade with Malta between non-approved zones as regards the diseases referred to in list II of Schedule A, must be accompanied by a certificate the model of which shall be laid down in accordance with the procedure of Article 7 (1) (d) of the Veterinary framework Act;

(b) consignments of live farmed fish, their eggs and gametes in trade with Malta from a farm infected with a disease referred to in list II of Schedule A towards other farms infected by the same disease, must be accompanied by a certificate the model of which shall be laid down accordance with the procedure of Article 7 (1) (d) of the Veterinary framework Act.

(2) The certificates referred to in sub-rule (1)(a) and (b) hereof must:

(a) be drawn up at least in the language or languages of Malta if the place of destination,

(b) accompany the fish, eggs or gametes in the original,

(c) consist of a single sheet of paper,

(d) be made out for a single consignee.

Onsite inspection

16. If an inspection is carried out onsite in the territory of the Republic of Malta by the experts of a relevant International organisation in conjunction with Maltese Government, the official service shall provide the experts with all the assistance necessary to complete their task. carried out on, the s shall give the experts all the assistance necessary to carry out their task.

Rules governing imports from third countries

17. Aquaculture animals and products imported into Malta shall satisfy the conditions laid down in Rules 18, 19 and 20.

Provenance of acquaculture animals and products

18. (1) Aquaculture animals and products must come from third countries or parts thereof appearing on a list drawn up in accordance with the procedure laid down in Article 8 (2) (a) of the Veterinary framework Act. That list may be supplemented or amended in accordance with the same procedure.

(2) In deciding whether a third country or part thereof may appear on the list referred to in sub-rule (1) particular account shall be taken of:

(a) the state of health of the aquaculture animals, particular attention being paid to exotic diseases and the environmental health situation in the third country which might endanger the health of livestock in Malta and in the Member States;

(b) the regularity and rapidity of the information supplied by the country relating to the existence of infectious or contagious diseases of aquaculture animals in its territory, in particular those diseases mentioned in list B of the "Office International des Epizooties";

(c) the rules of the third country on the prevention and control of diseases of aquaculture animals;

(d) the structure of the official services in the third country and their powers;

(e) the organisation and implementation of measures to prevent and control infectious or contagious diseases of aquaculture animals;

(f) assurances which the third country may provide concerning the rules laid down in this Rule.

(3) The list referred to in sub-rule (1) and all amendments thereto shall be published in the Official Journal of the European Communities Republic of Malta.

(4) Pending the drawing up of the list referred to in sub-rule (1), the requisite transitional measures may be adopted, in accordance with the procedure laid down in sub-rule (1).

Health conditions

19. (1) For each third country, aquaculture animals and products shall satisfy the health conditions adopted in accordance with the procedure laid down in Article 8 (1) of the Veterinary Framework Act.

(2) Depending on the animal health situation in the third country concerned, the conditions referred to in sub-rule (1) hereof may include in particular:

(a) restriction to imports from a part of the third country,

(b) restriction to certain species at any stage of development,

(c) the prescription of a treatment to be applied to the products, such as the disinfection of eggs,

(d) prescription of the use to which these animals or products are to be put,

(e) the measures to apply following importation, such as quarantine or the disinfection of eggs.

(3) Pending establishment of the import conditions provided for in this Order, Malta shall ensure that imports of aquaculture animals and products from third countries are subject to conditions at least equivalent to those applying to the production and placing on the market of its products and Member States products.

Certification

20. (1) Aquaculture animals and products shall be accompanied by a certificate drawn up by the official services of the exporting third country. This certificate must:

(a) be issued on the day of loading of the consignment for dispatch to the Member State of destination;

(b) accompany the consignment in the original;

(c) attest that the aquaculture animals and certain fishery products meet the requirements of this Rule and those laid down pursuant thereto with regard to importation from the third country;

(d) be valid for 10 days;

(e) consist of a single sheet of paper;

(f) be made out for a single consignee.

(2) The certificate referred to in sub-rule (1) must comply with a model established in accordance with the procedure laid down in Article 8 (2) (c) of the Veterinary Framework Act.

Inspections

21. (1) Inspections shall be carried out on the spot by Maltese veterinary experts and the Commission to verify whether the provisions of this Rule, and in particular Rules 18 and 19 thereof, are being applied in practice.

(2) The Maltese experts who are to be entrusted with the ask of carrying out these inspections shall be appointed by the Commission, acting on proposals from the Maltese government.

(3) Those inspections shall be made on behalf of the Community, which shall bear the expenditure incurred in this connection.

(4)The frequency of and the procedures for these inspections shall be determined in accordance with the procedure laid down in Article 26 of Directive 91/67/EEC.

Safeguard measures

22. The principles and rules laid down in Directives 91/496/EEC and 97/ 78/EC shall apply, with particular reference to the organisation of and follow-up to the checks to be carried out by Malta and the safeguard measures to be implemented.

SCHEDULE A
LISTED DISEASES/PATHOGENS OF FISH, MOLLUSCS AND CRUSTACEA

1	2
Disease/pathogen	**Susceptible species**
LIST I **Fish** Infectious salmon anaemia (ISA)	 Atlantic salmon (Salmo salar)
LIST II **Fish** VHS (Viral haemorrhagic septicaemia) Infectious haematopoietic necrosis (IHN)	 Salmonid species Grayling (Thymallus thymallus) Whitefish (Coregonus spp.) Pike (Esox lucius) Turbot (Scophthalmus maximus) Salmonid species Pike fry (Esox lucius)
Molluscs Bonamia ostreae Marteilla refringens	 Flat oyster (Ostrea edulis) Flat oyster (Ostrea edulis)
LIST III **Fish** Infectious pancreatic necrosis (IPN) Spring viraemia of carp (SVC) Bacterial kidney disease (BKD) (Renibacterium salmonidarum) Furunculosis (Aeromonas salmonicida) (Enteric redmouth disease) (ERM) (Yersinia ruckeri) Gyrodactylus salaris Crustaceans Crayfish plague (Aphanomyces astaci)	To be specified in the programme referred to in Articles 12 and 13 of Directive 91/67/EEC.

SCHEDULE B
APPROVED ZONES
I. **Continental zones for fish** (column 2 of . list . II in Schedule A)

(1) *Definition of continental zones*

A continental zone consists of

(a) a part of the territory comprising an entire catchment area from the sources of the waterways to the estuary, or more than one catchment area, in which fish is reared, kept or caught, or (b) a part of a atachment area from the sources of the waterways to a natural or artificial barrier preventing fish migrating from downstream of that barrier.

(b) The size and the geographical situation of a continental zone must be such that possibilities for recontamination, e.g. by migrating fish, are reduced to a minimum. That may require the establishment of a bufferzone in which a monitoring programme iscarried out without obtaining the status of approved zone.

(2) *Grant of appeal*
In order to obtain approved status, a continental zone must meet the following requirements:

(a) all fish are free for at least four years from any clinical or other sign of one or more of the diseases referred to in Schedule A, column 1 of . list . II;

(b) all farms in the continental zone are placed under the supervision of the official services. Two health inspections per year for two years must have been carried out.

(2) The health inspections must have been carried out at the times of the year when the water temperature favoursthe development of these diseases. The health inspection must at least consist of:

(a) an inspection of fish showing abnormalities,

(b) the taking of samples in accordance with a programme established under the procedure provided for in Article 15 of Directive 91/67/EEC, which are to be sent as quickly as possible to an approved laboratory to be tested for the pathogens in question.

(3) However, zones having a historical record of absence of the diseases referred to in Schedule A, column 1, list II, may obtain approved status if:

(a) their geographical situation does not permit easy introduction of disease;

(b) an official disease control system has been in place for an extended period of time of at least ten years, during which:

(i) there has been regular monitoring of all farms,

(ii) a disease notification system has been applied,

(iii) no case of disease has been reported,

(iv) under the rules in force, only fish eggs or gametes from non infected zones or farms, subject to official checks and p-resenting equivalent health guarantees, were able to be introduced into the zone.

(4) The period of 10 years referred to in the first sub-rule may be reduced to five years as a result of the testing carried out by the official service of Malta, provided that, in addition to the requirementsreferred to in the first subsub-rule, the regular monitoring of all farms referred to above has included at least two health inspections per year involving at least: an inspection of fish showing abnormalities, a taking of samples of at least 30 fish at each visit.

(5) If Malta wishes to benefit from the provisions relating to historical records must submit their request no later than 31 December 1996; if there isno farm in a continental zone to be approved, the official services must have subjected fish from the lower part of the catchment area to a health inspection twice a year for four years, in accordance with sub-rule 2; the laboratory examinations of fish taken during health inspections have produced negative results as regards the pathogens in question; where Malta has reques ted approval for a water catchment area or part of a water catchment area originating in a neighbouring Member State, or common to two Member States, the following provisions shall apply:

(a) the two Member States concerned should simultaneously submit a request for approval in accordance with the procedures laid down in Articles5 or 10,

(b) the Commission, in accordance with the procedure laid down in Article 26, after examining and checking the requests and evaluating the health situation, shall, if need be, lay down any other provisions necessary for granting such approval.

(6) The Member States, in accordance with Directive 89/608/EEC (1), shall grant each other mutual assistance for the application of this Directive, and in particular of this sub-rule.

2. *Maintenance of approval*

Maintenance of approval is subject to the following requirements:
(1) fish introduced into the zone must come from another approved zone or from an approved farm;

(2) each farm must undergo two health inspections annually in accordance with point B.2, except farms without broodstock which must be inspected once per year. However, samples will be taken by rotation
in 50 % of the fish farms in the continental zone each year;

(3) the results of the laboratory examinations on the fish sampled during the health inspections must have been negative as regards the agents of the diseases referred to in Schedule A, column 1 of .the list . II;

(4) a register must be kept by the farmers or the persons responsible for the introducing of fish, containing all the information necessary to enable the state of health of the fish to be monitored constantly.

3. *Suspension, re-establishment and withdrawal of approval*

(1) Any abnormal death or other symptom that might constitute grounds for suspecting an outbreak amongst fish of a disease referred to in Schedule A, column 1 of the. list . II must be notified as quickly
as possible to the official service.. The latter shall immediately suspend approval of the zone or of part of the zone, provided that the part of the zone which still has approved status continues to meet the definition in point A. .

(2) A sample of at least 10 sick fish must be sent to the approved laboratory in order to be tested for the pathogens in question. The results of the tests must be communicated immediately to the official service.

(3) Where the results are negative for the pathogens in question but positive for another cause, the official service shall restore approval.

(4) However, when no diagnosis can be made, a further health inspection must be made within 15 days of the first sampling and a sufficient number of sick fish must be taken and forwarded to the approved laboratory in order to be tested for the pathogens in question. If the results are again negative or if there are no more sick fish, the official service will restore the approval.

(5) Where the results are positive, the official service shall withdraw approval of the zone, part of the zone referred to in point 1.

(6) Restoration of approval of a zone or part of a zone referred to in point 1 is subject to the following requirements:

(a) when an outbreak occurs, all fish in the infected farms must have been slaughtered, and infected or contaminated fish must have been destroyed, facilities and equipment must have been disinfected in accordance with a procedure approved by the official services;

(b) after elimination of the outbreak, the requirements set up must be again complied with.

7. The central competent authority shall inform the Commission and the other Member States regarding the suspension, restoration or withdrawal of approval of zones, or parts of zones referred to in point 1.

II. **Coastal zones for fish** (column 2 of . list . II of Schedule A)

1. (1) A coastal zone consists of a part of the coast or sea water or an estuary with a precise geographical delimitation which consists of a homogeneous hydrological system or a series of such systems. If necessary, a coastal zone may be deemed to consist of a part of the coast or sea water or an estuary situated between the mouths of two watercourses or of a part of the coast or sea water or an estuary where there are one
or more farms, provided that provision is made for a buffer zone on both sides of the farm or farms, the extent of which shall be set by the Commission on a case-by-case basis in accordance with the procedure
laid down in Article 26 of Directive 91/67/EEC.

2.. *Grant of approval*

(1) In order to obtain approved status, a coastal zone for fish must meet the
requirements laid down for continental zones referred to in point I B.

3. *Maintenance of status*

(1) Maintenance of the approval for a coastal zone is subject to the requirements set out in point I C.

(2). *Suspension, restoration and withdrawal of approval*

The rules are identical to those set out in point I.D; however, where the zone is composed of a series of hydrological systems, suspension, restoration and withdrawal of approval may relate to a part of this series
where this part has a precise geographical delimitation and consists of a homogeneous hydrological system, provided that the part which still has approved status continues to meet the definition in point A.

4. **Coastal zones for molluscs** (column 2 of . list . II of Schedule A)

.(1).. A coastal zone must comply with the definition laid down in point II A.

2.. *Grant of approval*

(1)In order to be approved, a coastal zone must meet the following requirements:

(a) all molluscs have for at least two years shown no clinical or other sign of one or more of the diseases referred to in Schedule A, column 1 of list . II;

(b) all farms in the coastal zone are placed under the supervision of the official services. Health inspections are carried out at intervals adapted to the development of the pathogensin question. During these inspections samples are taken and sent without delay to the approved laboratory to be tested for the pathogens in question;

(c) if there is no farm in the continental zone, the official service must have submitted molluscs to a health inspection in accordance with point 2, at intervals adapted to the development of the pathogens in question. However, if detailed investigations of fauna show that the zone does not contain any molluscs belonging to vector, carrier or susceptible species, the official service may approve the zone before any molluscs are introduced;

(d). laboratory examinations of molluscs taken during health inspections by the official services have produced negative results as regards the pathogensin question. For zones having a historical record of absence of the diseases referred to in Schedule A, column 1 of list . II, this information may be taken into account for the grant of approval.

5. *Maintenance of approval*

(1) Maintenance of approval is subject to the following requirements:

(a). molluscs introduced into the coastal zone must come from other approved coastal zones or from approved farms in non-approved coastal zones;

(b). each farm must undergo a health inspection in accordance with point B 2 at intervals adapted to the development of the pathogens in question;
(c). the results of the laboratory examinations on the molluscs sampled during the health inspections must have been negative as regards the agents of the diseases referred to in Schedule A, column 1 of list . II;

(d). a register must be kept by the farmers or the persons responsible for the introduction of molluscs, containing all information necessary to enable the state of health of the molluscs to be monitored constantly.

6. *Suspension, restoration and withdrawal of approval*

(a). Any abnormal death or other symptom that might constitute grounds for suspecting an outbreak amongst molluscs of a disease, referred to in Schedule A, column 1 of list II, must be notified as quickly as
possible to the official service. The latter shall immediately suspend approval of the zone or, if the zone is composed of a series of hydrological systems, of part of that series where such part has a precise geographical delimitation and consists of a homogeneous hydrological system, provided that the part which still has approved status continues to meet the definition in point A. .

(b) A sample of sick molluscs must be sent to the approved laboratory in order to be tested for the pathogens in question. The results of the tests must be communicated immediately to the official service.

(c) Where the results are negative for the pathogens in question, but positive for another cause, approval shall be restored.

(d). However, when no diagnosis can be made, a further health inspection must be made within 15 days of the first taking of samples and a sufficient number of sick molluscs must be taken and forwarded to the approved laboratory in order to be tested for the pathogens in question. If the results are again negative or if there are no longer any sick molluscs, the official service will restore approval.

(e) Where the results are positive, the official service shall withdraw approval of the zone or part of the zone as referred to in point 1.

(f) Restoration of approval of a zone or part of a zone as referred to in point 1 is subject to the following requirements:

(i) when an outbreak occurs, infected or contaminated molluscs must have been destroyed, facilities and equipment must have been disinfected in accordance with a procedure approved by the official service;
(ii) after elimination of the outbreak, the requirements set out in point B must again be complied with.

(g) The central competent authority shall inform the Commission and the other Member States regarding suspension, restoration or withdrawal of approval of zones or parts of zones referred to in point 1.

SCHEDULE C
APPROVEDFARMS IN A NON-APPROVED ZONE

I. **Continental farms for fish** (Column 2 of . list . II of Schedule A)

1. *Grant of approval*

(1) In order to be approved a farm must meet the following requirements:

(a) water must be supplied by a well, a borehole or a spring. Where such water supply is situated at a distance from the farm, the water must be supplied directly to the farm, and be channelled through a pipe or, with the agreement of the official service, via an open channel or a natural conduit, provided that this does not constitute a source of infection for the farm and doesnot allow the introduction of wild fish. The water channel must be under the control of the farm or, in cases where this is not possible, the official service;

(b) there must be a natural or artificial barrier situated downstream which prevents fish from entering the said farm;

(c). if necessary, it must be protected against flooding and infiltration of water;

(d). it must comply, *mutatis mutandis*, with the requirementss et out in Schedule B.I.B. Furthermore, where approval is requested on the basis of a historical record with an official control system for a 10-year period, it must meet the following additional requirements: it must have been submitted, at least once per year, to a clinical inspection and the taking of samples to be tested for the pathogensin question in an approved laboratory;

(e) it may be the subject of additional measures imposed by the official service, when considered necessary to prevent the introduction of diseases. Such measures may include the establishment of a buffer zone around the farm in which a monitoring programme iscarried out, and the establishment of protection against the intrusion of possible pathogen carriers or vectors; . However: a new farm which meetsthe first three and fifth requirements but which commencesits activitieswith fish, eggs or gametesfrom an approved zone or an approved farm situated in a non-approved zone may obtain approval without undergoing the sampling required for the grant of approval; a farm which meets such requirements which recommences its activities after a break with fish, eggs or gametes from an approved zone or an approved farm situated in a
non-approved zone may obtain approval without undergoing the sampling required for the grant of approval provided that: the health history of the farm over the last four years of its operation is known to the official service; however, if the farm concerned has been in operation for less than four years, the actual period in which it hasbeen in operation shall be taken into account, the farm has not been subject to animal-health measures in respect of the diseases listed in list II of Schedule A and there have been no antecedents of those diseases on the farm, prior to the introduction of the fish, eggs or gametes, the farm is cleaned and disinfected, followed by depopulation for a minimum period of 15 days under official supervision.

2. *Maintenance of approval*

(1) Maintenance of approval shall be subject to the requirements set out in Schedule B I C. However, sampling must be carried out once a year.

3 *Suspension, restoration and withdrawal of approval*

(1) The requirements set out in Schedule B I D shall apply.

II. **Coastal farms for fish** (Column 2 of . list . II of Schedule A)

1. *Grant of approval*

(1) In order to be approved, a farm must meet the following requirements:

(1). It must be supplied with water by means of a system which includes equipment for the destruction of the agents of the diseases referred to in Schedule A, column 1, list II; the criteria required for the uniform application of these provisions and in particular those relating to the proper functioning of the system shall be laid down in accordance with the procedure provided for in Article 26 of Directive 91/67/EEC .

(2) It must comply, *mutatis mutandis,* with the requirements laid down in Schedule B II B. However:

(a) a new farm which meets these requirements but which commences its activities with fish, eggs or gametes from an approved zone or an approved farm situated in a non-approved zone may obtain approval without undergoing the sampling required for the grant of approval;

(b) a farm which meets these requirements which recommences its activities after a break with fish, eggs or
gametes from an approved zone or an approved farm situated in a non-approved zone may obtain approval without undergoing the sampling required for the grant of approval provided that:

(i) the health history of the farm over the last four years of its operation is known to the official service; however, if the farm concerned has been in operation for less than four years, the actual period in which it has been in operation shall be taken into account,

(ii) the farm has not been subject to animal-health measures in respect of the diseases listed in list II of Schedule A and there have been no antecedents of those diseases on the farm,

(iii) prior to introduction of the fish, eggs or gametes, the farm is cleaned and disinfected, followed by depopulation for a minimum period of 15 days under official supervision.

2. *Maintenance of approval*

(1) Maintenance of approval shall, *mutatis mutandis,* be subject to the requirements laid down in Schedule B II C.

3.. *Suspension, restoration and withdrawal of approval*

(1)The requirements laid down in Schedule B II D shall apply *mutatis mutandis*.

III. **Coastal farms for molluscs** (Column 2 of list . II of Schedule A)

1. *Grant of approval*

(1) In order to be approved, a farm must meet the following requirements:

(a). It must be supplied with water by means of a system which includes equipment for the destruction of the agent of the diseases referred to in Schedule A, column 1, list II; the criteria required for the uniform application of these provisions and in particular those relating to the proper functioning of the system shall be laid down in accordance with the procedure provided for in Article 26 of Directive 91/67/EEC.

(b) It must comply, *mutatis mutandis,* with the requirements as set out in Schedule B III B, however

(i) a new farm which meets the requirements referred to in a and b, but which commences its activities with molluscs from an approved zone or an approved farm situated in a non-approved zone may obtain approval without undergoing the sampling required for the grant of approval;
(ii) a farm which meetsthe requirements referred to in i, which recommences its activities after a break with molluscs from an approved zone or an approved farm situated in a non-approved zone may obtain approval without undergoing the sampling required for the grant of approval provided that: the health history of the farm over the last two years of its operation is known to the official service, the farm has not been subject to animal-health measures in respect of the diseases listed in list II of Schedule A and there have been no antecedents of those diseases on the farm, prior to the introduction of the molluscs, the farm is cleaned
and disinfected, followed by depopulation for a minimum period of 15 days under official supervision.

2. *Maintenance of approval*

(1) Maintenance of approval shall, *mutatis mutandis,* be subject to the guarantees laid down in Schedule B III C,

3 *Suspension, restoration and withdrawal of approval*
The requirements set out in Schedule B III D shall apply *mutatis mutandis*.

SCHEDULE D
RENEWAL OF WATER

1.Renewal of water during the transportation of aquaculture animals shall be carried out in facilities which are approved by Malta and meet the following requirements:

(a). The hygienic properties of the water available for changing must be such as not to alter the health situation of the species transported with regard to the agents of the diseases referred to in Schedule A, column 1 of . list . II.

(b). These facilities shall contain devices designed to prevent any contamination
of the host environment: either by facilitating disinfection of the water, or by ensuring that release of this water does not under any circumstances entail direct discharge into the open sea or free-flowing waterways.

Nru. 1199

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regolamenti li ġej skond l-artikolu 5 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni dwar Ikel u Regolamenti Veterinarji, fejn tiddikara kif fil-fehma tagħha r-regolamenti proposti jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regolamenti ta' l-2004 dwar il-Ġbir ta' Informazzjoni fuq Elementi Żoonotiċi u li Jikkaġunaw Żoonożi.

Id-19 ta' Novembru, 2004

No. 1199

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 5 of the Veterinary Services Act to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Collection of Information on Zoonoses and Zoonotic Agents Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Collection of Information on Zoonoses and Zoonotic Agents Rules, 2004

BY virtue of the powers conferred by article 5 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, has made the following draft rules:-

Title and scope

1. (1) The title of these rules is the Collection of Information on Zoonoses and Zoonotic Agents Regulations, 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 92/117/EEC concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of foodborne infections and intoxications in the territory of Malta.

Definitions

2. For the purposes of these rules -

(a) "approved national laboratory" means a laboratory approved or recognized by the competent authority of Malta to carry out examinations of official samples in order to detect a zoonotic agent;

(b) "competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act, or any other authority to which such responsibility has been delegated by the Veterinary Services;

(c) "Member State" means a State which is a Member within the European Community;

(d) "official sample" means a sample taken by the competent authority to test for a zoonotic agent. The official sample bears a reference to the species, the type, the amount and the method of collection, and the identification of the origin of the animal or the product of animal origin; this sample is to be taken without prior warning;

(e) "sample" means a sample taken by the owner of or person responsible for the establishment or the animals, or taken on his behalf, to be examined for a zoonotic agent;

(f) "Third country" means a State which is not a Member within the European Community;

(g) "zoonosis" means any disease and/or infection which is likely to be naturally transmitted from animals to man;

(h) "zoonotic" agent means any bacterium, virus or parasite which is likely to cause a zoonosis;

Measures taken in accordance with these rules

3. (1) In the territory of Malta measures taken in accordance with these rules by the competent authority are coordinated at national and local level, in particular in relation to epidemiological surveys.

(2) The competent authority at local level shall be assisted by approved national laboratories.

(3) The competent authority shall designate the approved national reference laboratories for the zoonoses and zoonotic agents listed in Schedule I, point I, at which the identification of a zoonotic agent or final confirmation of its presence may be carried out.

Collection of information on zoonoses and zoonotic agents

4. (1) The following regulations must be ensured in the territory of Malta:

(a) the operators or managers of establishments approved in accordance with European Union Council Directives 64/433/EEC, 71/118/EEC and 77/99/EEC are obliged to keep for a minimum

period to be specified by the competent authority and to communicate to the latter at its request, the results of examinations for the presence of the zoonoses listed in Schedule I, point I;

(b) the isolation and identification of zoonotic agents or the establishment of any other evidence of their presence rests with the person responsible for the laboratory or, where the identification is carried out elsewhere than at a laboratory, with the person responsible for the examination;

(c) the diagnosis and identification of a zoonotic agent are reported to the competent authority;

(d) the competent authority collects information on any zoonotic agents the presence of which has been confirmed in the course of the tests or examinations carried out and on any clinical cases in humans or animals of the zoonoses listed in Schedule I, point I;

(e) the other Member States are regularly informed within the Standing Veterinary Committee set up by European Decision 68/361/EEC of clinical cases recorded in accordance with (d).

(2) In accordance with the procedure laid down in article 5(3) of the Veterinary Services Act, the provisions of this regulation may be extended to cover the zoonoses and zoonotic agents listed in Schedule I, points II and III.

Evaluation of information collected

5. (1) The competent authority shall evaluate the information collected in accordance with rule 4 (1)(d). It shall report to the European Commission, by the 31st May of each year, the trends and sources of the zoonotic infections recorded during the previous year.

(2) Sub-regulation (1) hereof shall not rule out more frequent reporting for additional information, where the circumstances warrant.

Systems for tracing the movement of farm animals

6. The systems for tracing the movement of farm animals laid down in European Commission Decision 89/153/EEC shall be enforced in relation to the measures for zoonoses and zoonotic agents laid down in these rules.

National measures to be submitted by the competent authority

7. (1)(a) The competent authority shall submit to the Government the national measures which they are taking to achieve the objectives of these regulations in respect of the zoonoses listed in Schedule I, points I and II, with the exception of those already being taken for brucellosis and tuberculosis under plans

already approved within the framework of Veterinary legislation. These measures will be forwarded to the relevant International organisation and the Member States.

(b) Such measures may include measures to detect the zoonoses and zoonotic agents listed in Schedule I, point III.

(c) The competent authority shall forward to the European Commission, every year, a report on the epidemiological situation for trichinosis.

(2) In the case of salmonella in fowls, the competent authority must forward to the European Commission, plans drawn up in accordance with the criteria laid down in Schedules II and III. These plans shall:

(a) specify as regards salmonella the measures taken to comply with the minimum requirements laid down in Schedule III;

(b) take into account the specific situation in the territory of Malta;

(c) indicate the number of approved national laboratories at which examination and identification of salmonella will take place and the approval procedures for those laboratories.

(3) In accordance with the procedure laid down in article 5(3) of the Veterinary Services Act:

— the plans referred to in sub-regulation (2) hereof, shall be approved by the Minister,

— amendments or additions may be made to a plan previously approved in order to take account of developments in the situation in the territory of Malta.

Financial contribution towards the measures for slaughter and destruction and official sampling

8. (1)(a) Detailed rules governing the financial contribution towards the measures for slaughter and destruction and official sampling imposed pursuant to Schedule III, Section I, point V may be laid down in accordance with any European Community law and articles 18 and 19 of the Veterinary Services Act.

(b) As regards the measures provided for in Schedule III, the financial contribution provided for in articles 18 and 19 of the Veterinary Services Act, must not benefit breeders who have contravened the requirements of these regulations.

Measures to avoid the introduction of salmonella onto a farm

9. The competent authority shall establish rules specifying the measures to be taken to avoid the introduction of salmonella onto a farm, taking account of the principles set out in Annex II to European Union Council Directive 90/539/EEC.

On-spot checks by experts from the Commission

10. Experts from the European Commission may, in so far as in necessary for the uniform application of these regulations and in cooperation with the competent authorities of Malta, make on-the-spot checks. To do this, they may verify by checking a representative percentage of holdings whether the territory of Malta is ensuring compliance with these regulations. The European Commission shall inform the competent authority of the results of the checks made. The competent authority shall take any measures which may prove necessary to take account of the results of the checks.

Safeguard measures

11. The safeguard measures provided for in any European Community law and in articles 15(5) and 16(3) of the Veterinary Services Act, concerning veterinary checks to be carried out in trade with Member States or third countries shall apply for the purposes of these rules.

SCHEDULE I

LIST OF THE ZOONOSES COVERED BY REGULATION 4

I. — Tuberculosis due to *Mycobacterium bovis*
— Brucellosis and the agents thereof
— Salmonellosis and the agents thereof
— Trichinosis.

II. — Campylobacteriosis
— Echinococcosis
— Listeriosis
— Rabies
— Toxoplasmosis
— Yersiniosis
— Other zoonoses and the agents thereof.

III. Any other zoonosis not found in the European Community and the agents of that zoonosis.

SCHEDULE II

CRITERIA FOR DRAWING UP PLANS FOR MONITORING SALMONELLA IN FOWL FLOCKS

I. The plans must indicate:
- the number and type of samples to be taken,
- the number and type of official samples to be taken,
- the methods of sampling,
- the methods of examination of the samples and identification of the zoonotic agents.

II. The plans must take into account the following criteria for establishing the sampling procedures:
(a) factors likely to encourage the spread of one or more zoonoses;
(b) previous history of the zoonosis in question in a country or region, in domestic animals or wildlife;
(c) the animal population concerned as regards:
- total size of population,
- homogenity of the population group,
- age of animals,
- animal production;

(d) the environment of the farms as regards:
- regional differences,
- density of flocks,
- relations with urban areas,
- relations with areas populated by wildlife;

(e) farm production systems including:
- intensive farming units,
- extensive farming units,
- husbandry systems, in particular feeding regimes and animal health care measures;

(f) problems likely to arise in the light of known precedents and other information;
(g) the required degree of protection according to the nature and gravity of the zoonosis in question.

SCHEDULE III

INSPECTION FOR SALMONELLA

Sect ion I
MONITORING AND CONTROL — PRESENCE OF SALMONELLA IN BREEDING FLOCKS

I. **Breeding flocks**
A breeding flock comprises at least 250 birds *(Gallus gallus)*, kept or reared on a single holding for the production of hatching eggs.

II. **Monitoring for salmonella in breeding flocks**
The owner or the person responsible for hatcheries or for a breeding flock must, at his own expense, have samples taken for analysis for the detection of salmonella either in an approved national laboratory or in a laboratory recognized by the competent authority, with the minimum levels of sampling indicated below being respected.

A. *Rearing flocks*
1. Samples must be taken from birds being reared for breeding purposes at least when the chicks are one day old, when the birds are four weeks old and two weeks prior to pullets entering the laying phase.
2. The samples to be taken must comprise:
   (a) in the case of day-old chicks, samples from the internal linings of the boxes in which the chicks were delivered to a holding and from the carcases of chicks found to be dead on arrival; and
   (b) in the case of pullets at four weeks of age or two weeks prior to entering the laying phase, pooled faeces samples made up of separate samples of fresh faeces each weighing not less than 1 g taken at random from a number of sites in the building in which the birds are kept, or, where the birds have free access to more than one building on a particular holding, from each group of buildings on the holding in which the birds are kept;
   (c) the number of sites from which separate faeces samples are to be taken in order to make a pooled sample shall be as follows:

Number of birds kept in a building	Number of faeces samples to be taken in the building or group of buildings on the holding
1—24	(number equal to the number of birds up to a maximum of 20)
25—29	20
30—39	25
40—49	30
50—59	35
60—89	40
90—199	50
200—499	55
500 or more	60

B. *Adult breeding flocks*
1. All adult breeding flocks must be sampled at least every two weeks during the laying period.
2. Breeding flocks whose eggs are hatched at a hatchery with a total incubator capacity of less than 1000 eggs must be sampled on the holding and the samples to be taken

shall consist of a pooled faeces sample made up of separate faeces samples, each weighing not less than 1 g, collected in accordance with point A (2) (b).

3. Breeding flocks whose eggs are hatched at a hatchery with a total incubator capacity of 1 000 eggs or more must be sampled through the hatchery and the samples to be taken shall consist of:
   (a) pooled samples of meconium taken from 250 chicks hatched from eggs supplied to the hatchery from each breeding flock; or
   (b) samples of carcases of 50 chicks which are dead in the shells of eggs or which have been hatched from eggs supplied to the hatchery from each breeding flock.
4. Such samples must also be taken from breeding flocks comprising less than 250 birds whose eggs are hatched in hatcheries with a total incubator capacity of 1 000 eggs or more.
5. Every eight weeks, the sampling provided for in point B must be replaced by official sampling, which must be conducted in accordance with point 4.

C. *Examination of samples for salmonella*

The total number of samples taken in each building may be pooled for analysis. The analyses and tests for salmonella shall be carried out by methods recognized in accordance with the procedure laid down in article 5(3) of the Veterinary Services Act.

III. **Notification of results**

Where, as a result of monitoring carried out in accordance with point II, the presence of *Salmonella enteritidis* or *Salmonella typhimurium* is detected in a breeding flock, the person responsible for the laboratory carrying out the examination, the person carrying out the examination or the owner of the flock shall notify the results to the competent authority.

IV. **Investigation of flocks declared positive after monitoring**

Where the presence of *Salmonella enteritidis* or *Salmonella typhimurium* is notified in accordance with point III, the flock shall be officially sampled in order to confirm the initial results. A sample of birds must be taken at random from within each house of birds on the farm, the size of sample being selected in accordance with the table at point II (A)(2)(c). For the purposes of examination, the birds from each house must be grouped into batches of five and samples of liver, ovary and intestines taken from each bird in the batch must be examined for salmonella using analyses and tests recognized in accordance with the procedures laid down in article 5(3) of the Veterinary Services Act or pending such recognition by tried and tested national methods.

V. **Measures to be taken in respect of flocks where infection is confirmed**

The measures must comply with the following minimum standards.

1. Where, as a result of an investigation carried out in accordance with point IV, the presence of *Salmonella enteritidis* or *Salmonella typhimurium* is confirmed in the birds in a house, the following measures must be taken:
   (a) no bird may leave the house concerned unless the competent authority has authorized the slaughter and destruction under supervision or slaughter in a slaughterhouse designated by the competent authority in accordance with (c);
   (b) non-incubated eggs produced by the birds in the house in question must be destroyed on the spot or after appropriate marking be taken under supervision to an approved egg-processing establishment to be heat treated in accordance with the requirements of European Union Council Directive 89/437/EEC;
   (c) all the birds in the house must be slaughtered in accordance with Annex I, Chapter VI, point 31 (c) of European Union Council Directive 71/118/EEC, the official veterinarian of the slaughterhouse being informed of the decision to slaughter, in accordance with Annex I, Chapter VI, point 25 (a) of that Directive, or be slaughtered and destroyed so as to reduce as much as possible the risk of spreading salmonella.
2. Once a house occupied by a flock infected with *Salmonella enteritidis* or *Salmonella typhimurium* has been emptied of birds, effective cleansing and disinfection must be

carried out, including safe disposal of manure or litter, in accordance with procedures laid down by the local veterinary authority. Restocking must be with chicks satisfying the requirements of point II (A) (1).

3. Where eggs for hatching from flocks in which the presence of *Salmonella enteriditis* or *Salmonella typhimurium* has been confirmed are still present in a hatchery, they must be destroyed or treated as high risk material in accordance with European Union Council Directive 90/667/EEC (1).

VI. Under the procedure provided for in article 5(3) of the Veterinary Services Act,

(a) surveillance systems based on a serological check at the holding may be recognized if they offer guarantees equivalent to the system of inspection at the hatchery provided for in point II (A) (1), (B) (3) and (4) and (C);

(b) alternative solutions to compulsory slaughter provided for in point V (c), such as antibiotic treatment, may be approved for breeding flocks;

(c) specific rules may be established with a view to safeguarding valuable genetic material.

The checks provided for in this Chapter may, according to the procedure laid down in article 5(3) of the Veterinary Services Act, be reviewed in the light of the development of scientific knowledge.

Section II

INSPECTION FOR SALMONELLA AT THE FINAL PRODUCTION STAGE OF COMPOUND FEEDINGSTUFFS FOR POULTRY

When official samples are being taken on a holding or in cases of justified suspicion, sampling may be carried out on the compound feedingstuffs used to feed poultry.

Where a sample is positive for salmonella, the competent authority shall carry out an investigation in order to:

(a) identify the source of contamination, in particular by means of official samples taken at different stages of production;

(b) examine the application of rules and controls concerning the disposal and processing of animal waste and in particular those laid down in European Union Council Directive 90/667/EEC;

(c) establish procedures for good manufacturing practices and ensure compliance with recognized procedures.

Nru. 1200

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni mas-Servizzi Veterinarji, qiegħed b'din jippubblika r-regoli li ġejjin skond l-artikolu 5(1) ta' l-Att dwar is-Servizzi Veterinarji:-

Regolamenti ta' l-2004 li Jintroduċu l-Miżuri Minimi għall-Kontroll ta' ċertu Mard li jaffettwa Molluski Bivalvolari.

Id-19 ta' Novembru, 2004

No. 1200

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Veterinary Services, is hereby publishing the following rules in accordance with article 5(1) of the Veterinary Services Act:-

Introducing Minimum Measures for the Control of certain Diseases affecting Bivalve Molluscs Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Introducing Minimum Measures for the Control of certain Diseases affecting Bivalve Molluscs Rules, 2004.

IN exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has, with the concurrence of the Prime Minister and Minister of Finance, made the following Rules:-

Title, scope, and definitions.

1. (1) The title of these rules is Introducing Minimum Measures for the Control of certain Diseases affecting Bivalve Molluscs Rules, 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 95/70/EEC on the Introduction of Minimum European Community Measures for the Control of certain Diseases affecting Bivalve Molluscs, and in accordance with article 5 (1) of the Veterinary Services Act.

(3) These rules establish minimum measures for the control of the diseases affecting bivalve molluscs referred to in these rules.

(4) For the purposes of these rules, the definitions laid down in Article 2 of European Union Council Directive 91/67/EEC and Article 2 of European Union Council Directive 91/492/EEC shall apply as necessary.

(5) In addition, 'observed abnormal mortality' shall mean sudden mortality affecting approximately 15 % of stocks and occurring over a short period between two inspections (confirmed within 15 days). In hatchery a mortality shall be considered abnormal when the farmer cannot obtain larvae during a period which included successive spawns from different brood-stocks. In nursery a mortality shall be considered abnormal when a sudden sizeable mortality occurs in a short time on a number of tubes.

Registration and records to be kept by bivalve molluscs farms.

2. (1) All farms rearing bivalve molluscs on the territory of Malta shall be registered by the official service; this registration must be kept constantly up to date.

(2) All farms rearing bivalve molluscs on the territory of Malta shall keep a record of:

(a) live bivalve molluscs entering the farm, containing all information relating to their delivery, their number or weight, their size and their origin;
(b) bivalve molluscs leaving the farm for re-immersion, containing all information relating to their dispatch, their number or weight, their size and destination;
(c) observed abnormal mortality. This record, which shall be open to scrutiny by the official service at all times, on demand, shall be updated regularly and kept for four years.

Monitoring and sampling in bivalve molluscs farms.

3. (1) A monitoring and sampling programme shall be applied in bivalve mollusc farms, farming areas and harvested natural beds in order to observe whether there is an abnormal mortality and keep track of the health situation of stocks. In addition, the official service may apply the above programme to purification centres and storage tanks which discharge water into the sea. If, during application of this programme, any abnormal mortality is observed, or if the official service has information giving it reason to suspect the presence of diseases, the following measures shall be taken:

(a) a list shall be drawn up of the sites where the diseases referred to in Schedule A, list II to European Union Council Directive 91/67/EEC are present, provided that such diseases are not the subject of a programme approved pursuant to the said European Union Council Directive,
(b) a list shall be drawn up of the sites at which abnormal mortality has been observed as a result of the presence of the diseases referred to in Schedule B, or on which the official service has information giving it reason to suspect the presence of diseases,
(c) monitoring of the evolution and geographical spread of the diseases referred to in 1 (a) and (b).

(2) The detailed rules for implementing this rule, and *inter alia* the rules to be applied for establishing the programme referred to in sub-rule 1 of this rule, particularly as regards the frequency and timetable of monitoring, procedures for taking samples (statistically representative volume) and methods of diagnosis, shall be adopted, if necessary, in accordance with the requirements of the European Community and under the procedure provided for in article 5(1) of the Veterinary Services Act.

Measures to be taken in the event of suspicion of diseases.

4. (1) The suspected presence of any diseases referred to in rule 4 and any abnormal mortality rate observed in bivalve molluscs in farms, in farming areas or in harvested natural beds or in purification centres or storage tanks which discharge water into the sea shall be notified as soon as possible to the official service by the shellfish-farmers or any other person who has made such observations.

(2) In the case referred to in sub-ule 5 (1), the official service shall ensure that:

(a) samples are taken for examination in an approved laboratory;

(b) pending the result of the examination referred to in paragraph (a), no molluscs leave the affected farm, farming area or harvested natural beds or purification centres or storage tanks which discharge water into the sea for relaying or re-immersion in another farm or in the aquatic environment, unless authorized by the official service.

(3) If the examination referred to in sub-rule 5(2)(a) fails to demonstrate the presence of a pathogen, the restrictions referred to in sub-rule 5(2)(b) shall be lifted.

(4) (a) If the examination referred to in sub-rule 5(2) shows the presence of a pathogen causing the observed abnormal mortality capable of being the cause of that mortality, or of a pathogen of one of the diseases referred to in rule 4, an epizootic investigation must be carried out by the official service in order to determine the possible means of contamination and to investigate whether molluscs have left the farm, the farming area or the harvested natural beds for relaying or re-immersion elsewhere during the period preceding observation of the abnormal mortality.

(b) If the epizootic investigation shows that the disease has been introduced into one or more farms, farming areas or harvested natural beds as a result *inter alia* of molluscs being moved, the provisions of sub-rule 5(2) shall apply. However, by way of derogation from article 3 (1) (c) of European Union Council Directive 91/67/EEC, the official service may, within its territory, authorize the movement of live bivalve molluscs to other farms, farming areas or harvested natural beds which are infected with the same disease.

(c) If necessary, further appropriate measures may be decided by the official service in accordance with the requirements of the European Community and under the procedure laid down in article 5(1) of the Veterinary Services Act.

(5) The official service shall ensure that the European Commission and the other European Union Member States are immediately informed, in accordance with the current European Community procedures, of any cases of abnormal mortality rates observed involving a pathogen, of any measures taken to analyse and control the situation and of the cause of the mortality.

Sampling and testing.

5. (1) Sampling and laboratory testing for the determination of the cause of abnormal mortality of bivalve molluscs shall be carried out using the methods established by the European Community.

(2) A national reference laboratory for the territory of Malta is designated in Schedule A of these rules, with facilities and expert personnel enabling it to carry out the testing referred to in sub-rule 6(1).

(3) National reference laboratories shall cooperate with the European Community reference laboratory for molluscs diseases.

Spot-checks by European Commission experts.

6. (1) European Commission experts may, to the extent necessary to ensure uniform application of European Union Council Directive 95/70/EEC, carry out on-the-spot checks. In so doing, they may carry out random, non-discriminatory checks to ensure that the official service in charge of molluscs diseases is monitoring compliance with the said Directive.

(2) The checks referred to in sub-rule (1) shall be carried out in collaboration with the official service in charge of molluscs diseases in Malta.

(3) The official service in charge of molluscs diseases in Malta shall provide the experts with any assistance they require to accomplish their task.

SCHEDULE A

THE TERRITORY OF MALTA NATIONAL REFERENCE LABORATORY FOR DISEASES OF BIVALVE MOLLUSCS

The '*ISTITUTO ZOOPROFILATTICO SPERIMENTALE DELLE VENEZIE'*,
Area Ittiopatologia Laboratorio Patologia Molluschi,
Via della Roggia, 94
I-33030 Basaldella di Campoformido (UD)
Italy.

SCHEDULE B

DISEASES OF BIVALVE MOLLUSCS AND THE SUSCEPTIBLE HOST SPECIES

Disease	Pathogen	Susceptible Host Species
Bonamiosis	*Bonamia exitiosus*	*Tiostrea chilensis* and *Ostrea angasi*
	Mikrocytos roughleyi	*Saccostrea (Crassotrea) Commercialis*
Marteiliosis	*Marteilia sydneyi*	Marteiliosis *Saccostrea (Crassotrea) commercialis*
Microcytosis	*Mikrocytos mackini*	*Crassotrea gigas*; C. *virginica; Ostrea edulis*; O. *conchaphila*
Perkinsosis	*Perkinsus marinus*	*Crassotrea virginica* and C. *gigas*
	Perkinsus olseni/ atlanticus	*Haliotis ruber*; H. *cyclobates*; H. *scalaris*; H. *laevigata*; *Ruditapes philippinarum* and R. *decussates*
MSX disease	*Haplosporidium nelsoni*	*Crassotrea virginica* and C. *gigas*
SSO disease	*Haplosporidium costale*	*Crassotrea virginica*
Withering syndrome of abalones	*Candidatus Xenohaliotis californiensis*	Members of the genus *Haliotis* including black abalone (H. *cracherodii)*, red abalone (H. *rufescens*), pink abalone (H. *corruguta*), green abalone (H. *fulgens*) and white abalone (H. *sorenseni)*

Note: Susceptible host species also includes any other species specified, for the pathogen in question, in the International Office of Epizooties' (OIE) most recent edition of the International Aquatic Animal Health Code.

Nru. 1201

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regolamenti li ġej skond l-artikolu 13(a) ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti ma jistabbilixxux biżżejjed projbizzjoni ta' l-użu ta' sustanzi li jkollhom azzjoni ormonali jew tirostatika u ta' *betaagonists* fit-trobbija tal-bhejjem, jew jekk ikunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 il-Projbizzjoni ta' l-Użu ta' Sustanzi li jkollhom Azzjoni Ormonali jew Tirostatika u ta' *Betaagonists* fit-Trobbija tal-Bhejjem.

Id-19 ta' Novembru, 2004

No. 1201

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with articles 13(a) of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules do not sufficiently establish prohibition on the use in stock-farming of substances having a hormonal or thyrostatic action and of betaagonists, or how they are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Prohibition on the Use in Stock-Farming of Substances having a Hormonal or Thyrostatic Action and of Betaagonists Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT, 2001 (CAP. 437)

Prohibition on the Use in Stock-Farming of Substances having a Hormonal or Thyrostatic Action and of Betaagonists Rules, 2004

IN exercise of the powers conferred under article 13(a) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title and scope and applicability

1. (1) The title of these rules is Prohibition on the Use in Stock-Farming of Substances having a Hormonal or Thyrostatic Action and of Betaagonists Rules, 2004.

(2) The scope of these regulations is to implement the rules found under European Union Council Directive 96/22/EEC on the Prohibition on the Use in Stock-Farming of Certain Substances having a Hormonal or Thyrostatic Action and of Betaagonists .

Definitions

2. For the purpose of these rules, and unless the context otherwise requires –

(a) "Competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

(b) "farm animals" shall mean domestic animals of the bovine, porcine, ovine and caprine species, domestic solipeds, poultry and rabbits, as well as wild animals of those species and wild ruminants which have been raised on a holding;
(c) "illegal treatment" shall mean the use of unauthorised substances or products or the use of substances or products authorised under national legislation for purposes or under conditions other than those laid down in national legislation;

(d) "Member State" means a State which is a Member within the European Community;

(e) "the Commission" means the European Commission;

(f) "the Community" means the European Community as established under the Treaty establishing the European Community;

(g) "therapeutic treatment" shall mean the administering under rule 4 of these rules to an individual farm animal of an authorised substance to treat, after examination by a veterinarian, a fertility problem including the termination of unwanted gestation and, in the case of betaagonists, to induce tocolysis in cows when calving and to treat respiratory problems and to induce tocolysis in equidae raised for purposes other than meat production;

(h) "Third country" means a State which is not a Member within the European Community.

(i) "Veterinary Services" means the competent authority within the territory of Malta as established under article 2 of the Veterinary Services Act.

(j) "zootechnical treatment" shall mean the administering:

(i) to an individual farm animal of any substance authorised under rule 6 of these rules for synchronising oestrus and preparing donors and recipients for the implantation of embryos, after examination of the animal by a veterinarian or, in accordance with the second paragraph of rule 6, under his responsibility;

(ii) in the case of aquaculture animals, to a group of breeding animals for sex inversion, on a veterinarian's prescription and under his responsibility.

Prohibitions within the territory of Malta

3. In the territory of Malta, the following shall be prohibited -

(i) the placing on the market of stilbenes, stilbene derivatives, their salts and esters and thyrostatic substances for administering to animals of all species;

(ii) the placing on the market of betaagonists for administering to animals the flesh and products of which are intended for human consumption for purposes other than those provided for in sub-paragraph (ii) of rule 5.

Further prohibitions within the territory of Malta

4. In the territory of Malta, the following shall also be prohibited -

(i) the administering to a farm or aquaculture animal, by any means whatsoever, of substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and of betaagonists;

(ii) the holding, except under official control, of animals referred to in paragraph (i) on a farm, the placing on the market or slaughter for human consumption of farm animals or of aquaculture animals which contain the substances referred to in (i) or in which the presence of such substances has been established, unless proof can be given that the animals in question have been treated in accordance with rules 5 or 6;
(iii) the placing on the market for human consumption of aquaculture animals to which substances referred to in paragraph (i) have been administered and of processed products derived from such animals;

(iv) the placing on the market of meat of the animals referred to in paragraph (ii) ;

(v) the processing of the meat referred to in paragraph (iv).

Exemptions to prohibitions

5. Notwithstanding rules 3 and 4, in the territory of Malta, the following is authorised:

(i) the administering to farm animals, for therapeutic purposes, of ßoestradiol 17, testosterone and progesterone and derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application.

Veterinary medicinal products used for therapeutic treatment must comply with the requirements for placing on the market laid down in Order (81/851) and be administered only by a veterinarian, by injection or for the treatment of ovarian dysfunction in the form of vaginal spirals, but not by implant, to farm animals which have been clearly identified. Treatment of identified animals must be registered by the veterinarian responsible. The latter must record at least the following details in a register, which may be the one provided for in Order (81/851) –

(a) type of treatment;

(b) the type of products authorised;

(c) the date of treatment;
(d) the identity of the animals treated.

The register must be made available to the Veterinary Services at its request;

(ii) the administering for therapeutic purposes of authorised veterinary medicinal products containing:

(a) allyl trenbolone, administered orally, or betaagonists to equidae and pets, provided they are used in accordance with the manufacturer's instructions;

(b) betaagonists, in the form of an injection to induce tocolysis in cows when calving.

Such substances must be administered by a veterinarian or, in the case of the veterinary medicinal products referred to in paragraph (a) hereof, under his direct responsibility; treatment must be registered by the veterinarian responsible, who shall record at least the details referred to in point (i).

Farmers shall be prohibited from holding veterinary medicinal products containing betaagonists which may be used for induction purposes in the treatment of tocolysis.

However, without prejudice to the first subparagraph of point ii (b), therapeutic treatment of production animals, including breeding animals at the end of their reproductive life, shall be prohibited.

Certain treatments permitted within the Maltese territory

6. (1) Notwithstanding rule 4 (i) and without prejudice to rule 3, in the territory of Malta the administering to farm animals is authorised, for the purpose of zootechnical treatment, of veterinary medicinal products having an oestrogenic, androgenic or gestagenic action which are authorised in accordance with Orders (81/851) and (81/852). Such veterinary medicinal products must be administered by a veterinarian to clearly identified animals; the treatment must be recorded by the veterinarian responsible in accordance with rule 5 (i):

Provided that Veterinary Services may allow the synchronisation of oestrus and the preparation of donors and recipients for the implantation of embryos to be effected not by the veterinarian direct, but under his responsibility.

(2) With regard to aquaculture animals, young fish may be treated for the first three months for the purpose of sex inversion with veterinary medicinal products that have an androgenous action and are authorised in accordance with Orders (81/851) and (81/852).

(3) In the cases provided for in this rule, the veterinarian shall make out a non-renewable prescription, specifying the treatment in question and the quantity of the product required and shall record the products prescribed:

Provided that zootechnical treatment of production animals, including during the fattening period for breeding animals at the end of their reproductive life, shall be prohibited.

Authorisation of administration of hormonal products and Betaagonists

7. (1) Hormonal products and Betaagonists the administration of which to farm animals is authorised in accordance with rules 5 and 6 must meet the requirements of Orders (81/851) and (81/852).

(2) The following are not, however, authorised in accordance with sub-rule (1)

(a) the following hormonal products:

(i) products acting as a deposit;

(ii) products with a withdrawal period of more than 15 days after the end of treatment;

(iii) products:

(1) which were authorised under rules that preceded the national legislation laying down procedures in conformity with international agreement for the authorisation and supervision of medicinal products for human and veterinary use,

(2) whose conditions of use are not known,

(3) or which no reagents or equipment exist for use in the analytical techniques for detecting the presence of residues in excess of the permitted limits,

(b) veterinary medicinal products containing betaagonists which have a withdrawal period of more than 28 days after the end of treatment.

Trade, breeding and relative health marks

8. (1) For the purpose of trade, it is permitted in the territory of Malta, the placing on the market of animals for breeding and breeding animals at the end of their reproductive life which, during the latter period, have undergone a treatment referred to in rules 5 and 6 and may authorise the affixing of the health mark of Annex I, Chapter XI, (50) of Order (64/433) to meat from such animals where the conditions laid down in rules 5 and 6 and the minimum withdrawal periods laid down in rule 7 (2), under paragraph (a) (ii) or (b) respectively or the withdrawal periods provided for in the authorisation to place on the market are complied with.

However, trade in highvalue horses, and in particular racehorses, competition horses, circus horses or horses intended for stud purposes or for exhibitions, including registered equidae to which veterinary medicinal products containing allyl trenbolone or betaagonists have been administered for the purposes referred to in regulation 5, may take place before the end of the withdrawal period, provided that the conditions governing administration are fulfilled and that the type and date of treatment are entered on the certificate or passport accompanying these animals.

(2) Meat or products from animals to which substances having an oestrogenic, androgenic or gestagenic action or betaagonists have been administered in accordance with the dispensatory provisions of these regulations may not be placed on the market for human consumption unless the animals in question have been treated with veterinary medicinal products complying with the requirements of rule 7 and in so far as the withdrawal period laid down was observed before the animals were slaughtered.

Possession and use of substances by authorised persons

9. Within the territory of Malta -

(i) at the time of the import, manufacture, storage, distribution, sale and use of the substances referred to in rules 3 and 4 (i), their possession is

restricted to the persons authorised by national legislation in accordance with Article 1 (5) of Order (81/851);

(ii) in addition to the checks provided for in the Orders governing the placing on the market of the various products in question, the official checks provided for in Article 11 of Order (96/23) are carried out by the competent national authorities without prior notice, with a view to ascertaining:

(a) the possession or presence of substances or products prohibited under rule 3, intended to be administered to animals for the purpose of fattening;

(b) the illegal treatment of animals;

(c) failure to observe the withdrawal periods provided for in regulation 7;

(d) failure to observe the restrictions on the use of certain substances or products laid down in rules 5 and 6;

(iii) the tests for the presence of:

(a) the substances referred to in point (i) in animals, in the drinking water of animals and in all places where animals are bred or kept;

(b) residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products

are carried out in accordance with Annexes III and IV to Order (96/23);

(iv) where the checks provided for in points (ii) and (iii) reveal:

(a) the presence of substances or products the use or possession of which is prohibited, or the presence of residues of substances the administering of which comes under the heading of illegal treatment, such substances or products are confiscated, while any animals treated or the meat therefrom is placed under official supervision until the requisite penalties have been applied;
(b) failure to comply with the requirements of points (ii) (b) and (c), the Veterinary Services takes appropriate measures consistent with the gravity of the infringement.

Keeping of registers of substances

10. (1) Without prejudice to Order (81/851), undertakings buying or producing substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and betaagonists, undertakings authorised in any capacity to market such substances and undertakings buying or producing pharmaceutical and veterinary medicinal products from such substances shall be required to keep registers detailing, in chronological order, quantities produced or acquired and those sold or used for the production of pharmaceutical and veterinary medicinal products and the names of the persons to whom such quantities were sold or from whom they were purchased.

(2) The information in sub-rule (1) hereof shall be made available to the Veterinary Services at its request and, in the case of computerised records, in the form of a print-out.

Failure to comply with the requirements of these rules

11. Where the results of checks carried out in the territory of Malta show failure to comply with the requirements of these regulations in the country of origin of the animals or products, the Veterinary Services shall have recourse to provisions taken according to the procedure laid down in Article RE1 of the Veterinary Framework Act on mutual assistance between the administrative authorities of Malta and of the Member States to ensure the correct application of legislation on veterinary and zootechnical matters.

Limitation of importation

12. (1) Third countries whose legislation authorizes the placing on the market and administration of stilbenes, stilbene derivatives, their salts and esters, or of thyrostatic substances for administering to animals of all species may not appear on any of the lists of countries provided for under veterinary legislation from which Malta authorizes to import farm or aquaculture animals or meat or products obtained from such animals.

(2) In the territory of Malta, it is prohibited to import from third countries on any of the lists referred to in sub-rule (1) of:

(a) farm or aquaculture animals

(i) to which products or substances referred to in point (i) of rule 3 have been administered by any means whatsoever;

(ii) to which substances or products referred to in point (i) of rule 4 have been administered, unless those substances or products were administered in compliance with the provisions and requirements laid down in rules 5, 6 and 8 and the withdrawal periods allowed in international recommendations have been observed;

(b) meat or products obtained from animals the importation of which is prohibited under point (a).

(3) However, animals intended for breeding, breeding animals at the end of their reproductive life, or meat there from, from third countries may be imported subject to their affording guarantees at least equivalent to those laid down in these regulations or which have been established for the implementation and enforcement of Chapter V of Order (96/23) on measures to be taken in the event of infringement.

(4) Checks on imports from third countries shall be carried out in accordance with Article 17 (2) and (3) of the Veterinary Framework Act.

Nru. 1202

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regolamenti li ġej skond l-artikoli 22 sa 28 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 Sustanzi u Prodotti mhux Mixtieqa fin-Nutrizzjoni tal-Bhejjem

Id-19 ta' Novembru, 2004

No. 1202

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with articles 22 to 28 of the Veterinary Services Act to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Undesirable Substances and Products in Animal Nutrition Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT

(CAP. 437)

Undesirable Substances and Products in Animal Nutrition Regulations, 2004

BY virtue of the powers conferred by articles 22 to 28 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, has made the following rules:-

Title and scope

1. (1) The title of these rules is the Undesirable Substances and Products in Animal Nutrition Rules, 2004.

(2) The scope of these regulations is to implement the rules found under European Union Council Directive 99/29/EC regarding undesirable substances and products in animal nutrition and the relevant measures to be taken in the territory of Malta.

(3) These rules shall apply without prejudice to the provisions on:

(a) additives in feedingstuffs;

(b) the marketing of feedingstuffs;

(c) the fixing of maximum permitted levels for pesticide residues on and in products intended for animal feeding, where these residues are not listed in Section B of Schedule I;

(d) micro-organisms in feedingsstuffs;

(e) certain products used in animal nutrition;

(f) feedingstuffs for particular nutritional purposes.

Definitions

2. For the purposes of these rules -

(a) "animals" means animals belonging to species normally nourished and kept or consumed by man as well as animals living freely in the wild in cases where they are nourished with feedingstuffs;

(b) "the competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act, or any other authority to which such responsibility has been delegated by the Veterinary Services;

(c) "complementary feedingstuffs" means mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if they are used in combination with other feedingstuffs;

(d) "complete feedingstuffs" means mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;

(e) "compound feedingstuffs" means mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;

(f) "daily ration" means the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;

(g) "feedingstuffs" means products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;

(h) "feed materials" means various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding, either directly as such or after processing, in the preparation of compound feedingstuffs or as carriers of premixtures;

(i) "Member State" means a State which is a Member within the European Community;

(j) "pet animals" means animals belonging to species normally nourished and kept but not consumed by man, except animals bred for fur production;

(k) "Third country" means a State which is not a Member within the European Community;

Feed materials must be sound, genuine and of merchantable quality.

3. (1) Feed materials may only be put into circulation in the territory of Malta if they are sound, genuine and of merchantable quality.

(2) In particular, and subject to the provisions in Part A of Schedule II, feed materials cannot be considered as sound, genuine and of merchantable quality if the

level of undesirable substances or products is so high as to make it impossible to respect the maximum levels fixed for compound feedingstuffs in Schedule I.

Substances and products that can be tolerated in feedingstuffs

4. (1) Substances and products listed in Schedule I shall be tolerated in feedingstuffs only under the conditions therein set out.

(2) The competent authority may authorise the maximum permitted levels provided for in Schedule I in respect of feedingstuffs to be exceeded in the case of fodder which is produced and used in the same state on the same agricultural holding, where this is necessary for particular local reasons. The competent authority shall ensure that neither animal nor human health can suffer harm thereby.

Feed materials that may be put into circulation

5. (1) The feed materials listed in Schedule II, part (A) may be put into circulation only if their content of the undesirable substance or product mentioned in column 1 of the said Schedule does not exceed the maximum level laid down in column 3 of that Schedule.

(2) Where the content of the undesirable substance or product listed in column 1 of Schedule II, part (A) exceeds the level laid down in column 3 of Schedule I in respect of feed materials, the feed materials listed in column 2 of Schedule II, part (A) may, without prejudice to paragraph 1, be put into circulation only if:

(a) it is intended for use by establishments which meet the conditions of European Union Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector, and

(b) it is accompanied by a document stating:

— that the feed materials are intended for manufacturers of compound feedingstuffs who fulfil the conditions laid down in paragraph (a),

— that the feed materials may not be fed unprocessed to livestock,

— the amount of the undesirable substance or product contained in the feed material.

(3) Paragraph 2(a) and (b) shall also apply to the feed materials and undesirable substances or products listed in Schedule II, part (B) the maximum level of which is not restricted in Schedule II, part (A), if the level of the undesirable substance or product present in the feed materials exceeds that laid down in column 3 of Schedule I for the corresponding feed materials.

Restrictions

6. The competent authority may restrict the application of rule 5(2)(a) to those manufacturers of compound feedingstuffs who use the materials in question for the production and the putting into circulation of compound feedingstuffs.

Feed material of with undesirable substance must not be mixed with other consignments of feed materials or feedingstuffs

7. A consignment of a feed material detailed in part A of Schedule II with a content of an undesirable substance or product higher than the maximum level fixed in column 3 of the above-mentioned Schedule must not be mixed with other consignments of feed materials or with consignments of feedingstuffs.

8. In sofar as there are no special provisions for complementary feedingstuffs, these may not, allowing for the dilutions prescribed for their use, contain levels of the substances and products listed in Schedule I in excess of those fixed for complete feedingstuffs.

When the competent authority may reduce maximum content or prohibit the presence of a substance in feedingstuffs or feed materials

9. (1) Where the competent authority, as a result of new information or of a reassessment of existing information has detailed grounds for establishing that a maximum content fixed in Schedule I or II or a substance or product not listed therein constitutes a danger to animal or human health or the environment, the competent authority may provisionally reduce that content, fix a maximum content or prohibit the presence of that substance or product in feedingstuffs or feed materials. It shall immediately inform the other Member States and the European Commission thereof, giving reasons for its decision.

(2) In accordance with the procedure laid down in article 22 of the Veterinary Services Act, an immediate decision shall be made as to whether the Schedules should be modified. So long as no decision has been made by either the European Council or the European Commission, the competent authority may maintain the measures it has implemented.

Amendments to the Schedules and defining acceptability of feed materials in certain decontamination processes

10. In accordance with the procedure laid down in article 22 of the Veterinary Services Act, and in the light of developments in scientific and technical knowledge and in agreement with decisions of the European Commission:

(a) the amendments to be made to the Schedules shall be adopted;

(b) a consolidated version of the Schedules shall be drawn up periodically incorporating the successive amendments made pursuant to paragraph (a) hereof;

(c) criteria for the acceptability of feed materials which have undergone certain decontamination processes may be defined.

No further restrictions on feedingstuffs and feed materials which conform to these rules

11. Feedingstuffs and feed materials which conform to these rules are not subject to any other restrictions on their circulation as regards the presence of undesirable substances and products.

12. (1) The competent authority shall take all necessary measures to ensure that feedingstuffs and feed materials are officially controlled, at least by random sampling, to verify whether the conditions laid down in these rules are satisfied.

(2) The competent authority shall inform the Member States and the relevant International Organisation of the name of the departments appointed to carry out this control.

Regulations apply to feedingstuffs intended for export to third countries

13. (1) The competent authority shall apply at least the provisions of these rules to feedingstuffs intended for export to third countries.

(2) Sub-regulation (1) hereof does not affect the right of the competent authority to allow the re-exportation to the exporting third country of consignments of feedingstuffs which do not fulfil the requirements of these regulations.

SCHEDULE 1

(Regulation 3(2), Regulation 4, Regulation 5(2) and (3), Regulation 8)

Substances, products	Feedingstuffs	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
A. Substances (ions or elements)		
1. Arsenic	Feed materials with the exception of:	2
	— meal made from grass, from dried lucerne and from dried clover, and dried sugar beet pulp and dried molasses sugar beet pulp	4
	— phosphates and feedingstuffs obtained from the processing of fish or other marine animals	10
	Complete feedingstuffs with the exception of:	2
	— complete feedingstuffs for fish	4
	Complementary feedingstuffs with the exception of:	4
	— mineral feedingstuffs	12
2. Lead	Feed materials with the exception of:	10
	— green fodder	40
	— phosphates	30
	— yeasts	5
	Complete feedingstuffs	5
	Complementary feedingstuffs with the exception of:	10
	— mineral feedingstuffs	30
3. Fluorine	Feed materials with the exception of:	150
	— feedingstuffs of animal origin	500
	— phosphates	2 000
	Complete feedingstuffs with the exception of:	150
	— complete feedingstuffs for cattle, sheep and goats	
	— in milk	30
	— other	50
	— complete feedingstuffs for pigs	100

Substances, products	Feedingstuffs	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
	— complete feedingstuffs for poultry	350
	— complete feedingstuffs for chicks	250
	Mineral mixtures for cattle, sheep and goats	2 000 (1)
	Other complementary feedingstuffs	125 (2)
4. Mercury	Feed materials with the exception of:	0,1
	— feedingstuffs produced by the processing of fish or other marine animals	0,5
	Complete feedingstuffs with the exception of:	0,1
	— complete feedingstuffs for dogs and cats	0,4
	Complementary feedingstuffs except:	0,2
	— complementary feedingstuffs for dogs and cats	
5. Nitrites	Fish meal	60 (expressed as sodium nitrite)
	Complete feedingstuffs excluding:	15 (expressed as sodium nitrite)
	— feedingstuffs intended for pets except birds and aquarium fish	
6. Cadmium	Feed materials of vegetable origin	1
	Feed materials of animal origin except:	2
	— feedingstuffs for pets	
	Phosphates	10 (3)
	Complete feedingstuffs for cattle, sheep and goats except:	1
	— complete feedingstuffs for calves, lambs and kids	
	Other complete feedingstuffs except:	0,5
	— feedingstuffs for pets	
	Mineral feedingstuffs	5 (4)
	Other complementary feedingstuffs for cattle, sheep and goats	0,5
B. **Products**		
1. Aflatoxin B_1	Feed materials with the exception of:	0,05
	— groundnut, copra, palm-kernel, cotton seed, babassu, maize and products derived	0,02

Substances, products	Feedingstuffs	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
	from the processing thereof	
	Complete feedingstuffs for cattle, sheep and goats with the exception of:	0,05
	— dairy cattle	0,005
	— calves and lambs	0,01
	Complete feedingstuffs for pigs and poultry (except young animals)	0,02
	Other complete feedingstuffs	0,01
	Complementary feedingstuffs for cattle, sheep and goats (except complementary feedingstuffs for dairy animals, calves and lambs)	0,05
	Complementary feedingstuffs for pigs and poultry (except young animals)	0,03
	Other complementary feedingstuffs	0,005
2. Hydrocyanic acid	Feed materials with the exception of:	50
	— linseed	250
	— linseed cakes	350
	— manioc products and almond cakes	100
	Complete feedingstuffs with the exception of:	50
	— complete feedingstuffs for chicks	10
3. Free gossypol	Feed materials with the exception of:	20
	— cotton-seed cakes	1 200
	Complete feedingstuffs with the exception of:	20
	— complete feedingstuffs for cattle, sheep and goats	500
	— complete feedingstuffs for poultry (except laying hens) and calves	100
	— complete feedingstuffs for rabbits and pigs (except piglets)	60
4. Theobromine	Complete feedingstuffs with the exception of:	300
	— complete feedingstuffs for adult cattle	700
5. Volatile mustard oil	Feed materials with the exception of:	100
	— rape-seed cakes	4 000 (expressed as allyl isothiocyanate)
	Complete feedingstuffs with the exception of:	150

Substances, products	Feedingstuffs	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
		(expressed as allyl isothiocyanate)
	— complete feedingstuffs for cattle, sheep and goats (except young animals)	1 000 (expressed as allyl isothiocyanate)
	— complete feedingstuffs for pigs (except piglets) and poultry	500 (expressed as allyl isothiocyanate)
6. Vinyl thiooxazolidone (Vinyloxazolidine thione)	Complete feedingstuffs for poultry with the exception of:	1 000
	— complete feedingstuffs for laying hens	500
7. Rye ergot *(Claviceps purpurea)*	All feedingstuffs containing unground cereals	1 000
8. Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination including		3 000
(a) *Lolium temulentum* L.,	All feedingstuffs	1 000
(b) *Lolium remotum* Schrank,		1 000
(c) *Datura stramonium* L.		1 000
9. Castor oil plant — *Ricinus communis* L.	All feedingstuffs	10 (expressed in terms of castor-oil plant husks)
10. *Crotalaria* spp.	All feedingstuffs	100
11. Aldrin 12. Dieldrin } singly or combined expressed as dieldrin	All feedingstuffs with the exception of: — fats	0,01 0,2
13. Camphechlor (toxaphene)	All feedingstuffs	0,1
14. Chlordane (sum of cis- and trans-isomers and of oxychlordane, expressed as chlordane)	All feedingstuffs with the exception of:	0,02
	— fats	0,05
15. DDT (sum of DDT-, TDE- and DDE-isomers, expressed as DDT)	All feedingstuffs with the exception of:	0,05
	— fats	0,5
16. Endosulfan (sum of alpha- and beta-isomers and of endosulfansulphate expressed as endosulfan)	All feedingstuffs with the exception of:	0,1
	— maize	0,2
	— oilseeds	0,5
	— complete feedingstuffs for fish	0,005

Substances, products	Feedingstuffs	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
17. Endrin (sum of endrin and of delta-keto i-endrin, expressed as endrin)	All feedingstuffs with the exception of:	0,01
	— fats	0,05
18. Heptachlor (sum of heptachlor and of heptachlorepoxide, expressed as heptachlor)	All feedingstuffs with the exception of:	0,01
	— fats	0,2
19. Hexachlorobenzene (HCB)	All feedingstuffs with the exception of:	0,01
	— fats	0,2
20. Hexachlorocyclo-hexane (HCH)		
20.1. alpha-isomers	All feedingstuffs with the exception of:	0,02
	— fats	0,2
20.2. beta-isomers	Compound feedingstuffs with the exception of:	0,01
	— feedingstuffs for dairy cattle	0,005
	Feed materials with the exception of:	0,01
	— fats	0,1
20.3. gamma-isomers	All feedingstuffs with the exception of:	0,2
	— fats	2,0
21. Dioxin (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO — TEFs (toxic equivalency factors, 1997)) PCDD/F	All feed materials of plant origin including vegetable oils and by-products	0,75 ng WHO-PCDD/F-TEQ/kg (2) (4)
	Minerals	1,0 ng WHO-PCDD/F-TEQ/kg (3) (4)
	Animal fat, including milk fat and egg fat	2,0 ng WHO-PCDD/F-TEQ/kg (3) (4)
	Other land animal products including milk and milk products and eggs and egg products	0,75 ng WHO-PCDD/F-TEQ/kg (3) (5)
	Fish oil	6 ng WHO-PCDD/F-TEQ/kg (3) (4)
	Fish, other aquatic animals, their products and by-products with the exception of fish oil (7)	1,25 ng WHO-PCDD/F-TEQ/kg (3) (5)
	Compound feedingstuffs, with the exception of feedingstuffs for fur animals, pet foods and feedingstuffs for fish	0,75 ng WHO-PCDD/F-TEQ/kg (2) (4)
	Feedingstuffs for fish Pet foods	2,25 ng WHO-PCDD/F-TEQ/kg (2) (4)

Substances, products	Feedingstuffs	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
C. **Botanical impurities:**		
1. Apricots — *Prunus armeniaca* L.	All feedingstuffs	Seeds and fruit of the plant species listed opposite as well as their processed derivatives may only be present in feedingstuffs in trace amounts not quantitavely determinable
2. Bitter almond — *Prunus dulcis* (Mill.) D.A. Webb var. *amara* (DC.) Focke (= *Prunus amygdalus Basch* var. *amara* (DC.) Focke)		
3. Unhusked beech mast — *Fagus silvatica* L.		
4. Camelina — *Camelina sativa* (L.) Crantz		
5. *Mowrah, Bassia, Madhuca* — *Madhuca longifolia* (L.) Macbr. (= *Bassia longifolia* L., = *Illipe malabrorum* Engl.) *Madhuca indica* Gmelin (= *Bassia latifolia* Roxb.) = *Illipe latifolia* (Roscb.) F. Mueller)		
6. Purghera — *Jatropha curcas* L.		
7. Croton — *Croton tiglium* L.		
8. Indian mustard — *Brassica juncea* (L.) Czern. and Coss. ssp. *integrifolia* (West.) Thell.		
9. Sarepbian mustard — *Brassica juncea* (L.) Czern. and Coss. ssp. *juncea*		
10. Chinese mustard — *Brassica juncea* (L.) Czern. and Coss. ssp. *juncea* var. *lutea* Batalin		
11. Black mustard — *Brassica nigra* (L.) Koch		
12. Ethiopian mustard — *Brassica carinata* A. Braun		

(1) The competent authority may also prescribe a maximum fluorine content of 1,25% of the phosphate content.
(2) Fluorine content per 1 % phosphorus.
(3) The competent authority may also prescribe a maximum cadmium content of 0,5 mg per 1 % phosphorus.
(4) The competent authority may also prescribe a maximum cadmium content of 0,75 mg per 1 % phosphorus.
(5) Upper bound concentrations are calculated assuming that all values of the different congeners less than the limit of detection are equal to the limit of detection.

SCHEDULE II

PART B
(Regulation 3(2), Regulation 5, Regulation 7)

Substances, products	Feed materials	Maximum content in mg/kg (ppm) relative to feed materials with a moisture content of 12 %
(1)	(2)	(3)
1. Aflatoxin B_1	Groundnut, copra, palm-kernel, cotton seed, babassu, maize and products derived from the processing thereof	0,2
2. Cadmium	Phosphates	10 (1)
3. Arsenic	Phosphates	20
4. Dioxin (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO — TEFs (toxic equivalency factors, 1997)) PCDD/F	All feed materials of plant origin including vegetable oils and by-products	0,75 ng WHO-PCDD/F-TEQ/kg (2) (3)
	Minerals	1,0 ng WHO-PCDD/F-TEQ/kg (2) (3)
	Animal fat, including milk fat and egg fat	2,0 ng WHO-PCDD/F-TEQ/kg (2) (3)
	Other land animal products including milk and milk products and eggs and egg products	0,75 ng WHO-PCDD/F-TEQ/kg (2) (3)
	Fish oil	6 ng WHO-PCDD/F-TEQ/kg (2) (3)
	Fish, other aquatic animals, their products and by-products with the exception of fish oil (4)	1,25 ng WHO-PCDD/F-TEQ/kg (2) (3)
	Compound feedingstuffs, with the exception of feedingstuffs for fur animals, pet foods and feedingstuffs for fish	0,75 ng WHO-PCDD/F-TEQ/kg (2) (3)
	Feedingstuffs for fish	2,25 ng WHO-PCDD/F-TEQ/kg (2) (3)
	Pet foods	

(1) The competent authority may also prescribe a maximum cadmium content of 0,5 mg per 1 % phosphorus.
(2) Upper-bound concentrations; upper-bound concentrations are calculated assuming that all values of the different congeners less than the limit of determination are equal to the limit of determination.
(3) These maximum limits shall be reviewed for the first time before 31 December 2004 in the light of new data on the presence of dioxins and

PART B

(Regulation 5(3))

fur animals cannot enter the food chain and the feeding thereof is prohibited to farmed animals which are kept, fattened or bred for the production of food.

A. Substances (ions or elements)	
1. Arsenic	All feed materials with the exception of: — phosphates
2. Lead	All feed materials

Substances, products	Feed materials
(1)	(2)
3. Fluorine	All feed materials
4. Mercury	All feed materials
5. Nitrites	Fish meal
6. Cadmium	All feed materials of vegetable origin
	All feed materials of animal origin with the exception of:
	— feed materials for pets
B. **Products**	
1. Aflatoxin B1	All feed materials with the exception of:
	— groundnut, copra, palm-kernel, cotton seed, babassu, maize and products derived from the processing thereof
2. Hydrocyanid acid	All feed materials
3. Free gossypol	All feed materials
4. Volatile mustard oil	All feed materials
5. Rye ergot (Claviceps purpurea)	Unground cereals
6. Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination including	All feed materials
a) Lolium temulentum L.,	
b) Lolium remotum Schrank,	
c) Datura stramonium L.,	
7. Castor oil plant —Rizinus communis L.	All feed materials
8. Crotalaria ssp.	All feed materials
9. Aldrin (singly or combined expressed as dieldrin)	All feed materials
10. Dieldrin (singly or combined expressed as dieldrin)	All feed materials
11. Camphechlor (toxaphene)	All feed materials
12. Chlordane (sum of cis- and trans-isomers and oxychlordane, expressed as chlordane)	All feed materials
13. DDT (sum of DDT-, TDE- and DDE-isomers, expressed as DDT)	All feed materials
14. Endosulfan (sum of alpha- and beta-isomers and endosulfan sulphate expressed as endosulfan)	All feed materials
15. Endrin (sum of endrin and of delta-ketoendrin, expressed as endrin)	All feed materials
16. Heptachlor (sum of heptachlor and of heptachlor-epoxide, expressed as heptachlor)	All feed materials
17. Hexachlorobenzene (HCB)	All feed materials
18. Hexachlorocyclohexane (HCH)	
18.1. alpha-isomer	All feed materials
18.2. beta-isomer	All feed materials
18.3 . gamma-isomer	All feed materials
C. **Botanical impurities**	
1. Apricots — Prunus armeniaca L.	All feed materials
2. Bitter almond — Prunus dulcis (Mill.) D.A. Webb var. amara (DC.) Focke (= Prunus amygdalus Batsch var. amara	All feed materials

Substances, products	Feed materials
(1)	(2)
(DC.) Focke)	
3. Unhusked beech mast — Fagus silvatica (L.)	All feed materials
4. Camelina — Camelina sativa (L.) Crantz	All feed materials
5. Mowrah, Bassia, Madhuca — Madhuca longifolia (L.) Macbr. (=Bassia longifolia L. = Illipe malabrorum Engl.) Madhuca indica Gmelin (=Bassia latifolia (Roscb.)= Illipe latifolia (Roscb.) F. Mueller)	All feed materials
6. Purghera — Jatropha curcas L.	All feed materials
7. Croton — Croton tiglium L.	All feed materials
8. Indian mustard — Brassica juncea (L.) Czern. et Coss. ssp. integrifolia (West.) Thell.	All feed materials
9. Sareptian mustard — Brassica juncea (L.) Czern. and Coss. ssp. juncea	All feed materials
10. Chinese mustard — Brassica juncea (L.) Czern. and Coss. ssp. juncea var. lutea Batalin	All feed materials
11. Blach mustard — Brassica nigra (L.) Koch	All feed materials
12. Ethiopian mustard — Brassica carinata A. Braun	All feed materials

Nru. 1203

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikoli 11 u 12 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Regoli dwar is-Saħħa tal-Bhejjem li jirregolaw il-Produzzjoni, Proċessar, Distribuzzjoni u Introduzzjoni ta' Prodotti li Joriġinaw mill-Bhejjem għal Konsum mill-Bniedem.

Id-19 ta' Novembru, 2004

No. 1203

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with articles 11 and 12 of the Veterinary Services Act to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Animal Health Rules governing the Production, Processing, Distribution and Introduction of Products of Animal Origin for Human Consumption, Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Animal Health Rules governing the Production, Processing, Distribution and Introduction of Products of Animal Origin for Human Consumption, Rules, 2004

In exercise of the powers conferred by Article 11 and 12 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment in agreement with the Minister of Health, the Elderly and Community Care, has made the following Rules:-

Title, scope and applicability

1. (1) The title of these Rules is the Animal Health Rules governing the Production, Processing, Distribution and Introduction of Products of Animal Origin for Human Consumption, Rules, 2004.

(2) The scope of these Rules is to implement the provisions found under European Union Council Rule 2002/99/EC governing the production, processing, distribution and introduction of products of animal origin for human consumption.

(3) These Rules shall apply without prejudice to Community or national provisions on the production, processing, distribution and introduction of products of animal origin for human consumption.

Definitions

2. (1) For the purposes of this Rule, the definitions in Rule (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(8) and Directive 97/78/EC shall apply as necessary. The following definitions shall also apply:

"all stages of the production, processing and distribution" means any stage from and including the primary production of a food of animal origin, up to and including its storage, transport, sale or supply to the final consumer;
"introduction" means the bringing of goods into one of the territories listed in Annex I to Directive 97/78/EC for the purpose of placing them under the customs procedures referred to in Article 4(16)(a) to (f) of Council Rule (EC) No 2913/92 of 12 October 1992 establishing the Community Customs Code(9);

"official veterinarian" means a veterinarian qualified to act in that capacity appointed by the competent authority;

"products of animal origin" means products obtained from animals and products obtained therefrom, for human consumption, including live animals where they are prepared for such use.

General animal health requirements

3. (1) Malta shall take measures to ensure that at all stages of the production, processing and distribution of products of animal origin within the Community, food business operators do not cause the spread of diseases transmissible to animals, in accordance with the following provisions.

(2) Products of animal origin must be obtained from animals which fulfil the animal health conditions laid down by the relevant Community legislation.

(3) Products of animal origin shall be obtained from animals:

(a) which do not come from a holding, establishment, territory or part of a territory subject to animal health restrictions applicable to the animals and products concerned, under the rules set out in Sschedule I;

(b) which, in the case of meat and meat products, were not slaughtered in an establishment in which animals infected or suspected of being infected with one of the diseases covered by the rules referred to in (a), or carcasses or parts thereof of such animals, were present during the slaughtering or production process, unless such suspicion has been ruled out;

(c) which, in the case of aquaculture animals and products, comply with Directive 91/67/EEC(10).

Derogations

4. (1) Notwithstanding Rule 3 and subject to compliance with the disease control measures referred to in Schedule I, Malta may authorise the production, processing and distribution of products of animal origin which come from a territory or part of a territory subject to animal health restrictions but which do not come from a holding which is infected or suspected of being infected, provided that:

(a) before being subjected to the treatment referred to below, the products have been obtained, handled, transported and stored separately, or at different times, from products fulfilling all the animal health conditions, and the conditions for transport out of the territory subject to animal health restrictions have been approved by the competent authority;

(b) the products which are to undergo treatment are clearly identified;

(c) the products undergo treatment enabling the animal health problem concerned to be eliminated, and

(d) the treatment is applied at an establishment approved for that purpose by the Member State in which the animal health problem occurred.

(2) The provisions of the first subsub-rule shall be applied in accordance with Schedules II and III(1) hereto, or with detailed rules to be adopted in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

(3) The production, processing and distribution of aquaculture products not complying with the conditions laid down in Rule 3 shall be authorised, subject to the conditions laid down in Directive 91/67/EEC and, where necessary, in accordance with further conditions to be adopted in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

(4) Furthermore, where the health situation so permits, derogations from Rule 3 may be granted in certain situations, in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC. In such cases, particular account shall be taken of:

(a) the specific characteristics of the disease in the species concerned, and

(b) any tests or measures to which the animals must be subjected.

(5) Where such derogations are granted, steps must be taken to ensure that the degree of protection from animal disease will in no way be impaired. Any measures needed to ensure the protection of animal health in the Community shall therefore be adopted in accordance with the same procedure.

Veterinary certificates

5. (1) Malta shall ensure that products of animal origin intended for human consumption are subjected to veterinary certification where:

(a) provisions adopted for animal health reasons under Article 9 of Directive 89/662/EEC require products of animal origin from a Member State to be accompanied by a health certificate, or

(b) a derogation has been granted under Rule 4(4).

(2) Under the procedure referred to in Article 12(2) of Directive 2002/99/EC, detailed implementing rules, and in particular a model for such certificates, may be drawn up taking into account the general principles set out in Schedule IV. Certificates may include details required in accordance with other Community public and animal health legislation.

Official veterinary controls

6. (1) Pending adoption of Rules of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and rules for controls applicable to foodstuffs and animal feed, Malta shall ensure that official animal health controls are carried out by their competent authorities to ensure compliance with this Rule, its implementing rules and any safeguard measures relating to products of animal origin adopted pursuant to this Rule. As a general rule, inspections must be unannounced and checks carried out in accordance with the provisions of Directive 89/662/EEC.

(2) Pending adoption of Rules of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and rules for controls applicable to foodstuffs and animal feed, where infringements of animal health rules are identified, Malta shall take the necessary measures to remedy the situation in accordance with the provisions of Directive 89/662/EEC.

(3) Experts from the Commission may carry out on-the-spot checks, including audits, in cooperation with the competent authorities of Malta, insofar as is necessary for the uniform application of this Rule. Malta shall provide the experts if checks are being carried out in her territory, with all

the assistance necessary for carrying out their duties. The Commission shall inform the competent authority of the results of the checks made. If a serious animal health risk is identified during a Commission audit or inspection, Malta concerned shall immediately take all measures necessary to safeguard animal health. If such measures are not taken, or if they are considered to be insufficient, the Commission shall, in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC, take the measures necessary to safeguard animal health and inform the Member States thereof.

General provisions applicable to imports from third countries

7. (1) Malta shall take measures to ensure that products of animal origin intended for human consumption are introduced from third countries only if they comply with the requirements of this Rule applicable to all stages of the production, processing and distribution of such products in the Community or if they offer equivalent animal health guarantees.

(2) The rules for the application of this Rule, and in particular those governing the procedure for cooperation with the national authorities, shall be adopted in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

Compliance with Community rules

8. (1) In order to ensure compliance with the general obligation laid down in Rule 7, the following shall be established in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

(2) Lists of the third countries or regions of third countries from which imports of specified products of animal origin are permitted. A third country shall appear on such lists only if a Community audit of that country has taken place and demonstrates that the competent veterinary authority provides appropriate guarantees as regards compliance with Community legislation.

(3) When drawing up or updating those lists, particular account shall be taken of:

(a) the legislation of the third country;

(b) the organisation of the competent veterinary authority and its inspection services in the third country, the powers of these services, the supervision to which they are subject, and the means at their disposal, including staff capacity, to apply their legislation effectively;

(c) the actual animal health requirements applying to the production, manufacture, handling, storage and dispatch of products of animal origin intended for the Community;

(d) the assurances which the competent veterinary authority of the third country can give regarding compliance or equivalence with the relevant animal health conditions;

(e) any experience of marketing the product from the third country and the results of any import controls carried out;

(f) the results of Community inspections and/or audits carried out in the third country, in particular the results of the assessment of the competent authorities or, where the Commission so requests, the report submitted by the competent authorities of the third country on the inspections which they have carried out;

(g) the health status of livestock, other domestic animals and wildlife in the third country, with particular regard to exotic animal diseases and any aspects of the general health situation in the country which might pose a risk to public or animal health in the Community;

(h) the regularity, speed and accuracy with which the third country supplies information on the existence of infectious or contagious animal diseases in its territory, particularly the notifiable diseases listed by the World Organisation for Animal Health (OIE) or, in the case of diseases of aquaculture animals, the notifiable diseases listed in the Aquatic Animal Health Code of the OIE;

(i) the rules on the prevention and control of infectious or contagious animal diseases in force in the third country and their implementation, including rules on imports from other countries.

(4) The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Rule to be available to the public. Lists drawn up in accordance with this Rule may be combined with other lists drawn up for animal and public health purposes and may also include models of health certificates.

(5) Rules of origin for products of animal origin and the animals from which such products are obtained shall be established in accordance with the procedure referred to in Rule 12 (2).

(6) Special import conditions for each third country or group of third countries, having regard to the animal health situation of the third country or countries concerned shall be established in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

(7) Where necessary:

(a) the detailed rules for the application of this Rule,

(b) criteria for classifying third countries and regions thereof with regard to animal diseases, and

(c) specific rules concerning types of introduction or particular products, such as the introduction of products by travellers or the introduction of commercial samples, may be established in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

Documents

9. (1) A veterinary certificate meeting the requirements set out in Schedule IV shall be presented with consignments of products of animal origin upon their entry into the Community.

(2) The veterinary certificate shall certify that the products satisfy:

(a) the requirements laid down for such products under this Rule and under the Community legislation laying down animal health requirements or provisions that are equivalent to those requirements; and

(b) any special import conditions established in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

(3) Documents may include details required under other provisions of Community public and animal health legislation.

(4) In accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC:

(a) provision may be made for the use of electronic documents,

(b) model documents may be drawn up,

(c) rules and certification for transit may be established.

Community inspections

10. (1) Community inspections and/or audits at all stages covered by this Rule may be carried out in third countries by experts from the Commission in order to verify conformity with or equivalence to Community animal health rules. The experts from the Commission may be accompanied by experts

from the territory of Malta authorised by the Commission to carry out these inspections and/or audits.

(2) The inspections and/or audits in third countries referred to in sub-rule (1) hereof shall be carried out on behalf of the Community, and the Commission shall meet the costs incurred.

(3) The procedure for carrying out the inspections and/or audits in third countries referred to in sub-rule (1) may be established or modified in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC.

(4) If a serious animal health risk is identified during a Community inspection or audit, the Commission shall immediately take the measures necessary to safeguard animal health, in accordance with Article 22 of Directive 97/78/EC, and inform the Member States thereof.

Update of technical schedules

11. (1)The Schedules hereto may be amended in accordance with the procedure referred to in Article 12(2) of Directive 2002/99/EC in order to take account in particular of:

(a) scientific opinions and scientific knowledge, particularly concerning new risk assessments;

(b) technical developments; and

(c) the setting of safety targets for animal health.

SCHEDULE I

Diseases of relevance to trade in products of animal origin and for which control measures have been introduced under European Community legislation

DISEASE	DIRECTIVE
Classical swine fever	Council Directive 2001/89/EC on Community measures for the control of classical swine fever
African swine fever	Council Directive 2002/60/EC laying down specific provisions for the control of African swine fever
Foot-and-mouth disease	Council Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease
Avian influenza	Council Directive 92/40/EEC introducing Community measures for the control of avian influenza
Newcastle disease	Council Directive 92/66/EEC introducing Community measures for the control of Newcastle disease
Rinderpest Sheep and goat plague Swine vesicular disease	Council Directive 92/119/EEC introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease
Aquaculture diseases	Council Directive 91/67/EEC concerning the animal health conditions governing the placing on the market of aquaculture animals and products Council Directive 93/53/EEC introducing minimum Community measures for the control of certain fish diseases Council Directive 95/70/EC introducing minimum Community measures for the control of certain diseases affecting bivalve molluscs

SCHEDULE II

Special identification mark for meat from a territory or a part of a territory

(1) The health mark for fresh meat must bear a diagonal cross consisting of two straight lines intersecting at the centre of the stamp and enabling the information thereon to remain legible.

(2) The mark mentioned in sub-rule 1 may also be applied using a single oval stamp, 6,5 cm wide by 4,5 cm high; the following information must appear on the mark in perfectly legible characters:

(a) on the upper part, the name or ISO code of Malta in capitals:
(b) in the centre, the veterinary approval number of the slaughterhouse,
(c) on the lower part, one of the following sets of initials **KEE**,
(d) two straight lines crossing at the centre of the stamp in such a way that the information is not obscured.

(3)The letters must be at least,0,8 cm high and the figures at least 1 cm high.

(4)The stamp must also carry information whereby the veterinarian who inspected the meat can be identified.

(5) The mark must be applied under the direct supervision of the official veterinarian controlling the implementation of the animal health requirements.

SCHEDULE III

1. Treatments to eliminate certain animal health risks linked to meat and milk

MEAT Treatment (*)	Foot-and-mouth disease	Classical swine fever	Swine vesicular disease	African swine fever	Rinderpest	Newcastle disease	Avian influenza	Sheep and goat plague
(a) Heat treatment in a hermetically sealed container with an F0 value of 3.00 or more (**)	+	+	+	+	+	+	+	+
(b) Heat treatment at a minimum temperature of 70 °C. which must be reached throughout the meat	+	+	+	0	+	+	+	+
(c) Heat treatment at a minimum temperature of 80 °C. which must be reached throughout the meat	+	+	+	+	+	+	+	+
(d) Heat treatment in a hermetically sealed container to at least 60 °C for a minimum of 4 hours. during which time the core temperature must be at least 70 °C for 30 minutes	+	+	+	+	+	-	-	+
(e) Natural fermentation and maturation of not less than	+	+	+	+	+	0	0	0

MEAT Treatment (*)	Foot-and-mouth disease	Classical swine fever	Swine vesicular disease	African swine fever	Rinderpest	Newcastle disease	Avian influenza	Sheep and goat plague
nine months for boneless meat. resulting in the following characteristics: Aw value of not more than 0.93 or a pH value of not more than 6.0								
(f) Same treatment as in (e) above although meat may contain bone (*)	+	+	+	0	0	0	0	0
(g) Salami: treatment in accordance with criteria to be defined by the Article 12(2) procedure following an opinion by the relevant Scientific Committee	+	+	+	0	+	0	0	0
(h) Hams and loins: treatment involving natural fermentation and maturation during at least 190 days for hams and 140 days for loins	0	0	0	+	0	0	0	0
(i) Heat treatment ensuring a core temperature of at least 65 °C is reached for	+	0	0	0	0	0	0	+

MEAT Treatment (*)	Foot-and-mouth disease	Classical swine fever	Swine vesicular disease	African swine fever	Rinderpest	Newcastle disease	Avian influenza	Sheep and goat plague
the time necessary to achieve a pasteurisation value (pv) equal to or more than 40								
MILK and milk products (including cream) for human consumption								
(a) Ultra-high temperature (UHT) (UHT = minimum treatment at 132 °C for at least 1 second)	+	0	0	0	0	0	0	0
(b) If the milk has a pH of less than 7.0. simple high temperature - short-time pasteurisation (HTST)	+	0	0	0	0	0	0	0
(c) If the milk has a pH of 7.0 or more. double HTST	+	0	0	0	0	0	0	0

+: Effectiveness recognised.
0: Effectiveness not recognised.
(*) All the necessary measures must be taken to avoid cross contamination.
(**) F0 is the calculated killing effect on bacterial spores. An F0 value of 3,00 means that the coldest point in the product has been heated sufficiently to achieve the same killing effect as 121 °C (250 °F) in three minutes with instanteneousheating and chilling.

SCHEDULE IV

General principles of certification

(1) The representative of the competent authority of dispatch issuing a certificate to accompany a consignment of products of animal origin must sign the certificate and ensure that it bears an official stamp. This requirement applies to each sheet of the certificate if it consists of more than one.

(2) Certificates must be drawn up in the official language or languages of the Member State of destination and those of the Member State in which the border inspection takes place, or be accompanied by a certified translation into that language or those languages. However, Malta may consent to the use of an official European Community language other than its own.

(3) The original version of the certificate must accompany consignments on entry into the European Community.

(4) Certificates must consist of:

(a) a single sheet of paper; or

(b) two or more pages that are part of a single and indivisible sheet of paper; or

(c) a sequence of pages numbered so as to indicate that it is a particular page in a finite sequence (for example, "page 2 of 4 pages").

(5) Certificates must bear a unique identifying number. Where the certificate consists of a sequence of pages, each page must indicate this number.

(6) The certificate must be issued before the consignment to which it relates leaves the control of the competent authority of the country of dispatch.

SCHEDULE V

(1) Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat(1), as last amended by the Act of Accession of Austria, Finland and Sweden.
(2) Council Directive 80/215/EEC of 22 January 1980 on animal health problems affecting intra-Community trade in meat products(2), as last amended by the Act of Accession of Austria, Finland and Sweden.
(3) Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultrymeat(3), as last amended by Directive 93/121/EC.
(4) Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat(4), as last amended by the Act of Accession of Austria, Finland and Sweden.
(5) Council Directive 92/45/EEC of 16 June 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat(5), as last amended by Directive 97/79/EC.
(6) Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products(6).
(7). Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations(7).

(1) OJ L 302, 31.12.1972, p. 24.
(2) OJ L 47, 21.2.1980, p. 4.
(3) OJ L 268, 24.9.1991, p. 35.
(4) OJ L 268, 24.9.1991, p. 41.
(5) OJ L 268, 14.9.1992, p. 35.
(6) OJ L 268, 14.9.1992, p. 1.
(7) OJ L 368, 31.12.1994, p. 10.

Nru. 1204

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikoli 22 sa 28 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar il-Kategoriji ta' Materjali ta' Għalf li jistgħu jintużaw għall-finijiet ta' Tikkettjar ta' Komposti ta' l-Għalf għal Annimali eskluži Annimali Domestiċi.

Id-19 ta' Novembru, 2004

No. 1204

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 22 to 28 of the Veterinary Services Act to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

The Categories of Feed Materials which may be used for the purposes of Labelling Compound Feedingstuffs for Animals other than Pet Animals, Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

The Categories of Feed Materials which may be used for the purposes of Labelling Compound Feedingstuffs for Animals other than Pet Animals, Rules, 2004

IN exercise of the powers conferred under Articles 22 to 28 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, in agreement with the Minister of Health, the Elderly and Community Care has made the following Rules:-

Title and scope

1. (1) The title of these Rules is the Categories of Feed Materials which may be used for the purposes of Labelling Compound Feedingstuffs for Animals other than Pet Animals, Rules 2004.

(2) The scope of these Rules is to implement the provisions found under European Union Council Rule 91/357/EEC concerning the laying down of categories of feed materials which may be used for the purposes of labelling compound feedingstuffs for animals other than pet animals.

Labelling of category

2. (1)Where, pursuant to Article 5 (c) (3) of Directive 79/373/EEC, the indication of the specific name of the feed material may be replaced by the name of the category to which the feed material belongs, only the categories listed in the Schedule hereto may be indicated on the packaging, container or label of compound feedingstuffs for animals other than pet animals.

SCHEDULE

CATEGORIES OF FEEDMATERIALS. WHICH MAY BE INDICATED IN PLACE OF INDIVIDUAL .M2 FEEDMATERIALS . WHEN LABELLING COMPOUND FEEDS INTENDED FOR ANIMALS OTHER THAN PETS

1.**Category Definition**

(1) Cereal grains The whole of the grain from all cereal types (including buckwheat) regardless of their presentation, but from which no fraction other than hulls has been removed

(2) Cereal grain products and by-products Fractional products and by-products of cereal grains
other than oils included in category 15. These products and by-products shall contain not more than 25 % crude fibre in the dry matter.

(3) Oil seeds The whole of the seed or fruit from all types of oil seeds and oil fruits regardless of their presentation, but from which no fractions other than hulls or shells have been removed.

(4) Oil seed products and by-products Fractional products and by-products of oil seeds and oil fruits other than oils and fats included in category 15. These products and by-products shall contain not more than 25 % crude fibre in the dry matter unless they contain more than 5 % crude oils and fats in the dry matter, or more than 15 % crude protein in the dry matter.

(5) Products and by-products of legume seeds Whole and fractional products and by-products of legume seeds other than leguminous oil seeds included in categories 3 and 4. These products and by-products shall contain not more than 25 % crude fibre in the dry matter.

(6) Products and by-products of tubers and roots Products and by-products derived from tubers and roots other than sugar beet included in category 7. These products and by-products shall contain not more than 25 % crude fibre in the dry matter.

(7) Products and by-products of sugar production Products and by-products of sugar-beet and sugarcane. These products and by-products shall contain not more than 25 % crude fibre in the dry matterr.

(8) Products and by-products of fruit processing Products and by-products of fruit processing. These products and by-products shall not contain more than 25 % crude fibre in the dry matter, unless they contain more than 5 % crude oils and fats in the dry matter, or more than 15 % crude protein in the dry matter.

(9) Dried forages Aerial parts of forage plants, cut while green, artificially or naturally dried. These products shall contain not more than 25 % crude fibre in the dry matter unless they contain more than 15 % crude protein in the dry matter.

(10) Highfibre materials. Feed materials . containing more than 25 % crude fibre in the dry matter, such as straw, hulls and chaff, other than products included in categories 5, 9 and 9.

(11) Milk products Products derived from the processing of milk, other than separated milk fats included in category 15.

(12) Fishproducts. Whole or part of fish and other cold blooded marine animals, including products from fishprocessing other than fish oil and its derivations included in category 15. Also excluding products containing more than 50 % ash in the dry matter included in category 14.

(13) Minerals Inorganic or organic materials containing more than 50 % ash in the dry matter, ther than materials containing more than 5 % of ash insoluble in hydrochloric acid in the dry matter.

(14) Oils and fats Oils and fats from animal and vegetable sources, and their derivatives.

(15) Products from the bakery and pasta industries. Waste and surplus materials from the bakery and pasta industries.

Nru. 1205

ATT DWAR L-UNJONI EWROPEA (ATT NRU. V TA' L-2003)

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 4(2) ta' l-Att ta' l-2003 dwar l-Unjoni Ewropea, il-Prim Ministru u l-Ministru għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qegħdin b'din jippubblikaw l-abbozz ta' regoli li ġej skond l-artikolu 24 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermettu lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jirrakkomandawx biżżejjed l-użu ta' oġġetti ta' l-ikel ta' kwalità tajba xierqa, jew li jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Addittivi fl-Oġġetti ta' l-Ikel.

Id-19 ta' Novembru, 2004

No. 1205

EUROPEAN UNION ACT, 2003 (ACT NO.V OF 2003)

BY virtue of the powers conferred under article 4(2) of the European Union Act 2003, the Prime Minister and the Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, are hereby publishing the following draft regulations in accordance with article 24 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed regulations do not sufficiently recommend the use of appropriate good-quality feeding-stuffs, or how they are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Additives in Feeding-stuffs Regulations, 2004.

19th November, 2004

EUROPEAN UNION ACT, 2003 (ACT NO.V OF 2003)

IN exercise of the powers conferred under the article 4(2) of the European Union Act, 2003, the Prime Minister and the Minster for Rural Affairs and the Environment have made the following regulations:-

Title, scope and applicability.

1. (1) The title of these regulations is "Additives in Feeding-stuffs Regulations, 2004".

(2) The scope of these regulations is to implement the rules found under the European Union Council Directive 70/524/EEC concerning additives in feeding-stuffs and in accordance with article 24 of the Veterinary Services Act, 2001.

(3) These regulations shall apply to additives in feeding-stuffs.

(4) These regulations shall not apply to processing aids used deliberately as substances in the processing of feed materials or of feeding-stuffs in order to achieve a certain technological objective during treatment or processing which may result in the unintentional but technically unavoidable presence of residues of the substances or their derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect on the finished product.

(5) Provided they are not products specially enriched with substances corresponding to additives, substances present in their natural state in feed materials which are part of the normal composition of feeding-stuffs and which correspond to a substance authorized under these regulations shall not be regarded as additives.

Definitions.

2. For the purpose of these regulations –

(a) "additives" means substances or preparations used in animal nutrition in order to–

(i) affect favourably the characteristics of feed materials or of compound feeding-stuffs or of animal products; or

(ii) satisfy the nutritional needs of animals or improve animal production, in particular by affecting the gastro-intestinal flora or the digestibility of feeding-stuffs; or

(iii) introduce intro nutrition elements conducive to attaining particular nutritional objectives or to meeting the specific nutritional needs of animals at a particular
time; or

(iv) prevent or reduce the harmful effects caused by animal excretions or improve the animal environment;

(b) "additives subject to authorization linked to the person responsible for putting them into circulation" means the additives listed in Part I of Schedule C;

(c) "animals" means animals belonging to species normally nourished and kept or consumed by man;

(d) "competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

(e) "complete feeding-stuffs" means mixtures of feeding-stuffs which, by reason of their composition, are sufficient for a daily ration;

(f) "compound feeding-stuffs" means mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feeding-stuffs;

(g) "daily ration" means the average total quantity of feeding-stuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age category and yield, to satisfy all its needs;

(h) "feed materials" means various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such or after processing, in the preparation of compound feeding-stuffs or as carriers of premixtures, hereinafter referred to as feed materials;

(i) "feeding-stuffs" means products of vegetable or animal origin in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;

(j) "Member State" means a State which is a Member within the European Community;

(k) "Micro-organisms" means micro-organisms forming colonies;

(l) "person responsible for putting into circulation" means the natural or legal person who has responsibility for the conformity of the additive which has been granted Community authorization and for putting it into circulation;

(m) "pet animals" means animals belonging to species normally nourished and kept, but not consumed, by man, except animals bred for fur;

(n) "premixtures" means mixtures of additives or mixtures of one or more additives with substances used as carriers, intended for the manufacture of feeding-stuffs;

(o) "putting into circulation" or "circulation" means the holding of any product intended for animal nutrition for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale and other forms of transfer themselves;

(p) "other additives" means additives not subject to authorization linked to the person responsible for putting them into circulation and referred to in Part II of Schedule C;

(q) "supplementary feeding-stuffs" means mixtures of feeding-stuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if they are used in combination with other feeding-stuffs;

(r) "the Community" means the European Community as established under the Treaty establishing the European Community;

(s) "third country" means a State which is not a Member within the European Community;

(t) "trading partner" shall have the same meaning as provided under article 2 of the Veterinary Services Act and shall include Member States of the European Union.

PROCEDURE FOR THE AUTHORISATION OF ADDITIVES

Authorisation for circulation

3. No additive may be put into circulation in the territory of Malta unless it has been authorised to be put in circulation by the Trading Partners in accordance with the provisions laid down in regulation 5.

When authorisation is granted

4. Authorisation of an additive shall be given only if –

(a) when used in animal nutrition it has one of the effects referred to in regulation 2(a);

(b) taking account of the conditions of use, it does not adversely affect human or animal health or the environment, nor harm the consumer by impairing the characteristics of animal products;

(c) its presence can be monitored -

(i) as an additive per se;

(ii) in premixtures;

(iii) in feeding-stuffs or, where appropriate, in feed materials;

(d) at the level permitted, treatment or prevention of animal disease is excluded:

Provided that this condition shall not apply to additives belonging to the group of coccidiostats and other medicinal substances;

(e) for serious reasons concerning human or animal health its use must not be restricted to medical or veterinary purposes.

Procedure to obtain authorisation

5. (1) In order to obtain the authorization for a substance or a preparation as an additive or for a new use in the case of an already authorized additive, the applicant for authorization shall comply with the provisions of Schedule I Part A to these regulations.

(2) The additives which are already authorised are those mentioned in Schedule I Part B to these regulations.

(3) The competent authority shall publish every year in the Malta Government Gazzette the list of authorised additives.

Duty to confidentiality

6. (1) Any information which, if disseminated in the territory of Malta, could affect industrial and commercial property rights shall be kept confidential.

(2) Confidentiality shall not apply to:

(a) the name and composition of the additive;

(b) the physico-chemical and biological characteristics of the additive;

(c) the interpretation of the pharmacological, toxicological and ecotoxicological data relating to the additive;

(d) the analytical methods for monitoring the additive its elf and the additive in premixtures, in the feedingstuffs and, where appropriate, in feed materials;

(e) the methods for testing for residues of the additive or metabolites thereof in animal products.

DISTRIBUTION AND USE OF ADDITIVES

When additives can be put in circulation and used

7. (1) In the territory of Malta and in the field of animal nutrition, only additives authorized in accordance with these regulations may be put into circulation and that they may be used only if incorporated in feedingstuffs under the conditions set out in the authorization regulation:

Provided that additives belonging to groups other than "antibiotics", "coccidiostats and other medicinal substances", and growth promoters may be used if administered by a method other than incorporation in feedingstuffs, on condition that that method is provided for in the authorization regulation.

(2) In the territory of Malta, additives are added to feed materials and to straight feedingstuffs only where their use is expressly provided for in the authorization regulation.

MIXTURES AND ADDITIVE LEVELS

Mixing of additives

8. (1) The maximum and minimum levels set for certain additives shall refer to complete feedingstuffs with a moisture content of 12 % insofar as no special provisions are laid down in the authorization regulation. If the substance permitted as an additive also exists in the natural state in certain feed materials, the amount of additive to be incorporated shall be calculated so that the total of the elements added and the elements present naturally does not exceed the maximum level provided for in the authorization regulation.

(2) The mixing of additives shall be permitted in premixtures and feedingstuffs only where there is physico-chemical and biological compatibility between the components of the mixture in relation to the effects desired.

(3) Unless the mixture concerned is the subject of a specific authorization as an additive, the following provisions shall be observed in the territory of Malta in respect to mixtures of additives:

(a) antibiotics and growth promoters may not be mixed together, either with substances from their own group or with substances from the other group;

(b) coccidiostats and other medicinal substances may not be mixed with antibiotics and growth promoters where coccidiostats also act, for the same category of animal, as an antibiotic or as a growth promoter;

(c) coccidiostats and other medicinal substances may not be mixed together if their effects are similar.

(4) Mixing antibiotics, growth promoters, coccidiostats and other medicinal substances with micro-organisms shall be prohibited unless such a mixture is authorized by the regulation authorizing the microorganisms.

(5) By way of derogation from regulation 3 and sub-regulations (2) and (3) of this regulation, the use as additives of products which are not authorized at Community level or the use of additives under conditions other than those laid down in the authorization regulation may be authorized by the competent authority but only for practical tests conducted for scientific purposes and for non-commercial ends:

Provided that the tests are carried out in accordance with the principles and conditions to be laid down in European Union Council Directive 87/153/EEC and an adequate official inspection has been performed.

PACKAGING

Requisites for marketing

9. Additives and premixtures may be marketed in the territory of Malta only in closed packages or closed containers. Packages or containers must be closed in such a way that the fastener is damaged on opening and cannot be re-used.

SAFEGUARD AND MEASURES

Temporary suspension or restriction of regulations

10. Where the competent authority, as a result of new information or of a reassessment of existing information made since these regulations were adopted, has detailed grounds for establishing that the use of one of the additives authorised or its use in conditions which may be specified, constitutes a danger to animal or human health or the environment although it complies with these regulations, it may temporarily suspend or restrict application of these regulations in the territory of Malta:

Provided that it shall immediately inform the Trading Partners thereof, giving reasons for its decision.

ADDITIVE LEVELS IN COMPLEMENTARY FEEDINGSTUFFS

Additive levels in supplementary feedingstuffs

11. (1) Supplementary feedingstuffs, diluted as specified, may not contain levels of the additives named in these regulations which exceed those fixed for complete feedingstuffs.

(2) The levels of antibiotics, coccidiostats and other medicinal substances, growth promoters, D vitamins and antioxidants in supplementary feedingstuffs may exceed the maximum levels fixed for complete feedingstuffs in the case of:

(a) supplementary feedingstuffs, which the competent authority has authorised to be made available to all users, provided that their level of antibiotics, D vitamins or growth promoters does not exceed five times the fixed maximum level;

(b) supplementary feedingstuffs which are intended for certain species of animal and which the competent authority has authorised to be made available within the territory of Malta to all users

because of special feeding systems, provided that their level does not exceed:

(i) for antibiotics and growth promoters, 1 000 mg/kg and, provided that the use of these substances is permitted, 2 000 mg/kg in the case of cattle for fattening;

(ii) for antioxidants, coccidiostats and other medicinal substances, five times the fixed maximum level;

(iii) for D vitamins, 200 000 IU/kg.

Provided that when, in the manufacture of supplementary feedingstuffs, recourse is had to the possibility referred to in (a), the possibility referred to in (b) may not be made use of at the same time.

(3) Where sub-regulation (2) is invoked, the competent authority shall ensure that the feedingstuff has one or more compositional characteristics (as regards, for example, proteins or minerals) which in practice ensure that the level of additives fixed for complete feedingstuffs is not exceeded and that the feedingstuff is not used for other species of animal.

RULES FOR THE DISTRIBUTION AND INCORPORATION IN FEEDINGSTUFFS OF ADDITIVES AND PREMIXTURE

The distribution of additives by approved establishments to intermediaries or establishments and the incorporation of additives in feedingstuffs

12. (1) The competent authority shall require that certain additives covered by these regulations, premixtures prepared from those additives with a view to their being incorporated in compound feedingstuffs and compound feedingstuffs containing those premixtures may be put into circulation in the territory of Malta or used only by the establishments or intermediaries which meet the conditions laid down, as appropriate, in European Union Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector.

(2) The competent authority shall require that:

(a) additives referred to in Part A of Schedule A may be supplied only by approved establishments:

(i) to intermediaries or establishments which manufacture premixtures and which have been approved in accordance with the provisions laid down in Article 3(1) or Article 2(2)(b) respectively of European Union Council Directive 95/69/EC, and

(ii) in the form of premixtures, only to intermediaries or establishments which manufacture compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding and which have been approved in accordance with the provisions laid down in Article 3(1) or Article 2(2)(c) or (e) respectively of the above Directive;

(b) additives listed in Part B of Schedule A may be supplied only by approved establishments:

(i) to intermediaries or establishments which manufacture premixtures and which have been approved in accordance with the provisions laid down in Article 3(1) or Article2(2)(b) respectively of European Union Council Directive 95/69/EC, and

(ii) in the form of premixtures, only to:

- intermediaries which have been approved in accordance with the provisions laid down in Article 3 of the above Directive, or

-establishments which manufacture compound feedingstuffs with a view to putting them into circulation or for the exclusive requirements of their holding and which have been registered in accordance with the provisions laid down in Article 7(2)(c) or (d) respectively of the said Directive or, as appropriate, approved in accordance with the provisions laid down in Article 2(2)(c) or (e) of these regulations.

(3) Additives referred to in Schedule A (A) and (B) may be incorporated in compound feedingstuffs only if they have been prepared beforehand in the form of premixtures containing a carrier substance by establishments which meet the conditions laid down in Article 2(2)(b) of European Union Council Directive 95/69/EC:

Provided that such premixtures may be incorporated in compound feedingstuffs only in a proportion of at least 0,2 % by weight.

(4) By way of derogation from sub-regulation (3) of this regulation, the competent authority may allow premixtures to be incorporated in compound feedingstuffs in a proportion as low as 0,05 % by weight:

Provided that the quantitative and qualitative composition of the premixture so permits and that the competent authority has first concluded that the establishments

satisfy the conditions set out in Chapter I.2(b) of the Schedule to the European Union Council Directive 95/69/EC, with a view to achieving homogeneous distribution of premixtures and observing the additive levels set for the whole feedingstuff.

(5)These manufacturers as referred to in sub-regulation (4) of this regulation shall be entered on the national list under a special heading as follows: "Manufacturers of compound feedingstuffs authorised to use a minimum proportion of 0,05 % by weight of premixtures".

(6) By way of derogation from sub-regulation (2) of this regulation:

(a) the additives referred to in Schedule A (B) may be supplied to approved intermediaries or registered establishments which manufacture compound feedingstuffs for pets and fulfil the conditions laid down, as appropriate, in Article 3(1) or Article 3(2)(c) or (d) of European Union Council Directive 95/69/EC;

(b) the additives referred to in Schedule A (A) or (B) may be delivered at the last stage of circulation to establishments which manufacture compound feedingstuffs, provided that:

(i) the regulation authorising the additive as mentioned in regulation 5 provides, in the case of a specific preparation of the additive, for direct addition to feedingstuffs; and

(ii) the manufacturer of compound feedingstuffs is approved in accordance with Article 2(2)(c) of the European Union Council Directive 95/69/EC for the additives referred to in Schedule A (A) or is registered in accordance with Article 7(2)(c) of the Directive 95/69/EC for the additives referred to in Schedule A (B); and

(iii) it has been checked on the spot that the manufacturer is in possession of the appropriate technology defined in Chapter I(3) (b) or Chapter II(c) of the Schedule to the European Union Council Directive 95/69/EC in order to add the preparation in question directly to the compound feedingstuff.

(7) These manufacturers as referred to in sub-regulation (6) of this regulation shall appear on the national list under a special heading as follows: "Manufacturers of compound feedingstuffs referred to in point (b) authorised to add antibiotics, cocciodiostats and other medicinal substances, and growth promoters directly to compound feedingstuffs" or "Manufacturers of compound feedingstuffs authorised to add copper, selenium and vitamins A and D directly to compound feedingstuffs".

(8) Sub-regulations (1) to (5) of this regulation shall apply without prejudice to Article 4(2) and Article 9(2) of European Union Council Directive 95/69/EC.

LABELLING OF ADDITIVES

Details to be contained on package, contained or label of authorised additives

13. (1) Authorised additives may be put into circulation in the territory of Malta for use in feedingstuffs only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the Community, are given on the package, the container or a label affixed thereto –

(a) for all additives, with the exception of enzymes and micro-organisms:

(i) the specific name given to the additive upon authorisation, the EC registration number of the additive and, in the case of an additive within the meaning of regulation 2(b), the trade name and the registration number given to the person responsible for putting it into circulation;

(ii) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this regulation;

(iii) the net weight and, in the case of liquid additives, either the net volume or the net weight;

(iv) as applicable, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of European Union Council Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of the above Directive.

(b) In addition, with regard to:

(i) antibiotics, growth promoters, coccidiostats and other medicinal substances: the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars in the label, the active-substance level, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use and, where appropriate, a safety recommendation regarding use in the case of additives which are the subject of special provisions upon authorisation;

(ii) vitamin E: the alpha-tocopherol level and the expiry date of the guarantee of that level or storage life from the date of manufacture;

(iii) vitamins, other than vitamin E, provitamins and substances having a similar effect: the active-substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;

(iv) trace elements, colorants including pigments, preserving agents and other additives, with the exception of those belonging to the enzyme and micro-organism groups: the active-substance level. C.

(c) For additives belonging to the groups:

(i) of enzymes: the specific name of the active component or components in accordance with their enzyme activities, in conformity with the authorisation given, the International Union of Biochemistry identification number, units of activity (units of activity per gram or units of activity per millilitre which shall be expressed in micromoles of product released per minute,
per gram of enzyme preparation), the EC registration number of the additive, the name or business name and the address or registered place of business of the person responsible for the particulars on the label, the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of European Union Council Directive 95/69/EC, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage(s) by weight of target feed material(s) per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case-by-case basis in the authorisation for the additive and, where applicable, safety recommendations as provided for in the authorisation for the additive, the net weight and, in the case of liquid additives, either the net volume or the net weight, where appropriate indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorisation for the additive;

(ii) of micro-organisms: identification of the strain(s) in accordance with the authorisation granted, the file number of the strain(s), the number of colony-forming units (CFU per gram), the EC registration number of the additive, the name or business name and the address or registered place of business of the person responsible for the particulars on the label, the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of European Union Council Directive 95/69/EC, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use and, where applicable, safety recommendations as provided for in the authorisation for the additive, the net weight and, in the case of liquid additives, either the net volume or the net weight, where appropriate an indication of special significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorisation of the additive.

(2) The specific name of the additive may be accompanied, in cases where the indications are not required by virtue of sub-regulation(1) of this regulation:

(a) by the trade name;

(b) by the name or business name and the address or registered place of business of the manufacturer, if he is not responsible for the particulars on the label, the directions for use and, where appropriate, a safety recommendation regarding use.

(3) Any information other than that required or authorised pursuant to sub-regulations (1) and (2) of this regulation may appear on packages, containers or labels:

Provided that this information is clearly separated from the abovementioned marking particulars.

Details to be contained on package, contained or label of premixtures

14. (1) Premixtures may be marketed in the territory of Malta only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the territory of Malta or of a Trading Partner, are given on the package, the container or a label affixed thereto:

(a) For all premixtures:

(i) the description "premixture";
(ii) directions for use, and any safety recommendations regarding the use of the premixtures;

(iii) the animal species or category of animals for which the premixture is intended;

(iv) the name or business name and the address or registered place of business of the person responsible for the particulars referred to in this paragraph;

(v) the net weight and, in the case of liquids, either the volume or net weight;

(vi) as applicable, the approval number assigned to the establishment or the intermediary pursuant to Article 5 of European Union Council Directive 95/69/EC or the registration number assigned to the establishment or the intermediary pursuant to Article 10 of the above Directive.

(b) In addition, for the premixtures incorporating the additives listed below:

(i) antibiotics, growth promoters, coccidiostats and other medicinal substances: the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the details on the label, specific name given to the additive upon authorisation, active substance level and expiry date of the guarantee of that level, or storage life from the date of manufacture;

(ii) substances having antioxidant effects: specific name given to he additive upon authorisation, and active substance level, provided that a maximum level is fixed for complete feedingstuffs on authorisation of the additive;

(iii) colorants, including pigments: specific name given to the additive upon authorisation, and active substance level, provided that a maximum level is fixed for complete feedingstuffs upon authorisation of the additive;

(iv) vitamin E: specific name given to the additive upon authorisation, alpha-tocopherol level and expiry date of the guarantee of that level or storage life from the date of manufacture;

(v) vitamins other than vitamin E, provitamins and substances having a similar effect: specific name given to the

additive upon authorisation, active substance level and expiry date of the guarantee of that level or storage life from the date of manufacture;

(vi) trace elements: specific name given to the additive upon authorisation, and level of the various elements insofar as a maximum level is fixed for complete feedingstuffs upon authorisation of the additive;

(vii) preserving agents: specific name given to the additive upon authorisation, and active substance level, provided that a maximum level is fixed for complete feedingstuffs upon authorisation of the additive;

(viii) enzymes: the specific name of the active component(s) according to its (their) enzymatic activity(ies) in accordance with the authorisation given, the identification number according to the International Union of Biochemistry, the activity units (activity units per g or activity units per ml), the additive's EC registration number, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, the expiry date of the guarantee or the storage life from the date of manufacture, the batch reference number and the date of manufacture, the directions for use specifying in particular the recommended dose, in the form of a range if appropriate, in accordance with the percentage(s) by weight of target feed material(s) per kilogram of the whole feedingstuff in accordance with the requirements laid down on a case-by-case basis in the authorisation for the additive and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorisation of the additive;

(ix) micro-organisms: the identification of the strain(s) in accordance with the authorisation given, the file number of the strain(s) in accordance with the authorisation given, the file number of the strain(s), the number of colony-forming units (CFU/g), the additive's EC registration number, the name or business name and the address or registered place of business of the manufacturer if he is not responsible for the particulars on the label, the expiry date of the guarantee of the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristics due to the manufacturing process, in accordance with the provisions concerning labelling in the authorisation of the additive;

(x) other additives belonging to the groups referred to in (b) or (i) for which no maximum level is laid down and additives belonging to other groups authorised: specific name given to the additive upon authorisation and active substance level, provided that these additives fulfil a function in the feedingstuff as such and the amounts present can be determined by official methods of analysis or, failing this, by valid scientific methods.

(2) The following details shall also be included in package, container or label:

(a) the specific name of additives may be accompanied by the tradename;

(b) the name of the producer of the additives referred to in sub-regulation (1)(b)(i) of this regulation may be indicated in the labelling of premixtures:

Provided that the competent authority may stipulate that this indication shall be compulsory.

(c) the specific name of the additives authorised may be accompanied by the additive's EC registration number.

(3) Where, pursuant to sub-regulation(1) of this regulation, the expiry date of the guarantee or storage life from the date of manufacture of several additives belonging to the same group or different groups has to be stated, a single date of guarantee or a single reference to the storage life may be indicated for all the additives, namely the deadline which will be reached first.

(4) Any information other than that required or authorised pursuant to sub-regulations (1) to (3) may appear on packages, containers or labels:

Provided that this information is clearly separated from the abovementioned marking particulars.

Details to be contained on package, contained or label of specific feedingstuffs incorporating the additives

15. (1) Feedingstuffs incorporating the additives belonging to the groups listed below may be put into circulation in the territory of Malta only if the following particulars, which must be clearly visible, readily legible and indelible and must place responsibility on the producer, packer, importer, seller or distributor established within the territory of Malta or of a Trading Partner, are given on the package, the container or a label affixed thereto:

(a) for antibiotics, coccidiostats and other medicinal substances and growth promoters: the specific name given to the additive upon authorisation, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture, the approval number assigned to the establishment in accordance with Article 5 of European Union Council Directive 95/69/EC;

(b) for substances having antioxidant effects:

(i) in the case of pet foods: use of the words "with antioxidant" followed by the specific name given to the additive upon authorisation;

(ii) in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorisation;

(c) for colorants, including pigments provided(c) for colorants, including pigments provided that these are used for the coloration of feedingstuffs or animal products:

(i) in the case of pet foods: use of the words "colorant" or "coloured with" followed by the specific name given to the additive upon authorisation,

(ii)in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorisation;

(d) for vitamin E: the specific name given to the additive upon authorisation, the alpha-tocopherol level and the expiry date of the guarantee of that level or storage life from the date of manufacture;

(e) for vitamins A and D: the specific name given to the additive upon authorisation, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;

(f) for copper: the specific name given to the additive upon authorisation and the level expressed in Cu;

(g) for preserving agents:

(i) in the case of pet foods: use of the words "preservative" or "preserved with" followed by the specific name given to the additive upon authorisation,

(ii) in the case of compound feedingstuffs other than pet foods: the specific name given to the additive upon authorisation;

(h) for enzymes: the specific name of the active constituent(s) according to its (their) enzymatic activity(ies) in accordance with the authorisation given, the identification number according to the International Union of Biochemistry, the activity units (activity units per kilogram or activity unit per litre), the EC registration number of the additive, the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the authorisation of the additive;

(i) for micro-organisms: the identification of the strain(s) in accordance with the authorisation given, the file number of the strain(s), the number of colony-forming units (CFU/kg), the EC registration number of the additive, the expiry date of the guarantee or the storage life from the date of manufacture and, where applicable, indication of any particular significant characteristic due to the manufacturing process, in accordance with the provisions concerning labelling in the authorisation of the additive.

(2) In addition to the particulars provided for in sub-regulation (1), particulars concerning the proper use of the feedingstuffs may be laid down in the authorisation of the additive in accordance with the procedure provided for in article 24 of the Veterinary Services Act. These particulars must appear on the package or the container or on a label affixed thereto.

(3) The presence of trace elements other than copper and of vitamins other than vitamins A, D and E, provitamins and additives having a similar effect may be indicated if the amounts of these substances can be determined by official methods of analysis or, failing this, by valid scientific methods of analysis. In such cases the following details shall be given:

(a) for trace elements other than copper: the specific name of the additive in accordance with the authorisation given and level of the various elements;

(b) for vitamins other than vitamins A, D and E, provitamins and substances having a similar chemical effect: the specific name of the additive in accordance with the authorisation given, the active substance level and the expiry date of the guarantee of that level or storage life from the date of manufacture;

(4) The following details shall also be included on the package, container or label:

(a) the details provided for in sub-regulation (1) to (3) shall be printed close to the particulars which have to appear on the package, container or the label affixed thereto in accordance with rules on feedingstuffs;

(b) where a level or a quantity is stated pursuant to sub-regulation (1) to (3), such statement shall refer to the amount of additive incorporated in the feedingstuff;

(c) the details of additives may be accompanied by the EC registration number of the additive or the trade name where those particulars are not required by virtue of sub-regulation (1).

(5) Where, pursuant to sub-regulation (1) of this regulation, the expiry date of the guarantee or storage life from the date of manufacture of several additives belonging to the same group or different groups has to be stated, a single date of guarantee or a single reference to the storage life from the date of manufacture may be indicated for all the additives, namely the deadline which will be reached first.

(6) In the case of feedingstuffs distributed by road tankers or similar vehicles or in bulk, the details provided for in sub-regulation (1) to (3) shall be given in the accompanying document:

Provided that where small quantities intended for the end-user are involved, it shall be sufficient for such details to be conveyed to the purchaser by a suitable notice.

(7) In the case of pet foods containing colorants, preservatives or substances having antioxidant effects and put up in packages having a net weight of not more than 10 kilograms, it shall be sufficient for the package to bear the words "coloured with", or "preserved with", or the words "with antioxidant" as appropriate, followed by the words "EC additives", provided that:

(a) the package, container or label bears a reference number by means of which t h feedingstuff may be identified; nd

(b) the manufacturer gives, on request, the specific name, or names, of the additive or additives used.

(8) Any reference to additives other than in the form provided for in these regulations are prohibited.

Details to be specified in the case of supplementary feedingstuffs which contain additives in excess of the maximum levels fixed for complete feedingstuffs

16. (1) Without prejudice to the provisions of European Union Council Directive 79/373/EEC, supplementary feedingstuffs which contain additives in excess of the maximum levels fixed for complete feedingstuffs may be placed on

the market in the territory of Malta only if the directions for use state, according to the species and age of the animal, the maximum quantity in grams or kilograms of supplementary feedingstuff to be given per animal per day:

Provided that this information must be in accordance with the conditions of use prescribed upon authorisation of the additive.

(2) Sub-regulation (1) of this regulation shall not apply to products delivered to manufacturers of compound feedingstuffs or to their suppliers.

(3) The declaration referred to in sub-regulation (1) shall be so formulated that, when it is correctly followed, the proportion of additives does not exceed the maximum level fixed for complete feedingstuffs.

Marketing in a Trading Partener

17. Where feedingstuffs are intended to be marketed in a Trading Partner the details referred to in regulations 13 to 16 shall be given in at least one of the official languages of the Trading Partner of destination.

Marketing restrictions

18. In the territory of Malta, additives, premixtures and feedingstuffs which conform to these regulations or to the correspondent legislation in Trading Partners are subject only to the marketing restrictions provided for in these regulations.

No marketing restrictions in the case of livestock products

19. In the territory of Malta, livestock products are not subject to any marketing restriction as a result of the application of these regulations.

INSPECTION MEASURES

Inspections by competent authority

20. (1) The competent authority shall in particular take all necessary measures to ensure that additives, premixtures and feedingstuffs put on the market in the territory of Malta are officially checked, at least by random sampling, in respect of the identity of the additives used and to verify that the other conditions laid down in these regulations are satisfied. To this end, the competent authority shall require in particular that undertakings which intend to manufacture additives or to put them on the market must first inform the competent authorities thereof.

(2) Under the procedure provided for in Article 24 of the Veterinary Services Act, margins of tolerance may be fixed, to be allowed where there is a discrepancy between the result of the official check and the stated content of the additive in the compound feedingstuff.

MONITORING OF UNDESIRABLE INTERACTIONS

Measures to be adopted when there is an unforeseen undesirable interaction between additives

21. Where there is found to be unforeseen undesirable interaction between additives referred to in regulation 2(b) and other additives or veterinary medicines, the competent authority shall require that the person responsible for putting the additive into circulation, or his representative within the European Community where additives originate in third countries, gathers all the relevant information and forwards it to itself.

EXPORTS TO THIRD COUNTRIES

Inapplicability to exports to third countries

22. These regulations shall not apply to additives, premixtures and feedingstuffs which are shown, at least by an appropriate indication, to be for export to third countries.

SCHEDULE A

Referred to in regulation 12

PART A
— Antibiotics: all additives belonging to this group
— Coccidiostats and other medicinal substances: all additives belonging to thisgroup
— Growth promoters: all additives belonging to this group

PART B
— Trace elements: copper and selenium
— Vitamins, provitamins and chemically well-defined substances with similar effects: vitamins A and D.

SCHEDULE C

PART I

Additives subject to authorization linked to the person responsible for putting them into circulation referred to in regulation 2(b) of these regulations:

— antibiotics: all additives belonging to this group,
— coccidiostats and other medicinal substances: all additives belonging to this group,
— growth promoters: all additives belonging to this group.

PART II

Other additives referred to in regulation 2(n) of these regulations:

— antioxidant substances: all additives belonging to this group,
— flavouring and appetizing substances,
— emulsifying and stabilizing agents, thickeners and gelling agents: all additives belonging to this group,
— colourants, including pigments: all additives belonging to this group,
— preservatives,
— vitamins, provitamins and chemically well-defined substances having similar effect: all additives belonging to this group,
— trace elements: all additives belonging to this group,
— binders, anti-caking agents and coagulants: all additives belonging to this group,
— acidity regulators: all additives belonging to this group,
— enzymes: all additives belonging to this group,
— micro-organisms: all additives belonging to this group.

SCHEDULE D

The procedure to be applied in order to obtain the authorisation for a substance or a preparation as an additive or for a new use in the case of an already authorised additive, is the procedure laid down in Article 4 of the European Union Council Directive 70/524/EEC concerning additives in feedingstuffs and in European Union Council Directive 85/173/EEC fixing guidelines for the assessment of additives in animal nutrition.

Nru. 1206

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu 11 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermettu lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Kummerċ Intra-Komunitarju fil-Laħam Frisk ta' Annimali Domestiċi Bovini, Qżieqeż, Nagħaġ u Mogħoż u Solipedi.

Id-19 ta' Novembru, 2004

No. 1206

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 11 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Intra-Community Trade in Fresh Meat of Domestic Bovine Animals, Swine, Sheep and Goats and Solipeds, Rules, 2004

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Animal Health Conditions Governing Intra-Community Trade in Ovine and Caprine Animals Rules, 2004

BY virtues of the powers conferred by article 11 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title, scope and applicability

1.(1) The titles to these rules is the Intra-Community Trade in Fresh Meat of Domestic Bovine Animals, Swine, Sheep and Goats and Solipeds Rules, 2004

(2) All parts of these animals which are fit for human consumption shall be considered to be meat.

(3) All meat which has not undergone any preserving process shall be considered as fresh meat; however, for the purposes of these rules chilled and frozen meat shall be considered to be fresh meat.

The scope of these rules is to implement the provisions found under Directive 72/461/EEC on Intra-Community Trade in Fresh Meat of Domestic Bovine Animals, Swine, Sheep and Goats and Solipeds, Rules, 2004.

Definitions

2. For the purposes of these rules and unless the context otherwise requires:-

"the Act" means the Veterinary Services Act;

"the Commission" means the European Commission;

"the Community" means the European Community as established under the Treaty establishing the European Community;

"the Competent Authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"country of destination" means the Member State to which fresh meat is sent from another Member State;

"exporting country" means the Member State from which fresh meat is sent to another Member State;

"official veterinarian" means the veterinarian designated by the Veterinary Services.

Conditions to be fulfilled for transfer of meat from Malta to another Member State

3. Only fresh meat which fulfils the following requirements may be sent from the territory of Malta to the territory of another Member State:

(a) meat obtained from domestic sheep, goats or solipeds must, without prejudice to rule 6, come from animals which have stayed in the territory of the Community for at least twenty-one days immediately prior to slaughter or from birth in the case of animals less than twenty-one days old;

(b) the meat must not have been obtained from animals which come from a holding or area which for health reasons is subject to prohibition pursuant to Article 3 (2) (b) of the Council Directive of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine, as result of the outbreak of foot and mouth disease, swine fever, swine vesicular disease or contagious swine paralysis (Teschen disease) to which the animals in question are susceptible;

(c) the meat must not be obtained from slaughterhouses in which cases of foot and mouth disease, swine fever, swine vesicular disease or contagious swine paralysis (Teschen disease) have been recorded. Should there be an outbreak of one of these diseases, the Veterinary Services shall ensure that no meat suspected to be contaminated forms part of intra-Community trade; and

(d) the meat shall not be subject of animal health restrictive measures pursuant to the provisions of Council Directive 80/217/EEC of the 22 of January, 1980 introducing Community measures for the control of classical swine-fever.

Sending of animals to other Member States

4. Without prejudice to rule 3 (b), fresh meat from swine, sheep and goats may not be sent to the territory of another Member State only insofar as such animals do not come from a holding in the territory of Malta which is subject to prohibition for health reasons as

a result of the outbreak of porcine, ovine or caprine brucellosis. Such prohibition must last at least six weeks after the last case has been officially recorded.

Health Mark on fresh meat

5. (1) The Veterinary Services shall ensure that fresh meat obtained from animals which do not fulfil the requirements of rules 3 and 4 hereof shall not be given the health mark provided for in Chapter XI of Schedule I of the regulations relating to health problems affecting intra-Community trade in fresh meat.

Superimposition of mark

6. Notwithstanding rule 5 (1), and in so far as it is not intended for intra-Community trade in fresh meat, the meat referred to in that rule may carry the mark defined in Annex I, Chapter IX of Directive 64/433/EEC, provided that the special mark referred to in the Annex to these rules is immediately superimposed thereon. The provisions of Annex I, Chapter XI, point 49 of Directive 64/433/EEC shall apply *mutatis mutandis* to the keeping and use of marking instruments. Such meat must be obtained, cut, transported and stored separately from, or not at the same time as, meat intended for intra-Community trade in fresh meat.

Conditions to be fulfilled for transfer of meat from a Member State to Malta

7. (1) When Malta is considered as country of destination, Veterinary Services may grant to one or more exporting countries general authorisations or authorisations restricted to specific cases for the introduction into the territory of Malta of fresh meat, in derogation from rule 3 (a) does not come from animals which have stayed in the territory of the Community for at least twenty-one days immediately prior to slaughter or since birth in the case of animals less than twenty-one days old.

(2) When Veterinary Services grant a general authorisation, in accordance with sub-rule 1, it shall immediately inform the Member States and the European Commission.

(3) When Veterinary Services grant one of the authorisations provided for in sub-rule (1) hereof, a corresponding authorisation should be obtained, in cases of transit, from the countries of transit concerned.

African swine fever cases in the territory of Malta

8 (1) Where African swine fever has been recorded within the previous 12 months in the territory of Malta, exports of fresh pig-meat to the territory of the other Member States are prohibited. It may be decided, in accordance with the requirements of the European Commission that the provisions of the first subparagraph shall not apply to one or more parts of the territory. This derogation shall not preclude recourse to the provisions laid down in Council Directive 89/662/EEC should one or more cases of African swine fever reoccur in the above part or part of territory.

(2) Where there is an outbreak of African swine fever in the territory of Malta where the disease has not been recorded for at least 12 months, it may be decided, in accordance with the requirements of the European Commission, that the provisions of sub-rule (1) shall apply exclusively to a part of territory concerned. Pending this decision, and without prejudice to the safeguard measures decided under Council Directive 89/662/EEC, the Veterinary Services shall ensure the immediate prohibition of export to the other Member States of fresh pig-meat from the part of territory in which the epizootic disease has been recorded. The criteria laid down in sub-rule 9(2) shall be taken into account in determining that part of the territory. One or more cases of African swine fever on a part of Malta's territory which is not geographically linked to the main part of Malta shall not prevent the application of sub-rule (1).

Provided that the conditions prerequisite to the application of sub-rule (1) shall still be deemed to be fulfilled if the following conditions have been fulfilled:

(i) the outbreak or outbreaks recorded on the occurrence of African swine fever referred to in the first sub-paragraph was or were eradicated in the shortest possible period of time;

(ii) the new outbreak, which forms the subject of a fresh request for a decision, as provided for in the first subparagraph, is not connected epidemiologically with the outbreak or outbreaks referred to in sub-rule8(2)(i) hereof.

(3) Decisions to lift measures applied under sub-rule (2) shall be taken in accordance with the requirements of European Community and in accordance with the procedure laid down in articles 11 and 15 of the Veterinary Services Act,.

Defining parts of the territory

9 (1) For the purposes of defining the parts of territory referred to in sub-rule 8(1), particular account shall be taken of:

(a)the methods used to control and eradicate African swine fever,

(b) the absence of the disease for at least 12 months, recorded by all the methods of detection, including serological surveys

(c) the surface area of the parts of territory and their administrative and geographical boundaries,

(d) the protective measures taken to prevent the contamination or recontamination of pig herds,

(e) the measures taken to control the movement of pigs.

(2) For the purposes of defining the parts of territory referred to in sub-rule 8(2), particular account shall be taken of:

(a) the methods used to combat the disease, in particular the elimination of pigs from holdings which are infected, contaminated or suspected of contamination,

(b) the surface area of the parts of territory and their administrative and geographical boundaries,

(c) the incidence of the disease and its tendency to spread,
(d) the measures taken to prevent the disease from spreading,
(e) the measures taken to restrict and control the movement of pigs both inside and outside the part of territory concerned.

Implementation of European Community Law

10. Until European Community provisions relating to importation of fresh meat from third countries are implemented, national provisions relating to fresh meat imported from those countries shall not be more favourable than those resulting from the Council 72/461/EEC.

Veterinary checks applicable to intra-community trade

11. The rules laid down in Directive 89/662/EEC concerning veterinary checks applicable in intra-Community trade, with a view to the completion of the internal market, shall apply in particular to checks at origin, to the organization of and follow-up to the checks to be carried out by the Veterinary Services at destination, and to the protective measures to be implemented.

SCHEDULE

Mark for meat intended for a use other than intra-Community trade in fresh meat

1. The over-stamping must be done in such a way that the oval stamp defined in Annex I, Chapter XI, and No 50 of Directive 64/433/EEC is covered by a diagonal cross consisting of two straight lines crossing at right angles, with the point of intersection in the centre of the stamp and the information thereon remaining legible.

2. The marks mentioned in paragraph 1 may also be made with a single stamp which will be an oval stamp 6 · 5 cm long and 4 · 5 cm broad; the following information must appear on the mark in perfectly legible characters:

— on the upper part, the name of the exporting country in capitals,

— in the centre, the veterinary approval number of the slaughterhouse,

— on the lower part, one of the following sets of initials: CEE - EØF - EWG - EOK - EEC - EEG - ETY - EHS - EMÜ - EEK - EEB - EGK - KEE - EGS,

— two straight lines crossing the stamp diagonally, intersecting at right angles at the centre of the stamp in such a way that the information is not obscured.

The letters must be 0 · 8 cm high and the figures 1 cm high.

The stamp may also carry information whereby the veterinarian who inspected the meat may be identified.

Nru. 1207

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu 5(1) ta' l-Att dwar is-Servizzi Veterinarji, biex jippermettu lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jappoġġjawx biżżejjed l-annjentament tal-bruċellosi, tuberkolożi u lewkożi fil-baqar, jew jekk ikunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Miżuri għall-Annjentament tal-Bruċelloži, Tuberkoloži u Lewkoži fil-Baqar.

Id-19 ta' Novembru, 2004

No. 1207

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 5(1) of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules do not sufficiently support the eradication of brucellosis, tuberculosis and leucosis in cattle, or how they are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Measures for the Eradication of Brucellosis, Tuberculosis and Leucosis in Cattle Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Measures for the Eradication of Brucellosis, Tuberculosis and Leucosis in Cattle Rules, 2004

IN exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title, scope and applicability.

1. (1) The title of these rules is Measures for the Eradication of Brucellosis, Tubercolosis and Leucosis in Cattle Rules, 2004.

(2) The scope of these rules is to implement the rules contained in the European Union Council Directive 77/391/EEC concerning the introduction of Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle.

(3) These rules lay down rules to improve the state of health of cattle in the territory of Malta to accelerate or intensify the eradication of brucellosis and tuberculosis and to eradicate leucosis.

Definitions.

2. For the purpose of these rules, and unless the context otherwise requires –

"Member State" means a State which is a Member within the European Community;

"the Commission" means the European Commission of the Community;

"the Committee" means the Standing Veterinary Committee;

"the Community" means the European Community as established under the Treaty establishing the European Community;

"the competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"the Council" means the Council of Ministers of the Community;

"the Fund" means the European Agricultural Guidance and Guarantee Fund;

"the Treaty" means the Treaty establishing the European Community.

CHAPTER I

Technical Provisions relating to Brucellosis, Tuberculosis and Leucosis

Plans for accelerating the eradication of bovine brucellosis

3. (1) For the purpose of these rules, when in the territory of Malta the cattle population is infected by bovine brucellosis, the competent authority shall draw up plans for accelerating the eradication of this disease within its national territory, under the conditions laid down in sub-rules (2) and (3) of this rule.

(2) The plans for accelerating the eradication of bovine brucellosis shall be so devised by the competent authority that on their completion herds are classed as 'officially brucellosis-free', in accordance with Community law, and in particular European Union Council Directive 64/432/EEC on animal health problems affecting intra-Community trade in bovine animals and swine, as last amended by European Union Council Directive 75/379/EEC:

Provided that the plan shall list the measures to be taken to accelerate and intensify the eradication of bovine brucellosis and must specify the measures to combat and prevent this disease.

(3) The competent authority shall report to the Commission-

(a) the percentage and total number of herds subject to control measures, and of herds with confirmed bovine brucellosis;

(b) the total numbers-

(i) of animals subject to control measures;

(ii) of animals with suspected brucellosis or considered to be infected;

(iii) of infected animals;

(iv) of animals slaughtered;

(c) the scheduled duration of the initial eradication programmes and of the accelerated plans;

(d) the method applied for checking on the effective application of the accelerated plans;

(e) the national budgetary allocation for the eradication of bovine brucellosis and the breakdown by items of these allocations:

Provided that the information referred to under paragraphs (a), (b) and (e) hereof shall be provided for the three years preceding the application of the acceleration measures, and annually thereafter.

(4) When within the jurisdiction of the competent authority, the bovine population is brucellosis-free, the competent authority shall inform the Commission of all the measures taken to prevent the resurgence of this disease.

Plans for accelerating the eradication of bovine tuberculosis

4. (1) For the purpose of these rules, when within the territory of Malta the cattle populations are infected with bovine tuberculosis, the competent authority shall draw up plans for accelerating the eradication of this disease in their national territories, under the conditions laid down in sub-rules (2) and (3) of this rule.

(2) The plans for accelerating the eradication of bovine tuberculosis shall be so devised by the competent authority that on their completion herds in particular are classed as 'officially tuberculosis-free ', in accordance with Community law and European Union Council Directive 64/432/EEC:

Provided that the plans shall list the measures to be taken to accelerate, intensify or carry through the eradication of bovine tuberculosis and shall specify the measures to combat and prevent this disease.

(3) The competent authority shall report to the Commission-

(a) the percentages and total numbers of herds subject to control measures, and of herds with confirmed bovine tuberculosis;

(b) the total numbers-

(i) of animals subject to control measures;

(ii) of animals with suspected tuberculosis or considered to be infected;

(iii) of infected animals;

(iv) of animals slaughtered;

(c) the scheduled duration of the initial eradication programmes and of the accelerated plans;

(d) the methods applied for checking on the effective application of the accelerated plans;

(e) the national budgetary allocations for the eradication of bovine tuberculosis and the breakdown by items of these allocations:

Provided that the information referred to under paragraphs (a), (b) and (e) hereof, shall be provided for the three years preceding the application of the acceleration measures, and annually thereafter.

(4) When within the jurisdiction of the competent authority, the bovine population is tuberculosis-free, the competent authority shall inform the Commission of all the measures taken to prevent the resurgence of this disease.

Plans for accelerating the eradication of enzootic leucosis among cattle.

5. (1) For the purpose of these rules, when the competent authority has established the presence of enzootic leucosis among cattle in its jurisdiction, it shall draw up plans for the eradication of this disease.

(2) The plans must specify the measures for combating this disease.

(3) The tests or methods used to declare a herd free of leucosis shall be those laid down in European Union Commission Decision 73/30/EEC applying special health guarantees for the prevention of leucosis in the case of bovine animals imported for breeding or production, as last amended by European Union Commission Decision 75/64/EEC, or any other tests or methods recognized by the procedure laid down in rule 12.

(4) The competent authority shall furnish the Commission, at the latter's request,
with all information regarding the execution of the plans.

CHAPTER 2

Common and Financial Provisions

Measures to constitute common measures

6. In so far as they are intended to achieve the objectives defined in Article 39 (1)(a) of the Treaty, the measures provided for in Chapter 1 shall constitute common measures within the meaning of Article 6 (1) of Regulation (EC) 729/70.

Time for carrying out common measures and contribution by the Fund

7. (1) The time for carrying out the common measures by the Fund is three years.

(2) The total contribution by the Fund to the cost of the common measures is estimated at 130 million units of account, for the three years.

Expenditure by competent authority

8. (1) Expenditure by the competent authority in respect of measures taken under rules 3,4 and 5 shall be eligible for assistance from the Guidance Section of the Fund within the limits indicated in rule 7.

(2) The Guidance Section of the Fund shall pay to the competent authority 60 units of account per cow and 30 units of account per bovine animal other than cows slaughtered under the measures mentioned in Chapter 1.

(3) Detailed rules for applying this regulation shall be adopted according to the procedure laid down in Article 13 of Regulation (EC) 729/70.

(4) Measures taken by the competent authority shall not be eligible to benefit from financial contributions by the Community unless a favourable decision according to rule 10 has been given in respect of the provisions relating thereto.

Application for payment

9. (1) Applications for payment shall relate to slaughterings carried out by the competent authority in the course of a calendar year and shall be submitted to the Commission before the 1st July of the following year.

(2) The granting of aid from the Fund shall be decided according to Article 7(1) of Regulation (EC) 729/70.

(3) Detailed rules for applying this regulation shall be adopted according to the procedure laid down in Article 13 of Regulation (EC) 729/70.

Plans to be forwarded to Commission by the competent authority

10. (1) The competent authority shall forward to the Commission the plans provided for-

(a) in rules 3 and 4 and the information required under rule 3 (3)(c) and (d) and rule 4 (3)(c) and (d) prior to their implementation, not later than three months after the entry into effect of these rules, and annually thereafter;

(b) in rule 5 annually, and prior to their implementation in the case the competent authority has not yet drawn up plans.

(2) The Commission shall-

(a) examine the plans forwarded in accordance with sub-rule (1) hereof for the purpose of determining whether, in terms of conformity with European Union Directive 77/391/EEC and having regard to the objectives thereof, the conditions for financial contribution by the Community are met;

(b) submit a draft Decision to the Standing Veterinary Committee within two months following the receipt of any plans;

(c) issue its opinion in accordance with the procedure laid down in rule 12, within a time limit set by the chairman;

(d) consult the Fund Committee on the financial aspects.

Community controls

11. (1) The Commission shall make regular on-the-spot checks to verify from a veterinary viewpoint whether the plans are being applied.

(2) The competent authority shall take the necessary steps to facilitate these checks and shall in particular ensure that the experts are supplied at their request

with all information and documentation needed for assessing the execution of the plans.

(3) The provisions for implementing these rules, especially as regards the frequency and method of carrying out the checks referred to in sub-rules (1) and (2) hereof, the rules governing the appointment of official veterinarians and the procedure which they must follow when drawing up their report, shall be laid down according to the procedure set out in rule 12.

Community procedure adopted relative to these rules

12. (1) Where the procedure laid down in this rule is to be followed, the matter shall be referred by the chairman, either on his own initiative or at the request of the competent authority, to the Standing Veterinary Committee.

(2) The procedure shall be carried out as follows-

(a) the representative of the Commission shall submit to the Committee a draft of the measures to be taken;

(b) the Committee shall deliver its opinion on the draft within a time limit which the Chairman may lay down according to the urgency of the matter;

(c) the opinion shall be delivered by the majority laid down in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission;

(d) the votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in Article 148(2) of the Treaty;

(e) the Chairman shall not vote.

(3) Where the measures-

(a) are in accordance with the opinion of the Committee, the Commission shall adopt them and shall apply them immediately;

(b) are not in accordance with the opinion of the Committee, or if no opinion is delivered, the Commission shall without delay submit a proposal to the Council on the measures to be adopted.

(4) The Council shall adopt the measures by a qualified majority.

Provided that if the Council has not adopted any measures within three months of the date on which the proposal was referred to it, the Commission shall adopt the proposed measures and apply them immediately, save where the Council has decided against these measures by a simple majority.

Nru. 1208

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikoli 24 u 25 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermettu lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jirregolawx biżżejjed il-produzzjoni u l-użu ta' oġġetti ta' l-ikel, jew jekk ikunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Ċerti Prodotti użati fin-Nutrizzjoni ta' l-Annimali.

Id-19 ta' Novembru, 2004

No. 1208

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with articles 24 and 25 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules do not sufficiently regulate the production and use of feedingstuffs, or how they are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Certain Products used in Animal Nutrition Rules, 2004

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Certain Products used in Animal Nutrition Rules, 2004

IN exercise of the powers conferred under the articles 24 and 25 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title, scope and applicability

1. (1) The title of these rules is the Certain Products used in Animal Nutrition Rules, 2004".

(2) The scope of these rules is to implement the rules found under European Union Council Directive 82/471/EEC on certain products used in animal nutrition.

(3) These rules concern products which act as direct or indirect protein sources, are manufactured by certain technical processes and are put into circulation within the territory of Malta and the Member States as feedingstuffs or in feedingstuffs.

(4) These rules shall be without prejudice to other provisions concerning -

(a) additives in feedingstuffs;
(b) the fixing of maximum levels for undesirable substances and products in feedingstuffs;

(c) the fixing of maximum levels for pesticide residues on and in products intended for human or animal nutrition;
(d) the marketing compound;
(e) pathogenic micro-organisms in feedingstuffs.
(f) feedingstuffs for particular nutritional purposes;
(g) the circulation of feed materials.

(5) These rules do not apply to products which act as direct or indirect protein sources that fall within the scope of Rule (EC) 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.

Definitions.

2. (1) For the purpose of these rules –
"Member State" means a State which is a Member within the European Community;
"the Community" means the European Community as established under the Treaty establishing the European Community;
"the competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

(2) The definitions contained in Article 2 of European Union Council Directive 70/524/EEC shall also apply to these rules.

Products that can be marketed in the territory of Malta

3. (1) Feedingstuffs belonging to one of the product groups listed in the Schedule or containing such products, shall be authorized to be marketed in the territory of Malta only if –
(a) the product in question appears in the Schedule;
(b) any conditions laid down therein are fulfilled.

(2) Derogations from the provisions of sub-rule (1) of this rule may be granted by the competent authority for experimental or scientific purposes: Provided that an adequate official inspection is carried out by the competent authority.

(3) In the territory of Malta, products referred to in Chapter I.1 (a) of European Union Council Directive 95/69/EC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector may be put into circulation only by establishments or intermediaries which meet the conditions laid down in Article 2 or Article 3 of that Directive, as appropriate.

(4) Sub-rule 3 shall apply without prejudice to Article 4(2) of European Union Directive 95/69/EC.

Particulars which must appear on package, container or label

4. (1) Without prejudice to the labelling provisions applicable to straight and compound feedingstuffs, the products listed in the Schedule may not be marketed as feedingstuffs or incorporated in feedingstuffs unless any particulars laid down in the Schedule appear in the package or container or on a label attached thereto.

(2) Where the material is marketed in bulk, the particulars referred to in sub-rule 1 of this rule shall appear on an accompanying document.

Products contained in the Schedule

5. (1) In the Schedule, the following principles are observed:

(a) A product shall not be included in the Schedule unless:
(i) it has nutritional value for animals because it provides nitrogen or protein;
(ii) when used sensibly it has no detrimental effect on human or animal health or on the environment and does not harm the consumer by impairing the distinctive features of animal products;
(iii) it can be monitored in feedingstuffs.

(b) A product shall be deleted from the Schedule if one of the conditions listed in sub-rule 2(a) of this rule is not satisfied.

(3) Criteria making it possible to define the products included in these rules, particularly the criteria of composition and purity and the physico-chemical and biological properties, may be set in the light of scientific and technical knowledge.

Preparation and circulation of a dossier

6. (1) In order to ensure that the products referred to in Sections 1.1 and 1.2 of the Schedule comply with the principles set out in rules 5(2), a dossier shall be prepared in accordance with the provisions of sub-rule (2) of this rule and sent officially to the Member States, to the relevant International Organisation and, if it is requested that they be consulted, to the necessary scientific committees.

(2) The competent authorities and the other recipients of the dossier referred to in sub-rule (1) shall ensure, if requested on good grounds by an applicant, that information whose disclosure could adversely affect industrial or commercial property rights is kept confidential:

Provided that industrial and commercial secrecy shall not apply to:

(a) the names and composition of the product, and any information concerning the substrate and the micro-organism;
(b) the physico-chemical and biological properties of the product;

(c) the interpretation of the pharmacological, toxicological and ecotoxicological data;

(d) the analytical methods for monitoring the product in the feedingstuffs.

Temporary suspension or restriction of rule as safeguard measures

7. (1) If, on the basis of detailed grounds due to new data or a new evaluation of existing data that have become evident since the adoption of these rules, the competent authority finds that one of the products listed in the Schedule or its use under any conditions that have been set is found to represent a danger to human or animal health even though it complies with the provisions of these rules, it may temporarily suspend or restrict the application of those provisions within the territory of Malta:

Provided that the competent authority shall immediately inform the other Member States and the relevant International Organisation thereof, giving the reasons for its decision.

Marketing between Member States

8. With regard to marketing between Malta and other Member States, the particulars referred to in rule 4 shall be given in at least one of the official languages of the country of destination.

Marketing restrictions on feedingstuffs

9. Feedingstuffs that comply with these rules shall only be subject to the marketing restrictions contained in these rules:

Provided that this applies as far as the presence and labeling of the products listed in the Schedule is concerned.

Marketing restrictions on animal products

10. In the territory of Malta, animal products shall not be subject to any marketing restriction as a result of the application of these rules.

Monitoring by competent authority

11. The competent authority shall take all the necessary measures in order to ensure that the compliance of feedingstuffs with the requirements of these rules is officially monitored, including methods like sampling during marketing.

Nru. 1209

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu 34(g) ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jistabbilixxux biżżejjed is-saħħa ta' l-annimali applikabbli għall-kummerċ u importazzjoni ta' semen ta' annimali domestiċi ta' l-ispeċi bovini, jew jekk ikunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar is-Saħħa ta' l-Annimali applikabbli għall-Kummerċ Intra- Komunitarju Fi u Importazzjoni ta' Semen ta' Annimali Domestiċi ta' l-Ispeċi Bovini.

Id-19 ta' Novembru, 2004

No. 1209

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 34(g) of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules do not sufficiently establish animal health applicable to trade and import of semen of domestic animals of the bovine species, or how they are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Animal Health Requirements Applicable to Intra-Community Trade In and Imports of Semen of Domestic Animals of the Bovine Species Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Animal Health Requirements Applicable to Intra-Community Trade In and Imports of Semen of Domestic Animals of the Bovine Species Rules, 2004

IN exercise of the powers conferred by article 34(g) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title, scope and applicability

1. (1) The title of these rules is Animal Health Requirements Applicable to Intra-Community Trade In and Imports of Semen of Domestic Animals of the Bovine Species Rules, 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the bovine species.

(3) These rules lay down the animal health conditions applicable to intra-Community trade in and imports from third countries of semen of domestic animals of the bovine species.

(4) These rules shall not affect Community and/or national zootechnical provisions governing the organisation of artificial insemination in general and the distribution of semen in particular.

Definitions

2. For the purpose of these rules –

"approved laboratory" means a laboratory situated in the territory of Malta, a Member State or third country designated by the competent authority to carry out the tests laid down in these rules;

"centre veterinarian" means the veterinarian responsible for day-today compliance in the centre with the requirements laid down in these rules;

"collection" means a quantity of semen taken from a donor at any time;

"consignment" means a quantity of semen covered by a single certificate;

"country of collection" means Malta, a Member State or third country in which semen is collected and from which it is sent to Malta or to a Member State;

"Member State" means a State which is a Member within the European Community;

"official veterinarian" means the veterinarian designated by the competent authority of Malta, a Member State or a third country;

"semen" means the prepared or diluted ejaculate of a domestic animal of the bovine species;

"semen collection center" means an officially approved and officially supervised establishment situated in the territory of Malta, a Member State or third country, in which semen is produced for use in artificial insemination;

"semen storage center" means an officially approved and officially supervised establishment situated in the territory of Malta, a Member State or third country in which semen is stored for use in artificial insemination;

"the Commission" means the European Commission within the Community;

"the Community" means the European Community as established under the Treaty establishing the European Community;

"the competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"third country" means a State which is not a Member within the European Community.

CHAPTER II

Intra-Community Trade

Semen which can be sent from the territory of Malta to another Member State

3. Only semen meeting the following general conditions is sent from the territory of Malta to the territory of another Member State -

(a) it must have been collected and processed and/or stored if need be in a collection or storage centre or centres approved for the purpose in accordance with rule 5 (1), with a view to artificial insemination and for the purposes of intra-Community trade;

(b) it must have been collected from domestic animals of the bovine species whose health status complies with Schedule B;

(c) it must have been collected, processed, stored and transported in accordance with Schedules A and C;

(d) it must be accompanied, during transport to the country of destination, by an animal health certificate complying with rule 6 (1).

When tests are necessary before admission into territory of Malta

4. The competent authority may not oppose the admission of semen from bulls vaccinated against foot-and-mouth disease:

Provided that, where the semen was obtained from a bull which had been vaccinated against foot-and-mouth disease during the 12 month period prior to collection, 5 % of the semen from each collection (with a minimum of five straws) intended for sending to Malta or to another Member States shall be subjected, in a laboratory at destination or in a laboratory designated by the competent authority, to a virus isolation test for foot-and-mouth disease, with negative results.

Approval of semen collection or storage centres

5. (1) In the territory of Malta, the approval provided for in rule 3(a) shall be granted only where the provisions of Schedule A are observed and where the semen collection or storage centre is able to satisfy the other provisions of these rules. The competent authority shall also ensure that the official veterinarian

supervises the observance of these rules and shall withdraw approval when one or more of the rules is no longer observed.

(2) All approved semen collection or storage centres shall be registered by the competent authority, each centre being given a veterinary registration number. The competent authority shall send a list of semen collection or storage centres and their veterinary registration numbers to the other Member States and to the Commission and shall notify them of any withdrawal of approval.

(3) The general rules for applying this rule shall be adopted in accordance with the requirements of the Community and under the procedure laid down in article 8 of the Veterinary Services Act.

Animal health certificate

6. (1) The admission of semen shall be conditional upon submission of an animal health certificate drawn up by an official veterinarian of the Member State of collection in accordance with Schedule D.

(2) The certificate required by sub-rule (1) hereof must:

(a) be drawn up in at least one of the official languages of the Member State of collection and one of those of the Member State of destination;

(b) accompany the consignment to its destination in its original form;

(c) be drawn up on a single sheet of paper;

(d) be made out to a single consignee.

(3) The competent authority, where Malta is the country of destination, may –

(a) prohibit the admission of consignments if a documentary check reveals that rule 3 has not been observed;

(b) take the necessary measures, including storage in quarantine, in order to obtain definite proof in cases where semen is suspected of being infected or contaminated by pathogenic organisms;

Provided that decisions taken under paragraphs (a) or (b) must, at the request of the consignor or his representative, authorize the return of the semen, provided this is not contrary to considerations of animal health.

(4) If the admission of semen has been prohibited on any of the grounds set out in sub-rule (3)(a) and (b) and the Member State of collection does not within 30

days authorize the return of the semen, the competent authority of Malta as country of destination may order it to be destroyed.

(5) The decisions taken by the competent authority under sub-rules (3) and (4) must be communicated to the consignor or his representative, together with the reasons therefor.

CHAPTER III

Imports from Third Countries

When importation into the territory of Malta is authorized

7. (1) Importation of semen into the territory of Malta may be authorized only from those third countries which appear on a list drawn up by the Commission in accordance with the relevant procedure of the Community. That list is supplemented or amended in accordance with the same procedure.

(2) In deciding whether a third country may appear on the list referred to in sub-rule (1), particular account shall be taken of:

(a) the state of health of the livestock, other domestic animals and wildlife in the third country, with particular reference to exotic animal diseases, and of the environmental health situation in that country, which might endanger animal health in the territory of Malta and other Member States;

(b) the regularity and rapidity of the information supplied by the third country concerning the existence of contagious animal diseases in its territory, in particular those diseases mentioned in lists A and B of the International Office of Epizootic Diseases;

(c) that country's rules on animal disease prevention and control;

(d) the structure of the veterinary services in the country and their powers;

(e) the organization and implementation of measures to prevent and control contagious animal diseases; and

(f) the guarantees which the third country can give with regard to compliance with these rules.

Submission of animal health certificate to authorize importation

8. (1) The importation of semen into the territory of Malta shall be authorized only on submission of an animal health certificate drawn up and signed by an official veterinarian of the third country of collection.

(2) The certificate required by sub-rule (1) hereof must:

(a) be drawn up in at least one of the official languages of Malta and one of those of the Member State where the import control is carried out;

(b) accompany the semen in the original;

(c) be drawn up on a single sheet of paper;

(d) be made out to a single consignee;

(e) must correspond to a specimen drawn up in accordance with the requirements of the Community.

Applicability of European Union Council Directive 90/675/EEC

9. The rules laid down in European Union Council Directive 90/675/EEC laying down the principles governing the organization of veterinary checks on products entering the Community from third countries shall apply in particular to the organization and follow-up of checks to be carried out by the competent authority and the safeguard measures to be applied.

CHAPTER IV

Safeguard and Control Measures

Applicability of European Union Council Directive 90/425/EEC

10. The rules laid down in European Union Council Directive 90/425/EEC concerning veterinary and zootechnical checks in intra-Community trade in certain live animals and products with a view to the completion of the internal market and in Article 15 of the Veterinary Services Act, shall apply in particular to checks at origin, to the organization of, and follow-up to, the checks to be carried out by the competent authority, and follow up to, the checks to be carried out at destination, and to the safeguard measures to be implemented.

On-the-spot checks

11. (1) Veterinary experts from the Commission may, in cooperation with the competent authority, make on-the-spot checks in so far as that is indispensable for ensuring uniform application of these rules.

(2) The competent authority shall –

(a) give all necessary assistance to the experts in carrying out their duties;

(b) take any measures which may prove necessary to take account of the results of the investigation.

SCHEDULE A

CHAPTER I

CONDITIONS FOR THE OFFICIAL APPROVAL OF CENTRES

1. Semen collection centres must:

(a) be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;

(b) have at least:

(i) animal housing, including isolation facilities;

(ii) semen collection facilities, including a separate room for the cleaning and disinfection or sterilisation of equipment;

(iii) a semen processing room which need not necessarily be on the same site;

(iv) a semen storage room which need not necessarily be on the same site;

(c) be so constructed or isolated that contact with livestock outside is prevented;

(d) be so constructed that the animal housing and the semen collecting, processing and storage facilities can be readily cleaned and disinfected;

(e) have isolation accommodation which has no direct communication with the normal animal accommodation;

(f) be so designed that the animal accommodation is physically separated from the semen processing room and both are separated from the semen storage room.

2. Semen storage centres must:

(a) be placed under the permanent supervision of a centre veterinarian authorised by the competent authority;

(b) be so constructed or isolated that contact with livestock outside is prevented;

(c) be so constructed that the storage facilities can be readily cleaned and disinfected.

CHAPTER II

CONDITIONS RELATING TO THE OFFICIAL SUPERVISION OF CENTRES

1. Collection centres must:

(a) be so supervised that they contain only animals of the species whose semen is to be collected. Other domestic animals which are strictly necessary for the normal operation of the collection centre may nonetheless also be admitted, provided that they present no risk of infection to those species whose semen is to be collected, and that they fulfil the conditions laid down by the centre veterinarian;

(b) be so supervised that a record is kept of all bovine animals at the centre, giving details of the breed, date of birth and identification of each of the animals, and also a record of all checks for diseases and all vaccinations carried out for each animal;

(c) be regularly inspected by an official veterinarian, at least twice a year, in the context of standing checks on the conditions of approval and supervision;

(d) be so supervised that the entry of unauthorised persons is prevented. Furthermore, authorised visitors must be required to comply with the conditions laid down by the centre veterinarian;

(e) employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;

(f) be so supervised that:

(i) only semen collected at an approved centre is processed and stored in approved centres, without coming into contact with any other consignment of semen. However, semen not collected in an approved centre may be processed in approved collection centers provided that:

— such semen is produced from bovine animals which fulfil the conditions laid down in Chapter I.1(d) of Schedule B,

— processing is carried out with separate equipment or at a different time from semen intended for intra-Community trade, the equipment in the latter case being cleaned and sterilized after use,

— such semen may not be the subject of intra-Community trade and cannot at any time come into contact with, or be stored with, semen intended for intra-Community trade,

— such semen is identifiable by a marking different from that provided for in point (vii);

Deep-frozen embryos may also be stored in approved centers provided that:

— such storage is authorised by the competent authority,

— the embryos meet the requirements of Council Directive 89/556/EEC on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species ,

— the embryos are stored in separate storage containers in the premises for storing approved semen;

(ii) collection, processing and storage of semen takes place only on the premises set aside for the purpose and under the strictest conditions of hygiene;

(iii) all instruments which come into contact with the semen or the donor animal during collection and processing are properly disinfected or sterilised prior to use, except for single-use instruments;

(iv) products of animal origin used in the processing of semen — including additives or a diluent — are obtained from sources which present no animal health risk or are so treated prior to use that such risk is prevented;

(v) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for single-use containers;

(vi) the cryogenic agent used has not been previously used for other products of animal origin;

(vii) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the breed and identification of the donor animal and the approval number of the centre can be readily established; the competent authority shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory;

(viii) the storage unit must comply with specific conditions relating to the supervision of semen storage centres provided for in point 2.

2. Storage centres must:

(a) be so supervised that a record is kept of all movement of semen (in and out the centre) and of the status of the donor bulls whose semen is stored there, and which must comply with the requirements of these rules;

(b) be regularly inspected by an official veterinarian, at least twice a year, in the context of the standing checks on the conditions of approval and supervision;

(c) be so supervised that the entry of unauthorised persons is prevented. Furthermore, authorised visitors must be required to comply with the conditions laid down by the centre veterinarian;

(d) employ technically competent staff suitably trained in disinfection procedures and hygiene techniques relevant to the control of the spread of disease;

(e) be so supervised that:

(i) only semen collected at collection centres approved in accordance with these rules is stored in approved storage centres, without coming into contact with any other semen. In addition, only semen coming from an approved collection or storage centre and transported in conditions offering every possible health guarantee, having had no contact with any other semen, may be brought into an approved storage centre.

Deep-frozen embryos may also be stored in approved centers provided that:

— such storage is authorised by the competent authority,

— the embryos meet the requirements of Council Directive 89/556/EEC on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species,

— the embryos are stored in separate storage containers in the premises for storing approved semen;

(ii) storage of semen takes place only on the premises set aside for the purpose and under the strictest conditions of hygiene;

(iii) all instruments which come into contact with the semen are properly disinfected or sterilised prior to use, except for single-use instruments;

(iv) storage containers and transport containers are either properly disinfected or sterilised before the commencement of each filling operation, except for single-use containers;

(v) the cryogenic agent used has not been previously used for other products of animal origin;

(vi) each individual dose of semen is clearly marked in such a way that the date of collection of the semen, the breed and identification of the donor animal and the approval number of the collection center can be readily established; the competent authority shall communicate to the Commission and other Member States the characteristics and form of the marking used in its territory.

SCHEDULE B

CHAPTER I

CONDITIONS APPLYING TO THE MOVEMENT OF ANIMALS INTO APPROVED SEMEN COLLECTION CENTRES

1. For all bovine animals admitted to a semen collection centre the following requirements shall apply:

(a) they must have been subjected to a period of quarantine of at least 28 days in accommodation specifically approved for the purpose by the competent authority or the competent authority of another Member State, and where only other clovenhoofed animals having at least the same health status are present;

(b) prior to their stay in the quarantine accommodation described in (a), they must have belonged to a herd which is officially tuberculosis free and officially brucellosis free inaccordan ce with European Union Council Directive 64/432/EEC. The animals shall not previously have been kept in a herd of a lower status;

(c) they must come from a herd officially free of enzootic bovine leukosis as defined in European Union Council Directive 64/432/EEC, or have been produced by dams which have been subjected, with negative results, to a test carried out in accordance with Schedule D (Chapter II) to European Union Council Directive 64/432/EEC, after removal of the animals from their dam. In the case of animals derived by embryo transfer, 'dam' means the recipient of the embryo;

If this requirement cannot be fulfilled, the semen shall not be the subject of trade until the donor has reached the age of two years and has been tested in accordance with Chapter II.1(c) with a negative result;

(d) within the 28 days preceding the period of quarantine specified in (a), they have been subjected to the following tests with negative results in each case, except for the BVD/MD antibody test mentioned in (v):

(i) for bovine tuberculosis, an intradermal tuberculin test carried out in accordance with the procedure laid down in Schedule B to European Union Council Directive 64/432/EEC;

(ii) for bovine brucellosis, a serological test carried out in accordance with the procedure described in Schedule C to European Union Council Directive 64/432/EEC;

(iii) for enzootic bovine leukosis, a serological test carried out in accordance with the procedure laid down in Schedule D (Chapter II) to European Union Council Directive 64/432/EEC;

(iv) for IBR/IPV, a serological test (whole virus) on a blood sample if the animals do not come from an IBR/IPV free herd as defined in Article 2.3.5.3. of the International Animal Health Code;

(v) for BVD/MD,

— a virus isolation test or a test for virus antigen, and

— a serological test to determine the presence or absence of antibodies.

The competent authority may give authorisation for the tests referred to in (d) to be carried out on samples collected in the quarantine station. In this case, the period of quarantine referred to in (a) may not commence before the date of sampling. However, should any of the tests listed in (a) prove positive, the animal concerned shall be immediately removed from the isolation unit. In the event of group isolation, the quarantine period referred to in (a) may not commence for the remaining animals until the animal which tested positive has been removed.

(e) within the period of quarantine specified in (a), and at least 21 days after being admitted to quarantine (at least seven days after being admitted to quarantine to search for *Campylobacter fetus* ssp. *venerealis* and *Trichomonas foetus*), they have been subjected to the following tests with negative results in each case, except for the BVD/MD antibody test (see point (iii) below):

(i) for bovine brucellosis, a serological test carried out in accordance with the procedure described in Schedule C to European Union Council Directive 64/432/EEC;

(ii) for IBR/IPV, a serological test (whole virus) on a blood sample;

If any animals test positive, these animals shall be removed immediately from the quarantine station and the other animals of the same group shall remain in quarantine and be retested, with negative results, not less than 21 days after removal of the positive animal(s).

(iii) for BVD/MD,

— a virus isolation test or a test for virus antigen, and

— a serological test to determine the presence or absence of antibodies.

Any animal (seronegative or seropositive) may only be allowed entry to the semen collection facilities if no sero-conversion occurs in animals which tested seronegative before entry into the quarantine station.

If sero-conversion occurs, all animals that remain seronegative shall be kept in quarantine over a prolonged time, until there is no more sero-conversion in the group for a period of three weeks. Serologically positive animals may be allowed entry into the semen collectionfacilities;

(iv) for *Campylobacter fetus* ssp. *venerealis*:

— in the case of animals less than six months old or kept since that age in a single sex group prior to quarantine, a single test on a sample of artificial vagina washings or preputial specimen;

— in the case of animals aged six months or older that could have had contact with females prior to quarantine, a test three times at weekly intervals on a sample of artificial vagina washings or preputial specimen;

(v) for *Trichomonas foetus*:

— in the case of animals less than six months old or kept since that age in a single sex group prior to quarantine, a single test on a sample of preputial specimen;

— in the case of animals aged six months or older that could have had contact with females prior to quarantine, a test three times at weekly intervals on a sample of preputial specimen.

If any of the above tests is positive, the animal must be removed forthwith from the isolation accommodation. In the case of group isolation, the competent authority must take all necessary measures to re-establish the eligibility of the remaining animals for entry into the collection centre in accordance with the Annex.

(f) prior to the initial dispatch of semen from BVD/MD serologically positive bulls, a semen sample from each animal shall be subjected to a virus isolation or virus antigen ELISA test for BVD/MD. In the event of a positive result, the bull shall be removed from the centre and all of its semen destroyed.

2. All tests must be carried out in a laboratory approved by the competent authority or the other Member State.

3. Animals may only be admitted to the semen collection centre with the express permission of the centre veterinarian. All movements, both in and out, must be recorded.

4. No animal admitted to the semen collection centre may show any clinical sign of disease on the day of admission. All animals must, without prejudice to paragraph 5, have come from isolation accommodation , as referred to in paragraph 1(a), which on the day of consignment officially fulfils the following conditions:

(a) is situated in the centre of an area of 10 kilometres radius in which there has been no case of foot-and-mouth disease for at least 30 days;

(b) has for at least three months been free from foot-and-mouth disease and brucellosis;

(c) has for at least 30 days beenfree from those bovine diseases which are compulsorily notifiable in accordance with Schedule E to European Union Council Directive 64/432/EEC.

5. Provided that the conditions laid down in paragraph 4 are satisfied and the routine tests referred to in Chapter II have been carried out during the previous 12 months, animals may be transferred from one approved semen collection centre to another of equal health status, without isolation or testing if transfer is direct. The animal in question must not come into direct or indirect contact with cloven-hoofed animals of a lower health status and the means of transport used must have been disinfected before use. If the movement from one semen collection centre to another takes place between Malta and the other Member States it must take place in accordance with European Union Council Directive 64/432/EEC.

CHAPTER II

ROUTINE TESTS WHICH MUST BE APPLIEDTO ALL BOVINE ANIMALS IN AN APPROVEDSEMEN COLLECTION CENTRE

1. All bovine animals kept at an approved semen collection centre must be subjected at least once a year to the following tests, with negative results:

(a) for bovine tuberculosis, an intradermal tuberculin test, carried out in accordance with the procedure laid down in Schedule B to European Union Council Directive 64/432/EEC;

(b) for bovine brucellosis, a serological test carried out in accordance with the procedure described in Schedule C to European Union Council Directive 64/432/EEC;

(c) for enzootic bovine leukosis, a serological test carried out in accordance with the procedure described in Schedule D (Chapter II) to European Union Council Directive 64/432/EEC;

(d) for IBR/IPV, a serological test (whole virus) on a blood sample;

(e) for BVD/MD, a serological antibody which is applied only to seronegative animals; Should an animal become serologically positive, every ejaculate of that animal collected since the last negative test shall be either discarded or tested for virus with negative results.

(f) for *Campylobacter fetus* ssp. *venerealis*, a test on a sample of preputial specimen. Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months shall be tested not more than 30 days prior to resuming production;

(g) for *Trichomonas foetus*, a test ona sample of preputial specimen.
Only bulls on semen production or having contact with bulls on semen production need to be tested. Bulls returning to collection after a lay-off of more than six months shall be tested not more than 30 days prior to resuming production.

2. All tests must be carried out ina laboratory approved by the competent authority or the other Member State.

3. If any of the above tests is positive, the animal must be isolated and the semen collected from it since the last negative test may not be the subject of intra-Community trade with the exception, for BVD/MD, of semen from every ejaculate which has beentested BVD/MD virus negative. Semen collected from all other animals at the centre since the date when the positive test was carried out shall be held inseparate storage and may not be the subject of intra-Community trade until the health status of the centre has been restored.

SCHEDULE C

CONDITIONS WHICH SEMEN FOR INTRA-COMMUNITY TRADE OR IMPORTEDINTO THE COMMUNITY MUST SATISFY

1. Semen must be obtained from animals which:

(a) show no clinical signs of disease on the day the semen is collected;

(b) (i) have not been vaccinated against foot-and-mouth disease during the 12 months prior to collection, or

(ii) have been vaccinated against foot-and-mouth disease during the 12 months prior to collection, in which case 5 % (with a minimum of five straws) of each collectionshall be submitted to a virus isolation test for foot-and-mouth disease with negative results;

(c) have not been vaccinated against foot-and-mouth disease within 30 days immediately prior to collection;

(d) have been kept at an approved semen collection centre for a continuous period of at least 30 days immediately prior to the collection of the semen in the case of collections of fresh semen;

(e) are not allowed to serve naturally;

(f) are kept in semen collection centres which have been free from foot-and-mouth disease for at least three months prior to collection of the semen and 30 days after collection or, in the case of fresh semen, until the date of dispatch, and which are situated in the centre of an area of 10 kilometres radius in which there has been no case of foot-and-mouth disease for at least 30 days;

(g) have been kept in semen collection centres which, during the period commencing 30 days prior to collection and ending 30 days after collection of the semen or, in the case of fresh semen, until the date of dispatch, have been free from those bovine diseases which are compulsorily notifiable in accordance with Annex E(I) to Directive 64/432/EEC.

2. Antibiotics as listed below must be added to produce these concentrations in the final diluted semen:

not less than:

— 500 μg streptomycin per ml final dilution,

— 500 IU penicillin per ml final dilution,

— 150 μg lincomycin per ml final dilution,

— 300 μg spectinomycin per ml final dilution.

An alternative combination of antibiotics with an equivalent effect against campylobacters, leptospires and mycoplasmas may be used.

Immediately after their addition the diluted semen must be kept at a temperature of at least 5 ºC for a period of not less than 45 minutes.

3. Semen for intra-Community trade must:

(a) be stored in approved conditions for a minimum period of 30 days prior to dispatch. This requirement shall not apply to fresh semen.

(b) be transported to Malta or to the Member State of destination in containers which have been cleaned and disinfected or sterilised before use and which have been sealed and numbered prior to dispatch from the approved storage facilities.

SCHEDULE D

<table>
<tr><td colspan="3">HEALTH CERTIFICATE FOR INTRA-COMMUNITY TRADE IN SEMEN OF DOMESTIC ANIMALS OF THE BOVINE SPECIES IN ACCORDANCE WITH EUROPEAN UNION COUNCIL DIRECTIVE 88/407/EEC</td></tr>
<tr><td colspan="2">1. Member state of provenance and competent authority</td><td>2. Health certificate number:</td></tr>
<tr><td colspan="3">A. ORIGIN OF SEMEN</td></tr>
<tr><td colspan="3">3. Approval number of the centre of origin/provenance ([1]) of the consignment: collection/storage ([1])</td></tr>
<tr><td colspan="2">4. Name and address of the centre of origin/provenance ([1]) of the consignment: collection/storage ([1])</td><td>5. Name and address of the consignor</td></tr>
<tr><td colspan="2">6. Country place of loading</td><td>7. Means of transport</td></tr>
<tr><td colspan="3">B. DESTINATION OF SEMEN</td></tr>
<tr><td colspan="2">8. Member State of destination</td><td>9. Name and address of the consignee</td></tr>
<tr><td colspan="3">C. IDENTIFICATION OF SEMEN</td></tr>
<tr><td>10. Identification marks of the doses</td><td>11. Number of doses</td><td>12. Approval number of the collection centre of origin</td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td></td><td></td><td></td></tr>
<tr><td colspan="3">D. HEALTH INFORMATION</td></tr>
<tr><td colspan="3">I, the undersigned veterinarian, certify that:
(a) the semen described above was collected, processed and/or stored under conditions which comply with the standards laid down in Directive 88/407/EEC;
(b) the semen described above, was sent to the place of loading in a sealed container under conditions which comply with Directive 88/407/EEC and bearing the number……...;
(c) the semen described above was collected from bulls:
(i) which have not been vaccinated against foot-and-mouth disease within 12 months prior to collection ([1]);
or
(ii) which have been vaccinated against foot-and-mouth disease with 12 months prior to collection, in which case the semen comes from a collection in which 5 % (with a minimum of 5 straws) of each collection shall be submitted to a virus isolation test for foot-and-mouth disease in …….. laboratory ([3]), with negative results([1]);
(d) the semen was stored in approved conditions for a minimum period of 30 days prior to dispatch ([4]).</td></tr>
<tr><td colspan="3">E. VALIDITY</td></tr>
<tr><td>13. Date and place:</td><td>14. Name and qualification of the official veterinarian:</td><td>15. Signature and stamp of the official veterinarian:</td></tr>
</table>

([1]) Delete as necessary.
([2]) Corresponding to the identification of the donor animals and date of collection.
([3]) Name of the laboratory specified in accordance with the second subparagraph of Article 4 of Directive 88/407/EEC.
([4]) May be deleted for fresh semen.

SCHEDULE E

Animal health certificate

No:_____

Country of collection:_____

Competent authority: _____

Competent local authority:_____

I. Identification of semen:

Number of doses	Date (s) of collection	Identification of donor animal	Breed	Date of birth

II. Origin of semen:

Address of semen collection centre (s) :_____

Approval number of semen collection centre (s) :_____

III. Destination of semen:

The semen will be sent from: _____
(place of loading)

to:_____

_____
(country and place of destination)

by: _____
(means of transport)

Name and address of consignor:_____

Name and address of consignee:_____

IV.:

I, the undersigned veterinarian, certify that:

1. the semen described above was collected, processed and stored under conditions which comply with the standards laid down in Directive 88/407/EEC;
2. the semen described above, was sent to the place of loading in a sealed container under conditions which comply with Directive 88/407/EEC and bearing the number.;
3. the semen described above was collected in a centre where all bulls gave a negative result to a serum neutralisation test or an ELISA test for infectious bovine rhinotracheitis or infectious pustular vulvovaginitis carried out in accordance with Directive 88/407/EEC ([1]) ;

4. the semen described above was collected from bulls:

(i) which gave a negative result to a serum neutralisation test or an elisa test for infectious rhinotracheitis or infectious pustular vulvovaginitis carried out in accordance with Directive 88/407/EEC ([1]) ; or

(ii) which gave a positive result to the tests referred to at (i) but which had already given a negative reaction to these tests prior to a first vaccination in accordance with the directive at the insemination centre ([1]);or

(iii) which gave a positive result to a serum neutralisation test or an ELISA test for infectious bovine rhinotracheitis or infectious pustular vulvovaginitis and have not been vaccinated in accordance with Directive 88/407/EEC ([1]): and in which case the semen comes from a collection which has been subjected, with a negative result, to an examination by inoculation or a virus isolation test ([1]) as referred to in the third subparagraph or Article 4 ([1]) of Directive 88/407/EEC in laboratory. ([2]);

5. the semen described above was collected from bulls:

(i) which have not been vaccinated against foot-and-mouth disease within 12 months prior to collection ([1]); or

(ii) which have been vaccinated against foot-and-mouth disease with 12 months prior to collection, in which case the semen comes from a collection in which 5 % of each collection intended for trade (with a minimum of 5 straws) has been subjected, with negative results, to a virus isolation test for foot-and-mouth disease in. laboratory ([2]) ;

6. the semen was stored in approved conditions for a minimum period of 30 days prior to dispatch ([3]).

Done at. _____

Seal

(Signature)

_____

(name in block letters)

([1]) delete as necessary.
([2]) name of the laboratory specified in accordance with the second subparagraph of Article 4 of Directive 88/407/EEC.
([3]) May be deleted for fresh semen.

Nru. 1210

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu 5(1) ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jikkontrollawx biżżejjed li jiskoppja ċertu mard fl-annimali, u b'mod partikolari l-marda veżikulari fil-qżieqeż jew jekk ikunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Kontroll ta' Ċertu Mard fl-Annimali (u Speċifikament il-Marda Veżikulari tal-Qżieqeż.

Id-19 ta' Novembru, 2004

No. 1210

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 5(1) of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules do not sufficiently control the outbreak of certain animal diseases, and in particular the swine vesicular disease, or how they are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Control of Certain Animal Diseases (and Specifically the Swine Vesicular Disease) Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Control of Certain Animal Diseases (and Specifically the Swine Vesicular Disease) Rules, 2004

IN exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title, scope and applicability

1. (1) The title of these rules is Control of certain animal diseases (and specifically the swine vesicular disease) Rules, 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 92/119/EEC introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease.

(3) These rules define the general control measures to be applied in the event of an outbreak of one of the diseases listed in Schedule I.

Definitions

2. For the purpose of these rules –

"animal" means any domestic animal of a species liable to be directly affected by the disease in question, or any wild vertebrate animal likely to participate in the epidemiology of the disease, by acting as a carrier or reservoir of infection;

"confirmation of infection" the declaration by the competent authority of the presence of any of the diseases listed in Schedule I based on laboratory results; however, in the event of an epidemic, the competent authority may also confirm the presence of the disease on the basis of clinical and/or epidemiological results;

"holding" means any establishment (agricultural or other), situated in the territory of Malta, in which animals are kept or bred;

"incubation period" means the period of time likely to elapse between exposure to the agent of the disease and the onset of clinical symptoms. The duration of this period shall be that indicated in Schedule I for the disease in question;

"Member State" means a State which is a Member within the European Community;

"official veterinarian" the veterinarian appointed by the competent authority;

"owner or keeper" means any person or persons, either natural or legal, having ownership of the animals, or charged with keeping the said animals, whether or not for financial reward;

"the Commission" means the European Commission within the Community;

"the Community" means the European Community as established under the Treaty establishing the European Community;

" the competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"vector" any wild vertebrate or invertebrate animal which, by mechanical or biological means, is liable to transmit and spread the agent of the disease in question.

Notification to the competent authority in case of suspected presence of disease

3. It is compulsory for the suspected presence in the territory of Malta of any of the diseases referred to in Schedule I to be notified immediately to the competent authority.

Official measures in the case of suspected infection or contamination

4. (1) When animals on a holding are suspected of being infected or contaminated with one of the diseases listed in Schedule I, the official veterinarian shall immediately activate official investigation arrangements to confirm or rule out the presence of the disease in question and, in particular, must take or have taken the samples necessary for laboratory examination. To that end the animals in question may be transported to the laboratories under the supervision of the competent authority, which shall take appropriate steps to prevent the disease from spreading.

(2) As soon as the suspected presence of the disease is notified, the competent authority shall have the holding placed under official surveillance and shall in particular require that:

(a) a census be made of all categories of animals of susceptible species and that, in respect of each of these categories, the number of animals already dead, infected or liable to be infected or contaminated be recorded; the census must be kept up to date to take account of animals born or dying during the period of suspicion; the information in the census must be kept up to date and produced on request and may be checked at each visit;

(b) all animals of susceptible species on the holding be kept in their living quarters or confined in some other place where they can be isolated taking into account the possible role of vectors, where appropriate;

(c) no animals of susceptible species enter or leave the holding;

(d) all movement:

(i) of persons, animals of other species not susceptible to the disease and vehicles to or from the holding;

(ii) of meat or animal carcases, or of animal feed, equipment, waste, droppings, litter, manure, or anything liable to transmit the disease in question;

(e) be subject to authorization by the competent authority, which shall

lay down the conditions for preventing any risk of the disease spreeding; appropriate means of disinfection be installed at the entrances and exits of buildings or places housing animals of susceptible species and of the holding itself;

(f) an epizootiological inquiry be carried out in accordance with rule 8.

(3) Until such time as the official measures laid down in sub-rule (2) are enforced, the owner or keeper of any animal in which disease is suspected shall take every appropriate measure to ensure compliance with sub-rule (2), except for paragraph (f) thereof.

(4) The competent authority may apply any of the measures provided for in sub-rule (2) to other holdings should their location, their configuration or contacts with the holding where the disease is suspected give reason to suspect possible contamination.

(5) The measures referred to in sub-rules (1) and (2) shall not be withdrawn until the suspicion of the presence of the disease has been ruled out by the official veterinarian.

Measures in the case of confirmation of existence of diseases

5. (1) Once it has been officially confirmed that one of the diseases listed in Schedule I is present on a holding, in addition to the measures laid down in rule 4(2), the competent authority shall require application of the following measures:

(a) all animals of susceptible species on the holding shall be killed on the spot, without delay. The animals which have died or been killed shall either be burnt or buried on the spot, if possible, or destroyed in a carcase disposal plant. These operations shall be carried out in such a way as to minimize the risk of disseminating the agent of the disease;

(b) any substance or waste, such as animal feed, litter, manure or slurry, which is liable to be contaminated, shall be destroyed or treated appropriately. This treatment, carried out in accordance with the instructions of the official veterinarian, must ensure that any agent or vector of the agent of the disease is destroyed;

(c) after carrying out operations listed in paragraphs (a) and (b), the buildings used for housing animals of susceptible species, their surroundings, the vehicles used for transport and all equipment liable to be contaminated shall be cleaned and disinfected in accordance with rule 16;

(d) an epizootiological inquiry shall be carried out in accordance with rule 8.

(2) When recourse is had to burial, it must be deep enough to prevent carnivorous animals from digging up the carcases or waste referred to in sub-rule (1)(a) and (b) hereof and must be in suitable ground so as to prevent contamination of water tables or any environmental nuisance.

(3) The competent authority may extend the measures provided for in sub-rule (1) to other neighbouring holdings should their location, their configuration or contacts with the holding where the presence of the disease has been confirmed give reason to suspect possible contamination.

(4) The restocking of the holding shall be authorized by the competent authority, following the satisfactory inspection by the official veterinarian of the cleaning and disinfection operations carried out in accordance with rule 16.

Animals living in the wild

6. Where animals living in the wild are infected or suspected of being infected, appropriate action shall be taken by the competent authority which shall inform the Commission and the other Member States, of the measures it has taken.

Holdings consisting of two or more separate production units

7. (1) In the case of holdings which consist of two or more separate production units, the competent authority may derogate from the requirements of rule 5 (1)(a) as regards healthy production units of a holding which is infected:

Provided that the official veterinarian has confirmed that the structure and size of these units and the operations carried out therein are such that they are completely separate as regards housing, keeping, staff, equipment and feeding, so as to prevent the spread of the agent of the disease from one unit to another.

(2) Where recourse is had to sub-rule (1) hereof, the rules laid down in Article 18(2) of European Union Council Directive 2003/85/EC on Community measures for the control of food-and-mouth disease repealing European Union Council Directive 85/511/EEC and Commission Decisions 89/531/EEC and 91/665/EEC and amending European Union Council Directive 92/46/EEC shall apply *mutatis mutandis*:

Provided that these rules may be amended for the disease in question according to the European Community requirements in order to take account of the specific nature of the disease.

The epizootiological enquiry

8. (1) The epizootiological enquiry shall deal with:

(a) the length of time during which the disease may have existed on the holding before being notified or suspected;

(b) the possible origin of the disease on the holding and the identification of other holdings on which there are animals of susceptible species which may have become infected or contaminated;

(c) the movement of persons, animals, carcases, vehicles, equipment or any other substances likely to have carried the agent of the disease to or from the holdings in question;

(d) the presence and distribution of disease vectors as appropriate.

(2) A crisis unit shall be established in order to provide full coordination of all measures necessary to ensure eradication of the disease as quickly as possible and for the purpose of carrying out the epizootiological enquiry.

(3) The rules concerning national crisis units shall be laid down according to European Community requirements.

When other holdings are placed under official surveillance

9. (1) Where the official veterinarian finds, or considers on the basis of confirmed data, that disease could have been introduced from other holdings onto the holding referred to in rule 4 or from the latter onto other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with rule 4, and such surveillance shall not be lifted until the suspected presence of disease on the holding has been officially ruled out.

(2) Where the official veterinarian finds, or considers on the basis of confirmed data, that disease could have been introduced from other holdings on to the holding referred to in rule 5 or from the latter onto other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with rule 4, and such surveillance shall not be lifted until the suspected presence of disease on the holding has been officially ruled out.

(3) When a holding has been subject to the provisions of sub-rule (2) hereof, the competent authority shall keep the provisions of rule 4 in force on the holding for at least the maximum incubation period pertaining to each disease following the likely

time of introduction of infection as established by the epizootiological enquiry carried out in accordance with rule 8.

(4) Where it considers that conditions permit, the competent authority may limit the measures provided for in sub-rules (1) and (2) hereof to a part of the holding and the animals contained therein provided that the holding can satisfy the conditions set out in rule 7, or to animals of susceptible species only.

Protection zone

10. (1) Once the diagnosis of one of the diseases in question has been officially confirmed, the competent authority shall establish around the infected holding a protection zone with a minimum radius of three kilometres, itself contained in a surveillance zone with a minimum radius of 10 kilometres:

Provided that the establishment of the zones must take account of geographical, administrative, ecological and epizootiological factors relating to the disease in question, and of monitoring facilities.

(2) Where the zones are situated in the territory of another Member State, the competent authority shall co-operate with the competent authorities of the Member States concerned in establishing the zones referred to in sub-rule (1). If necessary, the protection zone and the surveillance zone shall be established under the relevant procedure of the European Community.

(3) The decision to modify (in particular to reduce or increase, as appropriate) the boundaries of the zones laid down in sub-rule (1) or the duration of the restriction measures may be decided by the European Commission according to the relevant procedure of the European Community, taking into account:

(a) their geographical situation and ecological factors;

(b) the meteorological conditions;

(c) the presence, distribution and type of vectors;

(d) the results of the epizootiological studies carried out in accordance with rule 8;

(e) the results of laboratory tests;

(f) control measures actually applied.

Measures to be taken in the protection zone

11. (1) The competent authority shall ensure that the following measures are applied in the protection zone:

(a) all holdings within the zone having animals of susceptible species shall be identified;
(b) there shall be periodic visits to holdings having animals of susceptible species, a clinical examination of those animals including, if necessary, the collection of samples for laboratory examination; a record of visits and findings must be kept, with the frequency of visits being proportional to the seriousness of the epizootic on those holdings at greatest risk;

(c) the movement and transport of animals of susceptible species on public or private roads, excluding the service roads of holdings, shall be prohibited; the competent authority may, however, grant a derogation from that prohibition for the transit of animals by road or rail without unloading or stopping;

(d) animals of susceptible species must remain on the holding on which they are being kept, except to be transported under official supervision directly to a slaughterhouse located in that zone for emergency slaughter or, if that zone has no slaughterhouse under veterinary supervision, to a slaughterhouse in the surveillance zone designated by the competent authority:

Provided that such transport may be authorized by the competent authority only after the official veterinarian has carried out an examination of all the animals of susceptible species on the holding and confirmed that none of the animals is suspected of being infected. The competent authority responsible for the slaughterhouse shall be informed of the intention to send animals to it.

(2) The measures applied in the protection zone shall be kept in force for at least the maximum incubation period pertaining to the disease in question after animals from the infected holding have been disposed of in accordance with rule 5 and cleaning and disinfection operations have been carried out in accordance with rule 16.

(3) Notwithstanding sub-rule (2), where the disease is transmitted by an insect vector, the competent authority may fix the duration of the measures and lay down provisions for the possible introduction of sentinel animals. In such cases, the competent authority shall forthwith inform the Commission and the other Member States of the measures they have taken. On expiry of the period referred to in this rule, the rules applied to the surveillance zone shall also apply to the protection zone.

Measures to be taken in surveillance zone

12. (1) The competent authority shall ensure that the following measures are applied in the surveillance zone:

(a) all holdings having animals of susceptible species shall be identified;

(b) the movement of animals of susceptible species on public roads shall be prohibited except for the purpose of leading them to pasture or animal buildings:
Provided that the competent authority may grant a derogation from that prohibition for the transit of animals by road without unloading or stopping;

(c) the transport of animals of susceptible species within the surveillance zone shall be subject to authorization by the competent authority;

(d) animals of susceptible species must:

(i) remain inside the surveillance zone for a maximum incubation period after the most recent recorded case of disease;

(ii) thereafter, they may be removed from that zone to be transported under official supervision directly to a slaughterhouse designated by the competent authority for emergency slaughter;

(iii) be transport after being authorized by the competent authority and only after the official veterinarian has carried out an examination of all the animals of the susceptible species on the holding and confirmed that none of the animals is suspected of being infected.

The official veterinarian responsible for the slaughterhouse shall be informed of the intention to send animals to it.

(2) The measures applied in the surveillance zone shall be kept in force for a period at least equal to the maximum incubation period after animals from the holding have been disposed of in accordance with rule 5 and cleaning and disinfection operations have been carried out in accordance with rule 16.

(3) Notwithstanding sub-rule (2) hereof, where the disease is transmitted by an insect vector, the competent authority may fix the duration of the measures and lay down provisions for the possible introduction of sentinel animals. In such cases, the competent authority shall forthwith inform the Commission and the other Member States, of the measures they have taken.

Removal of animals from protection or surveillance zone

13. (1) Where the prohibitions provided for in rule 11 (1)(d) and rule 12 (1)(d) are maintained beyond 30 days because of the occurrence of further cases of the disease and as a result problems arise in keeping the animals, the competent authority may, following an application by the owner explaining the rounds for such application, authorize the removal of the animals from a holding within the protection zone or the surveillance zone:

Provided that:

(a) the official veterinarian has verified the facts;

(b) an inspection of all animals on the holding has been carried out;

(c) the animals to be transported have undergone a clinical examination, with negative result;

(d) each animal has been marked by ear marking or has been identified by any other approved method;

(e) the holding of destination is located either in the protection zone or within the surveillance zone.

(2) All the necessary precautions shall be taken, in particular by cleaning and disinfecting lorries after transport, to avoid the risk of spreading the agent of the disease in the course of such transport.

Right of information

14. (1) The competent authority shall take all the necessary measures to keep at least persons established in the protection and surveillance zones informed of the restrictions in force and makes all necessary arrangements for the appropriate implementation of those measures.

(2) Where, in a given region, the epizootic in question is exceptionally serious, all the additional measures to be taken in the territory of Malta shall be adopted according to the relevant procedure of the European Community.

Specific provisions

15. By way of derogation from the general provisions laid down in these rules, specific provisions relating to the control and eradication measures for each respective disease:

(a) are, for swine vesicular disease, set out in Schedule II for swine vesicular disease,

(b) are, for each of the other diseases listed in Schedule I, adopted in accordance with the provisions adopted by the European Community in those matters.

Cleaning, disinfection and disinsectization operations

16. The following procedure shall be observed –

(a) the disinfectants and insecticides to be used and, where appropriate, their concentrations, shall be officially approved by the competent authority;

(b) the cleaning, disinfection and disinsectization operations are carried out under official supervision –

(i) in accordance with the instructions given by the official veterinarian; and

(ii) in such a way as to eliminate any risk of spread or survival of the agent of the disease;

(c) on completion of the operations in paragraph (b), the official veterinarian makes sure that the measures have been carried out properly and that an appropriate period, of not less than 21 days, has elapsed to ensure that the disease in question has been completely eliminated before animals of susceptible species are re-introduced.

(2) The procedures for cleaning and disinfecting an infected holding –

(a) are, for swine vesicular disease, those set out in Schedule II;

(b) are determined, in the context of preparation of the specific measures for each disease listed in Schedule I, in accordance with the requirements of the European Community.

National laboratories

17. For the purpose of implementation of these rules in the Territory of Malta, there shall be designated –

(a) a national laboratory with facilities and expert personnel enabling it to show at all times, and especially when the disease in question first appears, the type, sub-type and variant of the relevant virus and to confirm results obtained in regional diagnostic laboratories;

(b) a national laboratory at which reagents used in regional diagnostic laboratories are tested.

(2) The national laboratories designated for each of the diseases referred to shall be responsible for coordinating diagnostic standards and methods, and for the use of reagents.

(3) The national laboratories designated for each of the diseases referred to shall be responsible for coordinating the diagnostic standards and methods laid down by each laboratory for diagnosis of the disease in question within the territory of Malta. To this end, they:

(a) may provide diagnostic reagents to national laboratories;

(b) shall control the quality of all diagnostic reagents used in the Member State;

(c) shall periodically arrange comparative tests;

(d) shall hold isolates of the virus of the disease in question from cases confirmed in the territory of Malta;
(e) shall ensure the confirmation of positive results obtained in regional diagnostic laboratories.

(4) By way of derogation from sub-rule (1) hereof, the national laboratories competent as regards the disease in question, may provide the services of a diagnostic laboratory.

(5) The list of laboratories for swine vesicular disease is designated in Schedule II.

(6) The national laboratories designated for each of the diseases referred to shall cooperate with the respective Community reference laboratories.

(7) The detailed rules for implementing this Article shall be adopted in accordance with the requirements of the European Community and under the procedure laid down in article 5(1) of the Veterinary Services Act.

Vaccination

18. (1) Vaccination against the diseases listed in Schedule I may not be carried out except as a supplement to control measures taken when the disease in question broke out, in accordance with the following provisions –

(a) the decision to introduce vaccination as a supplement to control measures shall be taken by the competent authority in cooperation with the Commission and under its approval;

(b) this decision shall be based on the following criteria in particular:

(i) the concentration of animals of the species concerned in the affected zone;

(ii) the characteristics and composition of each vaccine used;

(iii) the procedures for supervision of the distribution, storage and use of vaccines;

(iv) the species and age of the animals which may or must be vaccinated;

(v) the areas in which vaccination may or must be carried out;

(vi) the duration of the vaccination campaign.

(2) In the case referred to in sub-rule (1) hereof:

(a) the vaccination or re-vaccination of animals of susceptible species on the holdings referred to in rule 4 shall be prohibited;

(b) hyper-immune serum injection shall be prohibited.

(3) In the event of recourse to vaccination, the following rules shall apply:

(a) all vaccinated animals must be identified by a clear and legible mark in accordance with a method approved by the Community;

(b) all vaccinated animals must remain within the vaccination zone unless sent to a slaughterhouse designated by the competent authority

for immediate slaughter, in which case the movement of animals may be authorized only after the official veterinarian has carried out an examination of all the susceptible animals on the holding and confirmed that none of the animals is suspected of being infected.

(4) When the vaccination operations have been completed, movements of animals of susceptible species from the vaccination zone may be permitted under the relevant procedure of the Community.

(5) The competent authority shall inform the Commission, on a regular basis, of progress as regards the vaccination measures.

(6) By way of derogation from sub-rule (1), the decision to introduce emergency vaccination may be taken by the competent authority, following notification of the Commission, provided that the fundamental interests of the Community are not affected. That decision, which must in particular take into account the degree of concentration of the animals in certain regions, of the need to protect individual breeds and of the geographical area in which vaccination is carried out, shall forthwith be re-examined, under the relevant procedure of the Community and it may be decided to retain, modify or extend the measures or to bring them to an end.

Contingency plan

19. (1)The competent authority shall draw up a contingency plan applicable to all the diseases listed in Schedule I, specifying the national measures to be implemented in the event of an outbreak of any of these diseases. This plan must allow access to facilities, equipment, personnel and all other appropriate materials necessary for the rapid and efficient eradication of the outbreak.

(2) The general criteria to be applied for drawing up the contingency plans are laid down in points 1 to 5 and 10 of Schedule III, with points 6 to 9 representing criteria to be adapted according to the disease concerned:

Provided that the competent authority may confine itself to applying the criteria laid down in points 6 to 9 where the criteria in points 1 to 5 and 10 were already adopted when plans were submitted for the application of control measures for another disease.

(3) Contingency plans drawn up in accordance with the criteria listed in Schedule III shall be submitted to the Commission:

(4) The contingency plans shall be –

(i) examined by the Commission in order to determine whether they permit the desired objective to be attained and shall suggest to the

competent authority any amendments required in particular to ensure that they are compatible with those of the other Member States;

(ii) approved by the Commission, if necessary amended, in accordance with the relevant procedure of the Community;

(iii) subsequently be amended or supplemented, in accordance with the same procedure, to take into account developments in the situation and the specific nature of the disease in question.

SCHEDULE I

LIST OF COMPULSORILY NOTIFIABLE DISEASES

Disease	Maximum incubation period
Rinderpest	21 days
Peste des petits ruminants	21 days
Swine vesicular disease	28 days
Bluetongue	40 days
Epizootic haemorrhagic disease of deer	40 days
Sheep and goat pox (Capripox)	21 days
Vesicular stomatitis	21 days
African swine fever	40 days
Lumpy skin disease	28 days
Rift valley fever	30 days

SCHEDULE II

SPECIFIC MEASURES TO CONTROL CERTAIN DISEASES

In addition to the general provisions laid down in these rules, the following specific provisions shall be applicable to swine vesicular disease.

1. **Description of the disease**

A disease of swine that is clinically indistinguishable from foot-and-mouth disease, causing vesicles on the snout, lips, tongue and the coronary bands of the digits. The disease varies considerably in severity and may infect a pig herd without manifesting itself by clinical lesions. The virus is able to survive for long periods outside the body even in fresh meat; it is extremely resistant to normal disinfectants and noted for its persistence and stability over a pH range from 2,5 to 12. Particularly thorough cleaning and disinfection are, therefore, necessary.

2. **Incubation period**

For the purpose of these rules, the maximum incubation period shall be considered to be 28 days.

3. **Diagnostic procedures for the confirmation and differential diagnosis of swine vesicular disease**

The detailed methods for the collection of materials for diagnosis, the laboratory diagnostic tests, detection of antibodies and evaluation of the results of laboratory testing shall be decided in accordance with the relevant procedure of the Community.

4. **Confirmation of the presence of swine vesicular disease**

By way of derogation from rule 2(6), the presence of the disease shall be confirmed:

(a) on holdings on which swine vesicular disease virus is isolated either from the pigs or from the environment;

(b) on holdings containing pigs which are seropositive for swine vesicular disease provided those pigs or others on the holdings show lesions characteristic of swine vesicular disease;

(c) on holdings containing pigs which show clinical signs of disease or are seropositive, provided there is a direct epidemiological connection with a confirmed outbreak;

(d) on other herds in which seropositive pigs are detected. In the latter case the competent authority shall, before confirming the presence of the disease, undertake further investigations, in particular resampling and retesting with an interval of 28 days at least between collections of samples. The provisions of Article 4 shall continue to apply until such further investigations are completed. If subsequent investigations show no evidence of the disease, although the pigs are still seropositive, the competent authority shall ensure that the pigs tested are killed and destroyed under its supervision or slaughtered under its supervision in a slaughterhouse it has designated in its national territory.

The competent authority shall ensure that on arrival at the slaughterhouse the pigs are kept and slaughtered separately from other pigs and that their meat is exclusively used on the national market.

5. **Diagnostic laboratories**

Austria: Institut für Fischkunde, Veterinärmedizinische Universität, Wien.
Belgium: Institut national de recherches vétérinaires, Groeselenberg 99, B-1180 Bruxelles.
Denmark: Statens Veterinære Institut for Virusforskning, Lindholm.
Finland: Eläinlääkintä- ja elintarvikelaitos, Helsinki —Anstalten för veterinärmedicin och livsmedel, Helsingfors.
Germany: Bundesforschungsanstalt für Viruskrankheiten der Tiere, Paul-Ehrlich-Straße, 7400 Tübingen.
France: Laboratoire central de recherche vétérinaire, Maisons-Alfort.
Greece: *Ινστιτούτο Λοιμωδών και Παρασιτικών Νοσημάτων, Νεαπόλεως 21, Αγία Παρασκευή·*
Ireland: Institute for Animal Health, Pirbright, Woking, Surrey.
Italy: Istituto zooprofilattico sperimentale della Lombardia e dell'Emilia Romagna, Brescia.
Luxembourg: Institut national de recherches vétérinaires, Groeselenberg 99, B-1180 Bruxelles.
Netherlands: Centraal Diergeneeskundig Institut, Lelystad.
Portugal: Laboratório Nacional de Investigação Veterinária, Lisboa.
Spain: Laboratorio de Alta Seguridad Biológica (INIA), 28130 Madrid.
Sweden: Statens veterinärmedicinska anstalt, Uppsala.
United Kingdom: Institute for Animal Health, Pirbright, Woking, Surrey.
Czech Republic: Státní veterinární ústav Praha, Sídlištní 24/136,165 03 Praha 6.
Estonia: Veterinaar - ja Toidulaboratoorium, Kreutzwaldi 30, 51006 Tartu.
Cyprus: Istituto Zooprofilattico Sperimentale della Lombardia e dell' Emilia Romagna, Via Bianchi 9, IT - 25124 Brescia.
Latvia: Valsts veterinarmedicinas diagnostikas centrs, Lejupes iela 3, LV-1076 Riga.
Lithuania: Nacionaline veterinarijos laboratorija, J. Kairiukšèio g. 10, LT-2021 Vilnius.
Hungary: Országos Állategészségügyi Intézet (OÁI), Pf. 2., Tábornok u. 2., HU-1581 Budapest.
Malta: Institute for Animal Health, Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 ONF, United Kingdom.
Poland: Laboratorium Zak³adu Pryszczycy Pañstwowego Instytutu Weterynaryjnego, ul. Wodna 7, PL-98-220 Zduñska Wola.
Slovenia: Institute for Animal Health, Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 ONF, United Kingdom.
Slovakia: Institute for Animal Health, Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 ONF , United Kingdom.

6. **Community reference laboratory**

AFRC Institute for Animal Health,Pirbright Laboratory, Ash Road, Pirbright, Woking, Surrey GU24 ONF, United Kingdom.

7. **Protection zone**

1. The size of the protection zone shall be as defined in rule 10.

2. In the case of swine vesicular disease, by way of derogation, the measures in rule 11 shall be replaced by the following:

(a) all holdings within the zone having animals of susceptible species shall be identified;

(b) there shall be periodic visits to holdings having animals of susceptible species, a clinical examination of those animals including, if necessary, the collection of samples for laboratory examination; a record of visits and findings must be kept; with the frequency of the visits being proportional to the seriousness of the epizootic on those holdings at greatest risk;

(c) the movement and transport of animals of susceptible species on public or private roads, excluding the service roads of holdings, shall be prohibited. The competent authority may, however, derogate from this prohibition for the transit of animals by road and rail without unloading or stopping;

(d) however, in accordance with the requirements of the Community, an exemption may be granted for slaughter pigs coming from outside the protection zone and on their way to a slaughterhouse situated in that zone;
(e) trucks and other vehicles and equipment which are used within the protection zone to transport pigs or other livestock or material which may be contaminated (e.g. feedingstuff, manure, slurry, etc.) may not leave:

(i) a holding situated within the protection zone;

(ii) the protection zone;

(iii) a slaughterhouse,

without having been cleaned and disinfected in accordance with the procedures laid down by the competent authority. Those procedures shall provide in particular that no truck or vehicle which has been used in the transport of pigs may leave the zone without being inspected by the competent authority;

(f) pigs may not be removed from a holding in which they are kept for 21 days after completion of the preliminary cleaning and disinfection of infected holdings as laid down in Article 16; after 21 days, authorization may be given to remove pigs from the said holding:

(i) directly to a slaughterhouse designated by the competent authority, preferably within the protection or surveillance zone, provided that:
— an inspection of all the pigs on the holding has been carried out,
— a clinical examination of the pigs to be moved to slaughter has been carried out,
— each pig has been marked by ear marking or has been identified by any other approved method,
— the pigs are transported in vehicles sealed by the competent authority.

The competent authority responsible for the slaughterhouse shall be informed of the intention to send pigs to it.

On arrival at the slaughterhouse, the pigs shall be kept and slaughtered separately from other pigs. The vehicle and equipment which have been involved in the transport of the pigs shall be cleaned and disinfected before leaving the slaughterhouse.

During the pre-slaughter and *post mortem* inspection carried out at the designated slaughterhouse, the competent authority shall take into account any signs relating to the presence of the swine vesicular disease virus.

In the case of pigs slaughtered under these provisions, a statistically representative sample of bloods shall be collected. In the case of a positive result which leads to the confirmation of swine vesicular disease, the measures in 9 (3) will apply;

(ii) under exceptional circumstances, directly to other premises located within the protection zone, provided that:
— an inspection of all the pigs on the holdings has been carried out,

— a clinical examination of the pigs to be moved has been carried out, with negative results,
— each pig has been marked by ear marking or has been identified by any other approved method;

(g) fresh meat from the pigs referred to in point (f) (i) shall be marked in accordance with the Schedule to European Union Council Directive 72/461/EEC on health problems affecting intra-Community trade in fresh meat, and subsequently treated in accordance with the rules laid down in Article 4 (1) of European Union Council Directive 80/215/EEC on animal health problems affecting intra-Community trade in meat products. This must be done at an establishment designated by the competent authority. The meat shall be sent to the said establishment on condition that the consignment is sealed before departure and remains sealed throughout the transport. However, in accordance with the requirements of the Community, specific solutions may by adopted, in particular with respect to the marking of meat and its subsequent use, and the destination of the processed products.

3. The measures in the protection zone shall continue to be applied at least until:

(a) all measures laid down in rule 16 have been carried out;

(b) all the holdings in the zone have undergone:

(i) a clinical examination of the pigs which has revealed that they have no signs of disease suggesting the presence of swine vesicular disease; and

(ii) a serological examination of a statistical sample of the pigs without the detection of antibodies to swine vesicular disease. The programme for serological screening shall take into account the transmission of swine vesicular disease and the way in which pigs are kept. The programme shall be that fixed by the Community.

The examination and sampling referred to in (i) and (ii) shall not take place before 28 days have elapsed after the completion of preliminary cleaning and disinfection measures at the infected holding.

4. On expiry of the period referred to in point 3, the rules applied to the surveillance zone shall also apply to the protection zone.

8. **Surveillance zone**

1. The size of the surveillance zone shall be as laid down in rule 10.

2. In the case of swine vesicular disease, the measures laid down in rule 12 shall be replaced by the following:

(a) all holdings having animals of susceptible species shall be identified;

(b) any movement of pigs other than direct to a slaughterhouse from a holding in the surveillance zone shall be permitted, provided that no pigs have moved into that holding in the previous 21 days; the owner or the person responsible for the animals must keep a record of all pig movements;

(c) the movement of pigs from the surveillance zone may be authorized by the competent authority, provided that:

(i) an inspection of all pigs on the holding has been carried out with the 48 hours preceding the movement,

(ii) a clinical examination of the pigs to be moved has been carried out with negative results in the 48 hours preceding the movement,

(iii) a serological examination of a statistical sample of the pigs to be moved has been carried out without the detection of antibodies to swine vesicular disease within the 14 days preceding the movement. However, in the case of pigs for slaughter, the serological examination may be carried out on the basis of blood samples taken at the slaughterhouse of destination designated by the competent authority in its territory. In the event of positive results confirming the presence of swine vesicular disease, the measures provided for in point 9(3) shall be applied,
(iv) each pig has been marked with an individual eartag or by any other approved method of identification,

(v) trucks and other vehicles and equipment used for the transport of the pigs must be cleaned and disinfected after each transport operation;

(d) trucks and other vehicles and equipment used for the transport of the pigs or other livestock or material that may be contaminated and which are used within the surveillance zone shall not leave that zone without having been cleaned and disinfected in accordance with the procedures laid down by the competent authority.

3 (a) The size of the surveillance zone may be amended in accordance with the provisions laid down in rule 10 (3).

(b) The measures in the surveillance zone shall be applied at least until:

(i) all the measures laid down in rule 16 have been carried out;

(ii) all the measures required in the protection zone have been carried out.

9. **General common measures**

Additional measures in the case of swine vesicular disease shall be applied as follows:

1. in cases where the presence of swine vesicular disease is officially confirmed, Member States shall ensure that, in addition to the measures laid down in rules 4 (2) and 5, meat of pigs slaughtered during the period between the probable introduction of disease to the holding and the implementation of official measures is, wherever possible, traced and destroyed under official supervision in such a way as to avoid the risk of swine vesicular disease virus spreading;

2. when the official veterinarian has reason to suspect that pigs on any holding may have been contaminated as a result of the movement of any person, animal or vehicle or in any other way, pigson the holding shall remain under the movement restrictions referred to in rule 9 at least until the holding has undergone:

(a) a clinical examination of the pigs, with negative results;

(b) a serological examination of a statistical sample of the pigs without the detection of antibodies to swine vesicular disease in accordance with 7 (3) (b) (ii).

The examination referred to in (a) and (b) shall not take place until 28 days have elapsed since the possible contamination of the premises as the result of the movement of persons, animals, or vehicles, or in any other way.

3. Should the presence of swine vesicular disease be confirmed in a slaughterhouse, the competent authority shall ensure that:

(a) all pigs in the slaughterhouse are slaughtered without delay;

(b) the carcases and offal of infected and contaminated pigs are destroyed under official supervision in such a way as to avoid the risk of swine vesicular disease virus spreading;

(c) cleaning and disinfection of buildings and equipment, including vehicles, take place under the supervision of the official veterinarian, in accordance with instructions laid down by the competent authority;

(d) an epidemiological enquiry is carried out in accordance with rule 8;

(e) no pigs are re-introduced for slaughter until at least 24 hours after completion of the cleaning and disinfection operations carried out in accordance with (c).

10. **Cleansing and disinfection of infected holdings**

In addition to the measures laid down in rule 16, the following measures shall also apply -

1. Procedure for preliminary cleaning and disinfection -

(a) As soon as the carcases of the pigs have been removed for disposal, those parts of the premises in which the pigs have been housed and any other parts of the premises which have been contaminated during slaughter should be sprayed with disinfectant, approved in compliance with rule 16, at the concentration appropriate for swine vesicular disease. The disinfectant used should remain on the surface for at least 24 hours.

(b) Any tissue or blood which may have been spilled during slaughter should be carefully collected and disposed of with the carcases (slaughter should always be carried out on an impervious surface).

2. Procedure for further cleaning and disinfection -

(a) All manure, bedding, contaminated food, etc., should be removed from the buildings, stacked and sprayed with an approved disinfectant. Slurry should be treated by a method suitable for killing the virus.

(b) All portable fittings should be removed from the premises and cleansed and disinfected separately.

(c) Grease and other dirt should be removed from all surfaces by soaking with a degreasing agent and then washing with water under pressure.

(d) A further application of disinfectant should then be made by spraying all surfaces.

(e) Sealable rooms should be fumigated.

(f) Repairs to damaged floors, walls etc. should be agreed following inspection by an official veterinarian, and carried out immediately.

(g) Completed repairs should be inspected to ensure that they have been done satisfactorily.

(h) All parts of the premises which are completely free of combustible material may be heat-treated using a flame gun.

(i) All surfaces should be sprayed with an alkaline disinfectant having a pH greater than 12,5 or any other approved disinfectant. The disinfectant should be washed off after 48 hours.

3. Procedure for final cleaning and disinfection -

Treatment with flame gun or alkaline disinfectant (point 2 (h) or (i)) should be repeated after 14 days.

11. **Restocking of infected holdings**

In addition to the measures laid down in rule 5(4), the following measures shall apply:

1. Restocking should not commence until four weeks after completion of the first full disinfection of the premises, i.e. step 3 of the cleaning and disinfection procedures.

2. The re-introduction of pigs shall take account of the type of farming practised on the holding and must conform to one of the following procedures:

(a) in the case of outdoor pig holdings, restocking shall start with the introduction of a limited number of sentinel piglets which have been checked and found negative for the presence of antibodies against swine vesicular disease virus. The sentinel piglets shall be placed, in accordance with the requirements of the competent authority, throughout the infected holding and will be examined clinically 28 days after having been placed on the holding, and sampled for serological testing.

If none of the piglets shows clinical evidence of swine vesicular disease nor has developed antibodies against the virus of the disease, full restocking may take place;

(b) for all other forms of rearing, the re-introduction of pigs shall take place either in accordance with the measures provided for in paragraph (a) or by full restocking, provided that:

(i) all the pigs arrive within a period of eight days and come from holdings situated outside areas restricted as a result of swine vesicular disease, and are seronegative,

(ii) no pig may leave the holding for a period of 60 days after the arrival of the last pigs,

(iii) the repopulated herd is subjected to a clinical and serological examination in accordance with the requirements of the competent authority. That examination may be carried out at the earliest 28 days after the arrival of the last pigs.

SCHEDULE III

MINIMUM CRITERIA FOR THE CONTINGENCY PLANS

Contingency plans shall meet at least the following criteria:

1. the establishment of a crisis centre on a national level, which shall coordinate all control measures in the territory of Malta;

2. a list shall be provided of local disease control centres with adequate facilities to coordinate the disease control measures at a local level;

3. detailed information shall be given on the staff involved in control measures, their skills and their responsibilities;

4. each local disease control centre must be able to contact rapidly persons/organizations which are directly or indirectly involved in an outbreak;

5. equipment and materials shall be available to carry out the disease control measures properly;

6. detailed instructions shall be provided on action to be taken on suspicion and confirmation of infection or contamination, including means of disposal of carcases;

7. training programmes shall be established to maintain and develop skills in field and administrative procedures;

8. diagnostic laboratories must have facilities for *post mortem* examination, the necessary capacity for serology, histology, etc., and must maintain the skills for rapid diagnosis. Arrangements must be made for rapid transportation of samples;

9. details shall be provided of the quantity of vaccine against the disease in question estimated to be required in the event of recourse to emergency vaccination;

10. provisions shall be made to ensure the legal powers necessary for the implementation of the contingency plans.

Nru. 1211

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu 5(1) ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jikkontrollawx biżżejjed ċertu mard fil-ħut, jew jekk ikunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Miżuri għall-Kontroll ta' Ċertu Mard fil-Hut.

Id-19 ta' Novembru, 2004

No. 1211

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 5(1) of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules do not sufficiently control certain fish diseases, or how they are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Measures for the Control of Certain Fish Diseases Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Measures for the Control of Certain Fish Diseases Rules, 2004

IN exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title, scope and applicability.

1. (1) The title of these rules is Measures for the Control of Certain Fish Diseases Rules, 2004.

(2) The scope of these rules is to implement the rules contained in the European Union Council Directive 93/53/EEC introducing minimum Community measures for the control of certain fish diseases.

(3) These rules define the minimum measures to be carried out in the territory of Malta for the control of the fish diseases referred to in Schedule A, lists I and II, to European Union Council Directive 91/67/EEC.

Definitions

2. (1) For the purpose of these rules –

"farm suspected of being infected" means farm containing fish suspected of being infected;

"fish suspected of being infected" means fish showing clinical signs or post-mortem lesions or dubious reactions in laboratory tests giving rise to reasonable suspicion of the presence of a list I or list II disease;

"infected farm" means farm containing infected fish; also farm which has been evacuated but not yet disinfected.

"infected fish" means fish in which the presence of a list I or list II disease has been officially confirmed as the result of a laboratory examination or, in the case of ISA, as the result of a clinical examination and a post-mortem examination;

"list I diseases" means fish diseases referred to in Schedule A, list I, to European Union Council Directive 91/67/EEC;

"list II diseases" means fish diseases referred to in Schedule A, list II, to European Union Council Directive 91/67/EEC;

"Member State" means a State which is a Member within the European Community;

"the Community" means the European Community as established under the Treaty establishing the European Community;

"the official service" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"third country" means a state which is not a Member within the European Community.

(2) The definitions laid down in Article 2 of European Union Council Directive 91/67/EEC shall apply as necessary.

CHAPTER I

General Provisions

Fish susceptible to list I or list II diseases

3. (1) All farms rearing or keeping fish susceptible to list I or list II diseases shall-

(a) be registered by the official service; this registration must be kept constantly up to date;

(b) keep a record of:

(a) live fish, eggs and gametes entering the farm, containing all information relating to their delivery, their number or weight, their size, their source and their suppliers;

(b) live fish, eggs and gametes leaving the farm, containing all information relating to their dispatch, their number or weight, their size and destination;

(c) observed mortality:

Provided that this record, which shall be open to scrutiny by the official service whenever the latter so requests, must be regularly updated and shall be kept for four years.

Notification in case of suspected presence of disease

4. It is compulsory for the suspected presence of any of the list I and list II diseases to be notified as soon as possible to the official service.

CHAPTER II

Control Measures for List I Diseases

Measures to be taken in case of suspected presence of list I disease

5. (1) When fish on a farm are suspected of being infected with a list I disease, the official service shall immediately activate official investigation arrangements to confirm or rule out the presence of the disease, including clinical examination; in particular, it must take, or have taken, the samples necessary for laboratory examination.

(2) As soon as the suspected presence of the disease is notified, the official service shall have the farm placed under official surveillance and shall in particular require that:

(a) an official census be made of all species and categories of fish and that, in respect of each of these, the number of fish already dead, infected or suspected of being infected or contaminated be recorded; the census must be kept up to date by the owner or keeper to take account of the increase in the population or new mortality observed during the period of suspected infection; the information in the census must be produced on request and may be checked at each inspection;

(b) no fish, whether alive or dead, or eggs or gametes enter or leave the farm without the authorization of the official service;

(c) the disposal of dead fish or their offal be carried out under the supervision of the official service;

(d) the entry or exit of feedingstuffs, utensils, objects or other substances such as waste, liable to transmit disease be subject, if necessary, to authorization by the official service, which shall lay down the conditions required to prevent the spread of the pathogen;

(e) the movement of persons to or from the farm be made subject to authorization by the official service;

(f) the entry or exit of vehicles to or from the farm be made subject to authorization by the official service, which shall lay down the conditions required to prevent the spread of the pathogen;

(g) appropriate means of disinfection be used at the entrances end exits of the farm;

(h) an epizootic investigation be carried out in accordance with rule 8 (1);

(i) all of the farms situated in the same water catchment area or coastal area be placed under official surveillance, and no fish, eggs or gametes leave these farms without the authorization of the official service:

Provided that in the case of extensive water catchment areas or coastal areas, the official service may decide to limit this measure to a less extensive area close to the farm suspected of being infected, if it considers that this area affords maximum guarantees for the prevention of the spread of the disease:

Provided further that, if the necessity arises, the official services of neighbouring Member States or third countries must be informed of the suspected case; in that event, the official services of the Member States involved shall take appropriate action to apply the measures laid down in this rule. Where necessary, specific measures may be taken in accordance with the relevant procedure of the European Community.

(3) Until such time as the official measures laid down in sub-rule (2) are enforced, the owner or keeper of any fish in which disease is suspected shall take every appropriate measure to ensure compliance with sub-rule (2), except for (h) and (i) thereof.

(4) The measures referred to in sub-rule (2) shall not be withdrawn until the suspicion of disease has been officially ruled out.

Measures to be taken when presence of list I disease is confirmed

6. As soon as the presence of a list I disease has been officially confirmed, the official service shall order that, in addition to the measures listed in rule 5 (2), of the following measures be applied:

(a) in an infected farm:

(i) all fish shall be withdrawn in accordance with a scheme established by the official service and approved by the Commission in accordance with the relevant procedure of the European Community;

(ii) in the case of inland farms all pools must be drained for the purposes of cleaning and disinfection;
(iii) all eggs and gametes, dead fish and fish showing clinical signs of disease shall be regarded as high-risk material and must be destroyed under the supervision of the official service, in accordance with European Union Council Directive 90/667/EEC,

(iv) all live fish shall either be killed and destroyed under the supervision of the official service in accordance with European Union Council Directive 90/667/EEC, or else, in the case of fish which have reached commercial size and show no clinical sign of disease, be slaughtered under the supervision of the official service for marketing or processing for human consumption:

Provided that in the latter case, the official service shall ensure that the fish are immediately slaughtered and gutted, that these operations are carried out in conditions such as to prevent the spread of pathogens, that the fish waste and offal are regarded as highrisk material and are submitted to a treatment to destroy pathogens in accordance with European Union Council Directive 90/667/EEC and that the used water is submitted to a treatment which inactivates any pathogens it may contain;

(v) after removal of the fish, eggs and gametes, ponds, equipment and any material liable to be contaminated must be cleaned and disinfected as soon as possible following the instructions established by the official service in such a way as to eliminate any risk of the agent of the disease spreading or surviving. The procedures for cleaning and disinfecting an infected farm shall be determined in accordance with the relevant procedure of the European Community;

(vi) any substances which might be contaminated, referred to in rule 5 (2) (d), must be destroyed or treated in such a way as to ensure the destruction of any pathogen present;

(vii) an epizootic investigation must be carried out in accordance with rule 8 (1) and the provisions of rule 8 (4) must be applied; this investigation must include the taking of samples for laboratory examination;

(b) all farms situated in the water catchment area or in the coastal zone in which the infected farm is situated shall undergo health inspections. If these inspections reveal positive cases, the measures provided for under paragraph (a) of this rule shall be applied;

(c) the repopulation of the farm shall be authorized by the official service following satisfactory inspection of the cleaning and disinfection operations and at the end of a period deemed adequate by the official service to ensure eradication of the pathogen, and of other possible infections in the same water catchment area;

(d) if application of the measures laid down under paragraphs (a), (b), (c) and (d) of rule 5 (2) requires the cooperation of the official services of other Member States, the official services of the Member States concerned shall collaborate to ensure compliance with the measures laid down in this rule.

Where necessary, appropriate additional measures shall be adopted in accordance with the relevant procedure of the European Community.

Fish from the wild or fish in lakes, ponds and other installations

7. (1) Where fish from the wild and not belonging to any farm or fish in lakes, ponds or other installations intended for angling or holding ornamental fish are infected or suspected of being infected, appropriate measures shall be taken by the official service.

(2) The official service shall inform the Commission and the other Member States of the measures they have taken.

Epizootic investigation

8. (1) The epizootic investigation shall deal with:

(a) the likely length of time during which the disease may have existed on the farm before being notified or suspected;

(b) the possible origin of the disease on the farm and the identification of other farms on which there are eggs and gametes and fish of susceptible species which may have become infected;

(c) the movement of fish, eggs or gametes, vehicles or substances and persons likely to have carried the agent of the disease to or from the farms in question;

(d) the possible existence of carriers of the disease, and their distribution.

(2) If the epizootic investigation reveals that the disease could have been introduced from another water catchment area or another coastal area, or could have been transferred to another water catchment area or another coastal area as a result of a contact arising from the movement of fish, eggs or gametes, animals, vehicles or persons, or in any other way, the farms belonging to such water catchment areas and coastal areas shall be considered suspect and the measures laid down in rule 5 shall apply. If the presence of the disease is confirmed, the measures laid down in rule 6 shall apply.

(3) If the epizootic investigation reveals that the cooperation of the official services of other Member States is required, the official service of Malta shall take all necessary measures to ensure compliance with the provisions of these rules.

(4) A crisis unit shall be established by the official service in order to provide full coordination of all measures necessary to ensure eradication of the disease as quickly as possible and for the purpose of carrying out the epizootic investigation:

Provided that the general rules concerning national crisis unit in the territory of Malta in accordance with the requirements of the European Community.

CHAPTER III

Control Measures for List II Diseases

Epizootic investigation

9. (1) Where a list II disease is suspected and/or confirmed in an approved zone or on an approved farm situated in a non-approved zone, an epizootic investigation shall be carried out in accordance with rule 8. In the case where Malta wishes to regain its status defined in accordance with European Union Council Directive 91/67/EEC must comply with the provisions of Schedules B and C to that Directive.

(2) If the epizootic investigation reveals that the disease could have been introduced from an approved zone or from another approved farm, or could have been transferred to another approved farm as a result of the movement of fish, eggs or

gametes, vehicles or persons, or in any other way, those zones or farms shall be considered suspect and the appropriate measures shall apply.

(3) The official service may, however, authorize the fattening of fish to be slaughtered until they reach commercial size.

Non-approved farm in a non-approved zone

10. (1) Where a non-approved farm situated in a non-approved zone contains fish suspected of being infected with a list II disease, the official service shall:

(a) immediately sets in motion official means of investigation to confirm or rule out the presence of the disease including, where necessary, the taking of samples for examination in an approved laboratory;

(b) carries out or causes to be carried out an official census of the infected farms, this census being regularly updated;

(c) places, or causes to be placed, the infected farms under official supervision, in order to ensure that, by way of derogation from Article 3 (1) (c) of European Union Council Directive 91/67/EEC, the only movements authorized from infected farms are live fish or eggs or gametes intended either for other farms infected by the same disease or for slaughter for human consumption.

(2) For a fixed period, an optional or compulsory programme for the eradication of list II diseases in non-approved farms or in nonapproved zones may be set up in the territory of Malta, under the supervision of the official service and subject to the following provisions:

(a) during this period, the introduction into a zone or farm subject to such a programme of live fish, eggs or gametes from infected farms or farms of unknown health status shall be forbidden;

(b) these programmes, which will be set up on the basis of general criteria determined by the European Community, and will be submitted to the Commission for scrutiny, and approved and where necessary amended in accordance with the relevant procedure of the European Community.

CHAPTER IV

Final Provisions

Sampling and laboratory testing

11. (1) Sampling and laboratory testing for the presence of list I and list II diseases shall be carried out using the methods established in accordance with Article 15 of European Union Council Directive 91/67/EEC.

(2) Testing for the presence of disease or pathogens shall be carried out by a laboratory approved by the official service. Laboratory testing shall, if necessary and especially on the first appearance of the disease, identify the type, sub-type or the variant of the relevant pathogen, which must be confirmed by the national reference laboratory and may be confirmed, if necessary, by the Community reference laboratory on fish diseases.

National reference laboratory

12. (1) A national reference laboratory shall be designated in the territory of Malta, with facilities and expert personnel enabling it to show at all times, and especially when the disease in question first appears, the type, sub-type and variant of the relevant pathogen and to confirm results obtained by diagnostic laboratories.

(2) The national laboratory designated for the diseases in question shall be responsible for coordinating diagnostic standards and methods, and for the use of reagents.

(3) The national laboratory designated for the diseases in question shall be responsible for coordinating the diagnostic standards and methods in Malta. To this end, they:

(a) may provide diagnostic reagents to laboratories approved by the official service;

(b) shall control the quality of all diagnostic reagents used in the territory of Malta;

(c) shall periodically arrange comparative tests;

(d) shall hold isolates of the pathogen of the disease from cases confirmed in the territory of Malta;

(e) shall ensure confirmation of positive results obtained in diagnostic laboratories approved by the official service.

(4) By way of derogation from sub-rule (1), if a national laboratory is not designated in the territory of Malta, competent as regards the disease in question, the official service may use the services of a national laboratory with competence in the matter in another Member State.

(5) The list of national reference laboratories for fish diseases is set out in Schedule A.

Vaccination

13. (1) Vaccination against list II diseases in approved zones, in approved farms situated in non-approved zones or in zones or farms which have already begun the approval procedures laid down by European Union Council Directive 91/67/EEC and against list I diseases shall be forbidden.

(2) By way of derogation, vaccination may be authorised in the case of an outbreak of list I diseases provided the procedures for vaccination are specified in the approved contingency plans in accordance with rule 15 and account is taken of the criteria set out in Schedule D.

Contingency plan

14. (1) The official service shall draw up a contingency plan specifying how it will implement the measures laid down in these rules in the event of an outbreak of a list I disease. This plan must allow access to facilities, equipment, personnel and all other appropriate structures necessary for the rapid and efficient eradication of the outbreak.

(2) The general criteria to be applied for drawing up those plans are set out in Schedule C:

Provided that the official service may confine itself to the application of the criteria specific to the diseases concerned, where the general criteria have already been adopted in the context of the submission of plans relating to the application of measures for the control of another disease. Those criteria may be amended or supplemented, taking into account the specific nature of the disease and in accordance with the requirements of the European Community.

(3) Plans drawn up in accordance with the criteria set out in Schedule C shall be submitted to the Commission.

(4) The plans shall be examined by the Commission in order to determine whether they permit the desired objective to be attained and shall suggest to the official service any amendments required, in particular to ensure that they are compatible with the plans of the other Member States.

(5) The plans shall be approved by the Commission, amended if necessary, in accordance with the relevant procedure of the European Community:

Provided that the plans may subsequently be amended or supplemented, in accordance with the same procedure, to take into account developments in the situation.

On-the-spot checks by Commission experts

15. Commission experts may, in collaboration with the official service, and in so far as is necessary to ensure uniform application of these rules, make on-the-spot checks in the territory of Malta, as follows:

(a) they may check a representative percentage of holdings to see whether the official service is checking that these holdings are fulfilling the requirements of these rules;

(b) the official service shall be informed by the Commission of the result of the checks carried out;

(c) when a check is being carried out, the official service shall give all the necessary assistance to the experts in carrying out their duties.

SCHEDULE A

NATIONAL REFERENCE LABORATORIES FOR FISH DISEASES

Belgium: CODA — Centrum voor Onderzoek in Diergeneeskunde en Agrochemie
CERVA — Centre d'étude et de recherches veterinaries et agrochimiques
Groeselenberg 99 B-1180 Brussel/Bruxelles.

Czech Republic: Výzkumný ústav veterinárního lékaøství Hudcova 70 621 32 Brno-Medlánky.

Denmark: Statens Veterinære Serumlaboratorium Fødevareministeriet Hangøvej 2 DK-8200 Århus N.

Germany: Bundesforschungsanstalt für Viruskrankheiten der Tiere Boddenblick 5a D-17498 Insel Riems.

Estonia: Veterinaar- ja Toidulaboratoorium Väike-Paala 3 11415 Tallinn.

Greece: Laboratory of Fish Pathology and Bio-Pathology of Aquatic Organisms Centre of Athens Veterinary Institutes, Institute of Infectious and Parasitic Diseases 25 Neapoleos ST. GR-153 10 Ag. Paraskevi Attiki.

Spain: Laboratorio Central de Veterinaria de Algete Madrid.

France: Agence française de sécurité sanitaire des aliments (AFSSA) Laboratoire d'études et de recherches en pathologie des poissons (LERPP) Technopôle Brest Iroise — BP 70 F-29280 Plouzane.

Ireland: Fisheries Research Centre Abbotstown Castleknock Dublin15 Ireland.

Italy: Istituto zooprofilattico sperimentale delle Venezie Via Romea 14/A I-35020 Legnaro, Padova.

Cyprus: *Εργαστήριο Αναφοράς για τις Ασθένειες των Ζώων*, *Κτηνιατρικές Υπηρεσίες*, 1417 *Λευκωσία*
National Reference Laboratory for Animal Health Veterinary Services CY-1417 Nicosia.

Latvia: Valsts veterinarmedicinas diagnostikas centrs Lejupes iela 3 LV-1076 Riga.

Lithuania: Nacionaline veterinarijos laboratorija J.Kairiukšèio g. 10 LT-2021 Vilnius.

Luxembourg: CODA — Centrum voor Onderzoek in Diergeneeskunde en Agrochemie
CERVA — Centre d'étude et de recherches veterinaries et agrochimiques
Groeselenberg 99 B-1180 Brussel/Bruxelles.

Hungary: Országos Állategészségügyi Intézet (OÁI), Pf. 2. Tábornok u. 2. HU-1581 Budapest.

Malta: Istituto Zooprofilattico Sperimentale delle Venezie Legnaro (PD) Italy.

Netherlands: Fish Diseases Laboratory ID-Lelystad Institute for Animal Science and Health Edelhertweg 15PO Box 65 8200 AB Lelystad Nederland.

Austria: Institut für Hydrobiologie, Fisch- und Bienenkunde Veterinärmedizinische Universität Wien Veterinärplatz 1 A-1210 Wien.

Poland: Laboratorium Zak³adu Chorób Ryb Pañstwowego Instytutu Weterynaryjnego Al. Partyzantów 57 PL-24-100 Pu³awy.

Portugal: Laboratório Nacional de Investigação Veterinária Estrada de Benfica 701 P-1500 Lisboa.

Slovenia: Nacionalni veterinarski inštitut, Gerbièeva 60 SI-1000 Ljubljana.
Slovakia: Štátny veterinárny a potravinový ústav Janoškova 1611/58 026 80 SK-Dolný Kubín.

Finland: Eläinlääkintä- ja elintarvikelaitos (EELA)PL 368 FIN-00231 Helsinki.

Sweden: Statens Veterinärmedicinska Anstalt (SVA) S-751 89 Uppsala.

United Kingdom: CEFAS Weymouth Laboratory Barrack Road Weymouth DT4 8UB United Kingdom. The Marine LaboratoryPO box 101 Victoria Road Aberdeen AB9 8DB United Kingdom.

SCHEDULE B

COMMUNITY REFERENCE LABORATORY FOR FISH DISEASES

Statens Veterinære Serumlaboratorium
Landbrugsministeriet
Hangøvej 2
8200 Aarhus N
Denmark.

SCHEDULE C

MINIMUM CRITERIA FOR CONTINGENCY PLANS

Contingency plans shall meet at least the following criteria:

1. the establishment of a national crisis centre which shall coordinate all control measures in the Member State concerned;

2. a list shall be provided of local disease control centres with adequate facilities to coordinate the disease control measures at a local level;

3. detailed information shall be given on the staff involved in control measures, their skills and their responsibilities;

4. each local disease control centre must be able to contact rapidly persons/organizations which are directly or indirectly involved in an outbreak;

5. equipment and materials shall be available to carry out the disease control measures properly;

6. detailed instructions shall be provided on action to be taken on suspicion and confirmation of infection or contamination;

7. training programmes shall be established to maintain and develop skills in field and administrative procedures;

8. where appropriate, diagnostic laboratories must have facilities for postmortem examination, the necessary capacity for serology, histology, etc., and must maintain the skills for rapid diagnosis (to this end, arrangements must be made for rapid transportation of samples);

9. provisions shall be adopted to ensure the legal powers necessary for the implementation of the contingency plans.

SCHEDULE D

CRITERIA FOR VACCINATION PROGRAMMES

Vaccination programmes must contain at least the following information:

1. The nature of the disease calling for a request to be made to vaccinate.

2. Information shall be supplied on the coastal and mainland areas, the sites and farms in which vaccination may be carried out: under no circumstances may vaccination be conducted beyond the limits of the infected area and, if necessary, the buffer zone established around the infected area.

3. Detailed information on the vaccine to be used, including the type(s) of vaccine which may be used.

4. Detailed information on the conditions for use, frequency of vaccination and the limits on use of the vaccine (which fish, which cages, etc.).

5. The criteria for ceasing vaccination.

6. Provisions shall be adopted to ensure that a log is kept of past vaccinations (dates, sites and farms in which vaccination has been conducted, the establishment of a buffer zone, etc.).

7. Measures shall be taken for fish movements to be limited within the vaccination area so as to guarantee that fish can leave the vaccination area only if they are to be killed for human consumption, or if necessary to be destroyed.

8. Any other necessary provisions required for vaccination.

Nru. 1212

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikoli 10 u 11 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Problemi tas-Saħħa ta' l-Annimali li jolqtu l-Kummerċ Intra-Komunitarju fil-Prodotti tal-Laħam.

Id-19 ta' Novembru, 2004

No. 1212

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with articles 10 and 11 of the Veterinary Services Act to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Animal Health Problems affecting Intra-Community Trade in Meat Products Rules, 2004

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Animal Health Problems affecting Intra-Community Trade in Meat Products Rules, 2004

IN exercise of the powers conferred by articles 10 and 11 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has, after consultation with the Minister of Health, the Elderly and Community Care, made the following rules:-

Title and scope

1. (1) The title to these rules is the Animal Health Problems affecting Intra-Community Trade in Meat Products Rules, 2004.

(2) The scope of these rules is to implement the provisions found under European Union Council Directive 80/215/EEC regarding animal health requirements for intra-Community trade in meat products in meat products in accordance with articles 10 and 11 of the Veterinary Services Act.

Definitions

2. (1) For the purposes of these rules:

(a) "meat products" means the products prepared from or with meat which has undergone treatment such that the cut surface shows that the product no longer has the characteristics of fresh meat.

(b) "rendered animal fat" means the fat derived from rendering meat, including bones, and intended for human consumption;

(c) "greaves" means the protein-containing residue of rendering, after partial separation of fat and water;

(d) "heating" means the use of dry or damp heat;
(e) "drying" means the natural or artificial reduction of the water content;
(f) "treatment" means the chemical or physical process such as heating, smoking, salting, marinating, curing or drying, intended to lengthen the preservation of meat or animal products whether or not associated with other foodstuffs, or a combination of these various processes;
(g) "hermetically sealed container" means the container intended to protect the contents against the entry of microorganisms during and after treatment and which is impermeable to air.
(h) "maturation" means the treatment of salted raw meat, applied under climatic conditions which, in the course of a slow and gradual reduction of humidity, are capable of generating natural fermentation or enzymatic processes, involving changes over a period of time which give the product typical organoleptic characteristics and ensure its preservation and wholesomeness at normal ambient temperature.

(2) Products which have been subjected to natural fermentation and maturation for a long period shall be regarded as having undergone complete treatment until the Council, acting unanimously on a proposal by the Commission, amends the limits given in Annex A, Chapter V (27) (b) to Directive 77/99/EEC.

Definition of fresh meat

3. The territory of Malta shall ensure that meat products intended for intra-Community trade are prepared from or with:
   (a) fresh meat as defined in Article 2 of Council Directive 64/433/EEC of the 26th June, 1964 on health problems affecting intra-Community trade in fresh meat, as last amended by Directive 75/379/EEC, and fulfilling the animal health requirements of Articles 3 and 4 of Directive 72/461/EEC,
   (b) fresh meat as defined in Article 2 of Council Directive 72/462/EEC of the 12th December, 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries, as last amended by Directive 77/98/EEC, and complying with the animal health requirements of Directive 72/462/EEC.

Forms of treatment required for meat products

4. (1) By way of derogation from paragraph (a) hereof, and subject to the application of sub-rule (2) hereof, meat products may be intended for intra-Community trade, which are prepared in whole or in part from or with fresh meat as defined in Article 2 of Directive 64/433/EEC which fulfils the requirements laid down by Article 5a of Directive 72/461/EEC, may enter intra-Community trade if they have also undergone one of the following forms of treatment:
   (a) heat treatment carried out:
      (i) either in a hermetically sealed container, with an Fc value of 3,00 or more;
      (ii) or under the following conditions - in so far as the products concerned are prepared exclusively from or with pig meat from

farms or, in the case of the Member States referred to in Article 7a (1), from areas not subject to banning orders on health policy grounds, following the establishment of the existence of African swine fever:

— the meat must be fully boned and the main lymphatic glands removed,

— before heating, each piece of meat as referred to above must be enclosed in a hermetically sealed container to be marketed therein,

— the meat in its container must undergo heat treatment in strict conformity with the following conditions:

— the product must be kept at a temperature of at least 60 ºC for a minimum of four hours during which the centre temperature must be at least 70 ºC . for a minimum of 30 minutes,

— the temperature of a representative number of samples of each batch of products must be monitored constantly. Monitoring must be carried out using automatic apparatus enabling the temperature to be recorded both in the centre of the pieces of greater weight and inside the heating equipment,

— throughout these operations, the conditions laid down in the third subparagraph of Article 5a of Directive 72/461/EEC, as amended by Directive 80/213/EEC (1), must be fulfilled,

— after the treatment, a public health mark must be put on each of the containers referred to in the third and fourth indents, in accordance with points 31, 32 and 33 of Chapter VII of Annex A to Directive 77/99/EEC,

— the territory of Malta shall make use of the treatment provided for under this point shall communicate to the Commission and the other Member States the list of establishments which possess the equipment required to ensure that the temperatures prescribed above are complied with. In the case of the Member States referred to in Article 7a (2), the treatment may be used for meat from areas subject to a banning order following the discovery of African swine fever only after a decision has been taken in accordance with Article 7b (2);

(b) where the fresh meat has been obtained from animals which do not come from an infected holding subject to prohibition measures pursuant to Article 3 (2) (b) of Directive 64/432/EEC:

(i) heat treatment of a type different from those referred to in sub-rule (1) (a) of this rule, in which the centre temperature is raised to at least 70ºc, or

(ii) provided that, in addition, the disease in question is not swine vesicular disease, treatment consisting in natural fermentation and maturation of not less than nine months for boned or boneless hams weighing not less than 5·5 kg and having the following characteristics:

— aw value of not more than 0·93,

— pH value of not more than 6.

However, if the disease in question is foot-and-mouth disease, this treatment may be applied to bone-in ham which fulfils the other conditions provided for in the first sub-paragraph.

The products mentioned in this rule may be prepared only under official veterinary supervision and must be protected from any contamination or recontamination.

(2) The territory of Malta shall ensure that:

(a) the fresh meat referred to in sub-rule (1) is:

(i) transported and stored separately from, or not at the same time as, the fresh meat referred to in rule 3,

(ii) used in such a way as to avoid it being introduced into meat products intended for intra-Community trade other than those indicated in sub-rule (1),

(iii) where, as a result of the discovery or the continued existence of African' swine fever, the territory of Malta decides to make use of the treatment described in sub-rule (1) (a) (ii) hereof, it must ensure that fresh pig meat is marked with the stamp provided for in Article 5a of Directive 72/461/EEC;

(b) the health certificate specified in Annex A, Chapter VIII, to Directive 77/99/EEC contains, without prejudice to footnote 3 of that certificate, the following words under the entry 'Nature of products': 'Treated in accordance with Article 4 (1) (a) of Directive 80/215/EEC' or 'Treated in accordance with Article 4 (1) (b) of Directive 80/215/EEC'.

Giving of health mark

5. The territory of Malta shall ensure that meat products which do not fulfil the requirements of rules 3 and 4 are not given the health mark provided for in Directive 77/99/EEC, Annex A, Chapter VII.

African Swine Fever

6 (1) In the event that African swine fever has been recorded within the previous 12 months, the territory of Malta shall not export to the territory of other Member States pig meat products other than those having undergone the treatment referred to in rule 4 (1) (a) hereof.

It may be decided, in accordance with the procedure laid down in rule 8 hereof, that the provisions of the first subparagraph shall not apply to one or more parts of the territory of Malta:

Provided that this derogation shall not preclude recourse to Article 9 of Directive 89/662/EEC should one or more cases of African swine fever re-occur in the above part or parts of territory.

(2) (a) Where there is an outbreak of African swine fever in the territory of Malta and the disease has not been recorded for at least 12 months, it may be decided, in accordance with the procedure laid down in rule 8, that the provisions of sub-rule (1) shall apply exclusively to a part of Malta. Pending this decision, and without prejudice to Article 9 of Directive 89/662/EEC, the territory of Malta shall ensure the immediate prohibition of export to the other Member States of pig meat products from the part of territory in which the epizootic disease has been recorded. The criteria laid down in rule 7 (2) shall be taken into account in determining that part of the territory.

(b) One or more cases of African swine fever on a part of the Territory of Malta which is not geographically linked to the main part of the Territory of Malta shall not prevent the application of paragraph (a).

(c) The conditions prerequisite to the application of paragraph (a) shall still be deemed to be fulfilled if the following conditions have been fulfilled:

(i) outbreak recorded on the occurrence of African swine any fever referred to in paragraph (a) was eradicated in the shortest possible period of time;

(ii) the new outbreak, which forms the subject of a fresh request for a decision, as provided for in paragraph (a), is not connected epidemiologically with any outbreak referred to in sub-paragraph (i) hereof.

(3) Decisions to lift measures applied under sub-rule (2) shall be taken in accordance with the procedure laid down in rule 8.

Defining parts of Territory

7 (1) For the purposes of defining the parts of territory referred to in sub-rule 6 (1), particular account shall be taken of:

— the methods used to control and eradicate African swine fever,

— the absence of the disease for at least 12 months, recorded by all the methods of detection, including serological surveys,

— the surface area of the parts of territory and their administrative and geographical boundaries,

— the protective measures taken to prevent the contamination or recontamination of pig herds,

— the measures taken to control the movement of pigs.

(2) For the purposes of defining the parts of territory referred to in sub-rule 6(2), particular account shall be taken of:

— the methods used to combat the disease, in particular the elimination of pigs from holdings which are infected, contaminated or suspected of contamination,

— the surface area of the parts of territory and their administrative and geographical boundaries,

— the incidence of the disease and its tendency to spread,

— the measures taken to prevent the disease from spreading,

— the measures taken to restrict and control the movement of pigs both inside and outside the part of territory concerned;

and, in the case of non-application of prohibition measures to certain products:

— the treatment to which the products have been subjected,

— the manufacturing dates, and

— the measures taken to determine and guarantee the date of manufacture.

The Standing Committee

8 (1) The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health set up by Article 58 of Regulation (EC) No 178/2002(1).

(2) Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC (2) shall apply.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at fifteen days.

(3) The committee shall adopt its rules of procedure.

Import of meat products

9. (1) Acting on a proposal from the Commission, the Council shall lay down the animal health requirements applicable to intra-Community trade in fresh poultry meat and to imports of such poultry meat from third countries.
(2) Pending the entry into force of the Community provisions referred to in sub-rule (1) hereof, national animal health provisions concerning the import of meat products prepared in part or in whole from or with fresh poultry meat shall remain applicable while complying with the general provisions of the Treaty.

Implementation of Community animal health Directives

10. Until the implementation of Community animal health Directives concerning imports of meat products from third countries, other than those referred to in rule 9 hereof, national provisions applicable to the import of these products shall not be more favourable than those which result from these rules.

Veterinary checks

11. The rules laid down in Directive 89/662/EEC (1) concerning veterinary checks applicable in intra-Community trade, with a view to the completion of the internal market, shall apply in particular to checks at origin, to the organization of and follow-up to the checks to be carried out by the territory of Malta and to the protective measures to be implemented.

Nru. 1213

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikoli 22(ċ) u 25 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Metodi ta' Analiżi għall-Kontroll Uffiċjali ta' l-Oġġetti ta' l-Ikel.

Id-19 ta' Novembru, 2004

No. 1213

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority is hereby publishing the following draft rules in accordance with articles 22(c) and 25 of the Veterinary Services Act, to allow any person a period of four weeks to make representation to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed regulations are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Methods of Analysis for the Official Control of Feeding-Stuffs Rules, 2004.

19th November, 2004

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Definitions

1. For the purpose of these rules-

the 'Act' means the Veterinary Services Act;

'the Community' means the European Community as established under the Treaty establishing the European Community;

'the Commission' means the European Commission;

the 'Competent Authority' means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

'Member State' means a State which is a Member within the European Community;

Official controls

2. (1) The Competent Authority shall require that analyses for official controls of feeding-stuffs within its jurisdiction as regards their levels of hydrocyanic acid, calcium, carbonates, crude ash, ash insoluble in HCl chlorine from chlorides, lactose, potassium, sodium, sugars and urea, and the estimation of the urease activity of products derived from soya be carried out using the methods set out in the Schedule to these rules.

(2) The general rules contained in Part 1 of the Schedule shall apply to the methods of analysis adopted pursuant to Council Directive 70/373/EEC.

SCHEDULE

METHODS OF ANALYSIS OF THE COMPONENTS OF FEEDING STUFFS

1. GENERAL PROVISIONS ON METHODS OF ANALYSIS FOR FEEDINGSTUFFS

A. PREPARATION OF SAMPLES FOR ANALYSIS

1. **PURPOSE**

The procedures described below concern the preparation for analysis of final samples, sent to the control laboratories after sampling in accordance with the provisions laid down by First Commission Directive 76/371/EEC of 1 March 1976 establishing Community methods of sampling for the official control of feeding stuffs.

These samples must be prepared in such a way that the amounts weighed out, as provided for in the methods of analysis, are homogeneous and representative of the final samples.

2. **PRECAUTIONS TO BE TAKEN**

All the necessary operations must be performed in such a way as to avoid as far as possible contamination of the sample and changes of its composition. Grinding, mixing and sieving should be carried out as quickly as possible with minimal exposure of the sample to the air and light. Mills and grinders likely to appreciably heat the sample should not be used. Manual grinding is recommended for feedingstuffs which are particularly sensitive to heat. Care should also be taken to ensure that the apparatus itself is not a source of contamination of trace elements.

If the preparation cannot be carried out without significant changes in the moisture content of the sample, determine the moisture content before and after preparation according to the method laid down in Part 1 of the Annex to Second Commission Directive 71/393/EEC of 18 November 1971 establishing Community methods of analysis for the official control of feedingstuffs, as amended by Commission Directive 73/47/EEC of 5 December 1972.

3. **PROCEDURE**

Mix thoroughly the final sample either mechanically or manually. Divide the sample into two equal portions (the quartering method should be used where applicable). Keep one of the portions in a suitable clean, dry container, fitted with an air-tight stopper, and prepare the other portion or a representative part of it, of at least 100 g, as indicated below.

3.1. Feeding stuffs which can be ground as such

Unless otherwise specified in the methods of analysis, sieve the whole sample through a sieve with a square mesh of 1 mm side (in accordance with recommendation ISO R565) after grinding, if necessary. Avoid any overgrinding.

Mix the sieved sample and collect it in a suitable clean, dry container fitted with an air-tight stopper. Mix again, immediately before weighing out the amount for analysis.

3.2. Feeding Stuffs which can be ground after drying

Unless otherwise specified in the methods of analysis, dry the sample to bring its moisture content down to a level of 8 to 12 %, according to the preliminary drying procedure described under point 4.3 of the method of determination of moisture mentioned in section 2 above. Then proceed as indicated in section 3.1.

3.3. Liquid or semi-liquid feeding stuffs

Collect the sample in a suitable clean, dry container, fitted with an air-tight stopper. Mix thoroughly immediately before weighing out the amount for analysis.

3.4. Other feeding stuffs

Samples which cannot be prepared according to one of the above procedures should be treated by any other procedure which ensures that the amounts weighed out for the analysis are homogeneous and representative of the final samples.

4. **Storage of samples**

Samples must be stored at a temperature that will not alter their composition. Samples intended for the analysis of vitamins or substances which are particularly sensitive to light should be stored in brown glass containers.

B. PROVISIONS RELATING TO REAGENTS AND APPARATUS USED IN METHODS OF ANALYSIS

1. Unless otherwise specified in the methods of analysis, all analytical reagents must be analytically pure (a.p.). When determining trace elements, the purity of the reagents must be checked by a blank test. Depending upon the results obtained, further purification of the reagents may be required.

2. Any operation involving preparation of solutions, dilution, rinsing or washing, mentioned in the methods of analysis without indication as to the nature of the solvent or diluent employed, implies that water must be used. As a general rule, water should be demineralized or distilled. In particular cases, which are indicated in the methods of analysis, it must be submitted to special procedures of purification.

3. In view of the equipment normally found in control laboratories, only those instruments and apparatus which are special or require specific usage are referred to in the methods of analysis. They must be clean, especially when very small amounts of substances have to be determined.

C. APPLICATION OF METHODS OF ANALYSIS AND EXPRESSION OF THE RESULTS

1. In general a single method of analysis is established for the determination of each substance in feedingstuffs. Where several methods are given, the particular method used by the control laboratory must be indicated on the analysis report.

2. The result given in the analysis report shall be the average value obtained from at least two determinations, carried out on separate portions of the sample, and of satisfactory repeatability.

   This result shall be expressed in the manner laid down in the method of analysis to an appropriate number of significant figures and shall be corrected, if necessary, to the moisture content of the final sample prior to preparation.

2. DETERMINATION OF HYDROCYANIC ACID

1. **PURPOSE AND SCOPE**

This method makes it possible to determine the level of hydrocyanic acid, free and combined in the form of glycosides, in feeding-stuffs and in particular in products derived from flax seed, manioc flour and certain species of beans.

2. **PRINCIPLE**

The sample is suspended in water. The hydrocyanic acid is released by the action of enzymes, entrained by steam distillation and collected in a specific volume of acidified silver nitrate solution. The silver cyanide is separated by filtration and the excess silver nitrate is titrated with a solution of ammonium thiocyanate.

3. **REAGENTS**

3.1. A suspension of sweet almonds: crush twenty blanched sweet almonds in 100 ml of water at 37 to 40 ºC. Check that there is no hydrocyanic acid in 10 ml of the suspension using sodium picrote paper or by carrying out a blank test as described in the last paragraph of 5.

3.2. 10% solution (w/v) of sodium acetate, neutral to phenolphthalein.
3.3. Anti-foaming emulsion (e.g. silicone).
3.4. Nitric acid, d: 1·40.
3.5. Silver nitrate solution: 0·02 N.
3.6. Ammonium thiocyanate solution: 0·02 N.
3.7. Saturated solution of ammonium ferric sulphate.
3.8. Ammonia, d: 0·958.

4. **APPARATUS**
4.1. Oven with thermostat set at 38 ºC.
4.2. Apparatus for distillation by entrainment in steam fitted with a condenser with a curved extension piece.
4.3. 1000 ml flat-bottomed flasks with ground-glass stoppers.
4.4. Oil bath.
4.5. Burette graduated in 1/20 ml.

5. **PROCEDURE**
Weigh 20 g of the sample to the nearest 5 mg, place in 1 litre flat-bottomed flask and add 50 ml of water and 10 ml of sweet almond suspension (3.1.). Stopper the flask and transfer to the oven for sixteen hours at 38 ºC. Next, cool to room temperature and add 80 ml of water, 10 ml of sodium acetate solution (3.2) and a drop of anti-foaming emulsion (3.3).

Connect the flask to the steam distillation apparatus and place in an oil bath which has first been brought to a temperature slightly above 100 ºC. Distil 200 to 300 ml of liquid by passing a powerful current of steam through the flask and gently heating the oil-bath. Collect the distillate in an Erlenmeyer flask protected from the light and containing exactly 50 ml of silver nitrate solution 0·02 N (3.5) and 1 ml of nitric acid (3.4). Make sure that the condenser's extension piece is immersed in the silver nitrate solution.

Transfer the contents of the Erlenmeyer flask to a 500 ml volumetric flask, make up to volume with water, stir and filter. Remove 250 ml of the filtrate, add approximately 1 ml solution of ammonium ferric sulphate (3.7) and back-titrate the excess silver nitrate with the solution of ammonium thiocyanate 0·02 N (3.6) taken from the burette graduated in 1/20 ml.

A blank test may, if required, be carried out by applying the same procedure to 10 ml of sweet almond suspension (3.1), omitting the sample to be analysed.

6. **CALCULATION OF RESULTS**
If the blank test indicates that silver nitrate solution 0.02 N has been consumed, subtract the value of this from the volume consumed by the distillate of the sample. 1 ml of $AgNO_3$ 0·02 N corresponds to 0·54 mg of HCN. Express the result as a percentage of the sample.

7. **OBSERVATIONS**
If the sample contains a large quantity of sulphides (e.g. beans), a black precipitate of silver sulphide is formed which is filtered together with the silver cyanide deposit. The formation of this precipitate causes a loss of silver nitrate solution 0·02 N, the volume of which must be subtracted from the volume used to calculate the HCN content. To do this, proceed as follows:

Treat the deposit left on the filter with 50 ml of ammonia (3.8) in order to dissolve the silver cyanide. Wash the residue in dilute ammonia and then determine its silver content. Convert the value obtained into ml of silver nitrate solution 0·02 N.

The sample's HCN content may also be determined by titrating the acidified ammoniacal filtrate with nitric acid.

3. **DETERMINATION OF CALCIUM**

1. **PURPOSE AND SCOPE**
The method makes it possible to determine the total calcium content of feeding-stuffs.

2. **PRINCIPLE**
The calcium is ashed, the ash treated with hydrochloric acid and the calcium precipitated as calcium oxalate. Dissolve the precipitate in sulphuric acid and titrate the oxalic acid which forms with a solution of potassium permangante.

3. **REAGENTS**
3.6. Hydrochloric acid A.R., d: 1·14
3.2. Nitric acid A.R., d: 1·40
3.3. Sulphuric acid A.R., d: 1·13
3.4. Ammonia A.R., d: 0·98
3.5. Cold saturated solution of ammonium oxalate A.R.
3.6. 30% solution (w/v) of citric acid A.R.
3.7. 5% solution (w/v) of ammonium chloride A.R.
3.8. 0·04% solution (w/v) of bromo-cresol green
3.9. Solution of potassium permanganate 0·1 N

4. **APPARATUS**
4.1. Electric muffle-furnace with air circulation and thermostat.
4.2. Platinum, silica or porcelain crucibles for ashing.
4.3. Glass filter crucibles of G4 porosity.

5. **PROCEDURE**
Weigh approximately 5 g of the sample (or more if necessary) to the nearest mg, calcine at 550 ºC and transfer the ash to a 250 ml beaker.

Add 40 ml of hydrochloric acid (3.1), 60 ml of water and a few drops of nitric acid (3.2). Bring to the boil and keep at boiling point for thirty minutes. Cool and transfer the solution to a 250 ml volumetric flask. Rinse, bring the volume up to the mark with water, homogenise and filter.

Using a pipette, remove to a 250 ml beaker an aliquot amount containing 10 to 40 mg of calcium according to the assumed calcium content. Add 1 ml of citric acid solution (3.6) and 5 ml of ammonium chloride solution (3.7).

Make the volume up to approximately 100 ml with water. Bring to the boil, add eight to ten drops of bromo-cresol green solution (3.8) and 30 ml of a warm solution of ammonium oxalate (3.5). If a precipitate forms, dissolve it by adding a few drops of hydrochloric acid (3.1).

Neutralise very slowly with ammonia (3.4), stirring continuously until a pH reading of 4.4 to 4.6 is obtained (i.e. when the indicator changes colour).

Place the beaker in a boiling water bath and keep there for thirty minutes to allow the precipitate which has formed to settle. Remove the beaker from the water bath. Leave it to stand for an hour and filter through a G_4 filter crucible.

Wash the beaker and the crucible with water until the excess ammonium oxalate is completely removed (the absence of chloride in the washing water indicates that they have been sufficiently washed).

Dissolve the precipitate on the filter in 50 ml of warm sulphuric acid (3.3). Rinse the crucible with warm water and make the filtrate up to approximately 100 ml. Bring the temperature up to 70—80 ºC and titrate drop by drop with a solution of potassium permanganate (3.9) until a pink colour is obtained which lasts for one minute.

6. **CALCULATION OF RESULTS**
1 ml of potassium permanganate 0·1 N corresponds to 2·004 mg of calcium. Express the result obtained as a percentage of the sample.

7. **OBSERVATIONS**
7.1. For very low contents of calcium proceed as follows: filter the calcium oxalate precipitate through an ash-free filter paper. After washing, dry the filter and ash at 550 ºC in a platinum crucible. Redissolve the residue in a few drops of sulphuric acid (3.3), evaporate until dry, calcine again at 550 ºC and weigh. If W is the weight of the calcium sulphate obtained, the calcium content of the aliquot amount taken as a sample = W × 0·2944.

7.2. If the sample consists solely of mineral substances, dissolve in hydrochloric acid without ashing it first. In the case of products such as calcium-aluminium phosphate which are difficult to dissolve in acid, melt as follows by an alkaline process before dissolving: mix the sample to be analysed thoroughly in a platinum crucible with a mixture five times its weight, consisting of equal amounts of potassium carbonate and sodium carbonate. Heat carefully until the mixture is completely melted. Cool, and dissolve in hydrochloric acid.

7.3. If the magnesium content of the sample is high, precipitate the calcium oxalate a second time.

4. DETERMINATION OF CARBONATES

1. **PURPOSE AND SCOPE**
This method makes it possible to determine the amount of carbonates, conventionally expressed as calcium carbonate, in most feeding-stuffs.

However in certain cases (for example, with iron carbonate) a special method must be used.

2. **PRINCIPLE**
The carbonates are decomposed in hydrochloric acid; the carbon dioxide released is collected in a graduated tube, and its volume compared with that released under the same conditions by a known quantity of calcium carbonate A.R.

3. **REAGENTS**
3.1. Hydrochloric acid, d: 1·10.
3.2. Calcium carbonate, A.R.
3.3. Sulphuric acid, approximately 0·1 N, coloured with methyl red.

4. **APPARATUS**
Scheibler-Dietrich apparatus (see diagram) or equivalent apparatus.

5. **PROCEDURE**
According to the sample's carbonate content, weigh a portion of the sample as shown below:
0·5 g for products containing from 50 to 100 % of carbonates, expressed as calcium carbonate;
1 g for products containing from 40 to 50% of carbonates, expressed as calcium carbonate;
2 to 3 g for other products.

Place the portion of the sample in the special flask (4) of the apparatus, fitted with a small tube of unbreakable material containing 10 ml of hydrochloric acid (3.1), and connect the flask to the apparatus. Turn the three-way cock (5) so that the tube (1) connects with the outside. Using the mobile tube (2), which is filled with coloured sulphuric acid (3.3) and connected to the graduated tube (1), bring the level of the liquid up to the zero mark. Turn the cock (5) in order to connect up tubes (1) and (3) and check that the level is at zero.

Run the hydrochloric acid (3.1) slowly over the portion of the sample, tilting the flask (4). Make the pressure equal by lowering the tube (2). Shake the flask (4) until the release of carbon dioxide has stopped completely.

Restore pressure by bringing the liquid back to the same level in tubes (1) and (2). After a *few minutes*, when the volume of gas has become constant, take the reading.

Carry out a control test in the same conditions on 0·5 g of calcium carbonate (3.2).

6. **CALCULATION OF RESULTS**

The content in grammes of carbonates, expressed as calcium carbonate, as a percentage of the sample, is calculated by using the formula:

$$\frac{V \times 100}{T \times 2W}$$

where:

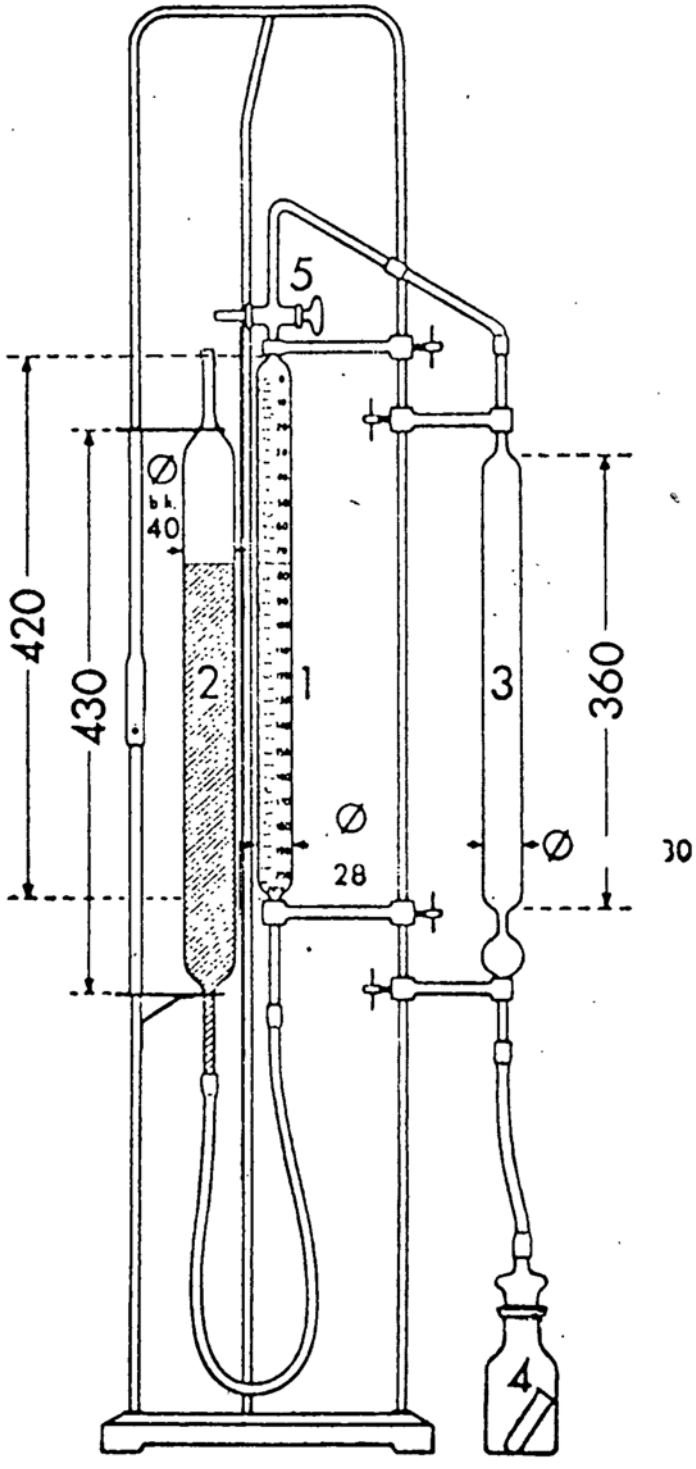
V = ml of CO_2 released by the portion of the sample.
T = ml of CO_2 released by 0·5 g of $CaCO_3$ A.R.
W = weight, in grammes, of the portion of the sample.

7. **OBSERVATIONS**

7.1. When the portion of the sample weighs more than 2 g, first place 15 ml of distilled water in the flask (4) and mix before beginning the test. Use the same volume of water for the control test.

7.2. If the apparatus used has a different volume from that of the Scheibler- Dietrich apparatus, the portions taken from the sample and from the control substance and the calculation of the results must be adapted accordingly.

SCHEIBER-DIETRICH APPARATUS FOR THE DETERMINATION OF CO_2



(measured in mm)

5. **DETERMINATION OF CRUDE ASH**

1. **PURPOSE AND SCOPE**
This method makes it possible to determine the crude ash content of feedingstuffs.

2. **PRINCIPLE**
The sample is ashed at 550 ºC; the residue is weighed.

3. **REAGENTS**
20% solution (w/v) of ammonium nitrate.

4. **APPARATUS**
4.1. Hot-plate.
4.2. Electric muffle-furnace with thermostat.
4.3. Crucibles for ashing made of platinum or an alloy of platinum and gold (10% Pt, 90 Au), either rectangular (60 × 40 × 25 mm) or circular (diameter: 60 to 75 mm, height: 20 to 25 mm).

5. **PROCEDURE**
Weigh out to the nearest mg approximately 5 g of the sample (2·5 in the case of products which have a tendency to swell) and place in a crucible for ashing which has first been calcined and tared. Place the crucible on the hot-plate and heat gradually until the substance carbonises. Put the crucible into the muffle-furnace set at 550 ºC ± 5 ºC. Keep at this temperature until white, light grey or reddish ash is obtained which appears to be free from carbonaceous particles. Place the crucible in a desiccator, leave to cool and weigh immediately.

6. **CALCULATION OF RESULTS**
Calculate the weight of the residue by deducting the tare.

Express the result as a percentage of the sample.

7. **OBSERVATIONS**
7.1. The ash of *substances which are difficult to ash* must be subjected to an initial ashing of at least three hours, cooled and then a few drops of 20% solution of ammonium nitrate added to it (carefully, to avoid dispersal of the ash or the formation of lumps). Continue calcining after drying in the oven. Repeat the operation as necessary until ashing is complete.

7.2. In the case of substances resistant to the treatment described under 7.1, proceed as follows: after ashing for three hours, place the ash in warm water and filter through a small, ash-free filter. Ash the filter and its contents in the original crucible. Place the filtrate in the cooled crucible, evaporate until dry, ash and weigh.

7.3. In the case of *oils and fats*, weigh accurately a sample of approximately 25 g in a suitably sized crucible. Carbonise by setting light to the substance with a strip of ash-free filter paper. After combustion, moisten with as little water as possible. Dry and ash as described under 5.

6. **DETERMINATION OF ASH WHICH IS INSOLUBLE IN HYDROCHOLORIC ACID**

1. **PURPOSE AND SCOPE**
This method makes it possible to determine the level in feeding-stuffs of mineral substances which are insoluble in hydrochloric acid. Two methods can be used, depending on the nature of the sample.

1.1. *Method A:* applicable to straight organic feeding-stuffs and to most compound feeding-stuffs;

1.2. *Method B:* applicable to mineral compounds and mixtures and to compound feeding-stuffs whose content in substances insoluble in hydrochloric acid, as determined by Method A, is greater than 1 %.

2. **PRINCIPLE**

2.1. *Method A:* the sample is ashed, the ash boiled in hydrochloric acid and the insoluble residue filtered and weighed.

2.2. *Method B:* the sample is treated with hydrochloric acid. The solution is filtered, the residue ashed and the ash thus obtained treated in accordance with Method A.

3. **REAGENTS**

3.1. Hydrochloric acid 3 N.

3.2. 20% solution (w/v) of trichloroacetic acid.

3.3. 1% solution (w/v) of trichloroacetic acid.

4. **APPARATUS**

4.1. Hot plate.

4.2. Electric muffle-furnace with thermostat.

4.3. Crucibles for ashing made of platinum or an alloy of platinum and gold (10% Pt, 90% Au), either rectangular (60 × 40 × 25 mm) or circular (diameter 60 to 75 mm, height: 20 to 25 mm).

5. **PROCEDURE**

5.1. *Method A*:

Ash the sample using the method described for the determination of crude ash. Ash obtained from that analysis may also be used. Place the ash in a 250 to 400 ml beaker using 75 ml of hydrochloric acid 3 N (3.1). Bring slowly to the boil and boil gently for fifteen minutes. Filter the warm solution through an ash-free filter paper and wash the residue with warm water until the acid reaction is no longer visible. Dry the filter containing the residue and ash in a tared crucible at a temperature of not less than 550 ºC and not more than 700 ºC. Cool in a desiccator and weigh.

5.2. *Method B:*

Weigh 5 g of the sample to the nearest mg and place in a 250 to 400 ml beaker. Add 25 ml of water and 25 ml of hydrochloric acid 3 N (3.1) successively, mix and wait for effervescence to cease. Add a further 50 ml of hydrochloric acid 3 N (3.1). Wait for any release of gas to cease then place the beaker in a boiling water bath and keep it there for thirty minutes or longer, if necessary, in order to hydrolyse thoroughly any starch which may be present.

Filter while warm through an ash-free filter and wash the filter in 50 ml of warm water (see observation 7). Place the filter containing the residue in a crucible for ashing, dry and ash at a temperature of not less than 550 ºC and not more than 700 ºC. Place the ash in a 250 to 400 ml beaker using 75 ml of hydrochloric acid 3 N (3.1); continue as described in the second subparagraph of 5.1.

6. **CALCULATION OF RESULTS**

Calculate the weight of the residue by deducting the tare. Express the result as a percentage of the sample.

7. **OBSERVATION**

If filtration proves difficult recommence the analysis, replacing the 50 ml of hydrochloric acid 3 N (3.1) by 50 ml of 20% trichloroacetic acid (3.2) and washing the filter in a warm solution of 1% trichloroacetic acid (3.3).

7. DETERMINATION OF CHLORINE FROM CHLORIDES

1. PURPOSE AND SCOPE

This method makes it possible to determine the amount of chlorine in chlorides which are soluble in water, conventionally expressed as sodium chloride. It is applicable to all feeding-stuffs.

2. PRINCIPLE

The chlorides are dissolved in water. If the product contains organic matter it is clarified. The solution is slightly acidified with nitric acid and the chlorides precipitated in the form of silver chloride by means of a solution of silver nitrate. The excess silver nitrate is titrated with a solution of ammonium thiocyanate, by Volhard's method.

3. REAGENTS

3.1. Solution of ammonium thiocyanate 0.1 N.
3.2. Solution of silver nitrate 0.1 N.
3.3. Saturated solution of ammonium ferric sulphate.
3.4. Nitric acid, d: 1.38.
3.5. Diethyl ether A.R.
3.6. Acetone A.R.
3.7. Carrez I solution: dissolve in water 21.9 g of zinc acetate, $Zn(CH_3COO)_2 \cdot 2H_2O$ and 3 g of glacial acetic acid. Make up to 100 ml with water.
3.8. Carrez II solution: dissolve in water 10·6 g of potassium ferrocynaide $K_4Fe(CN)_6 \cdot 3H_2O$. Make up to 100 ml with water.
3.9. Active carbon A.R., free from chlorides and not absorbing them.

4. APPARATUS

Mixer (tumbler): approximately 35 to 40 rpm.

5. PROCEDURE

5.1. *Preparation of the solution*

According to the nature of the sample, prepare a solution as shown under 5.1.1, 5.1.2 or 5.1.3.

At the same time carry out a *blank test* omitting the sample to be analysed.

5.1.1. *Samples free from organic matter*

Weigh to the nearest mg a sample of not more than 10 g and containing not more than 3 g of chlorine in the form of chlorides. Place with 400 ml of water in a 500 ml volumetric flask at approximately 20 ºC. Mix for thirty minutes in the tumbler, bring up to volume, homogenise and filter.

5.1.2. *Samples containing organic matter, excluding the products listed under 5.1.3.*

Weigh approximately 5 g of the sample to the nearest mg and place with1 g of active carbon in a 500 ml volumetric flask. Add 400 ml of water at approximately 20 ºC and 5 ml of Carrez solution I (3.7), stir then add 5 ml of Carrez solution II (3.8). Mix for thirty minutes in the tumbler, bring up to volume, homogenise and filter.

5.1.3. *Cooked feeding-stuffs, flax cakes and flour, products rich in flax flour and other products rich in mucilage or in colloidal substances (for example, dextrinated starch)*

Prepare the solution as described under 5.1.2 but do not filter. Decant (if necessary centrifuge), remove 100 ml of the supernatant liquid and transfer to a 200 ml measuring flask. Mix with acetone (3.6) and bring up to volume with this solvent, homogenise and filter.

5.2. *Titration*

Using a pipette, transfer to an Erlenmayer flask from 25 ml to 100 ml of the filtrate (according to the assumed chlorine content) obtained as described under 5.1.1, 5.1.2 or 5.1.3. The aliquot portion must not contain more than 150 mg of chlorine (C l). Dilute if necessary to not less than 50 ml with water, add 5 ml of nitric acid (3.4.), 20 ml of saturated solution of ammonium ferric sulphate (3.3) and two drops of ammonium thiocyanate solution (3.1) transferred by means of a burette filled up to the zero mark. Using a burette, transfer the silver nitrate solution (3.2) in such a way that an excess of 5 ml is obtained. Add 5 ml of diethyl ether (3.5) and shake hard to coagulate the precipitate.

Titrate the excess silver nitrate with the ammonium thiocyanate solution (3.1) until the reddish-brown tint has lasted for one minute.

6. **CALCULATION OF RESULTS**

The amount of chlorine (w), expressed as sodium chloride, present in the volume of filtrate taken for titration is calculated by using the following formula:

$$W = 5{\cdot}845\ (V_1 - V_2)\ mg$$

where: V_1 = ml of silver nitrate solution C·1 N added
V_2 = ml of ammonium thiocyanate solution 0·1 N used for titration.

If the blank test indicates that silver nitrate solution 0·1 N has been consumed deduct this value from the volume ($V_1 - V_2$).

7. **OBSERVATIONS**

7.1. Titration may also be carried out by potentiometry;
7.2. In the case of products which are very rich in oils and fats, first de-fat with diethyl ether or light petroleum;
7.3. In the case of fish-meal, titration may be carried out by Mohr's method.

9. **DETERMINATION OF LACTOSE**

1. **PURPOSE AND SCOPE**

This method makes it possible to determine the level of lactose in feedingstuffs containing more than 0·5% of lactose.

2. **PRINCIPLE**

The sugars are dissolved in water. The solution is subjected to fermentation by the yeast *Saccharomyces cerevisiae* which leaves the lactose intact. After clarification and filtration the lactose content of the filtrate is determined by the Luff-Schoorl method.

3. **REAGENTS**

3.1. Suspension of *Saccharomyces cerevisiae:* suspend 25 g of fresh yeast in 100 ml of water. The suspension will keep for a maximum period of one week in a refrigerator.
3.2. Carrez solution I: dissolve in water 21·9 g of zinc acetate $Zn(CH_3COO)_2 \cdot 2H_2O$ and 3 g of glacial acetic acid. Make up to 100 ml with water.
3.3. Carrez solution II: dissolve in water 10·6 g of potassium ferrocyanide $K_4Fe(CN)_6 \cdot 3H_2O$. Make up to 100 ml with water.
3.4. Luff-Schoorl reagent:
Stirring carefully, pour the citric acid solution (3.4.2) into the sodium carbonate solution (3.4.2). Add the copper sulphate solution (3.4.1) and make up to 1 litre with water. Leave to settle overnight and filter. Check the normality of the reagent thus obtained (Cu 0·1 N; Na_2CO_3 2N). The solution's pH should be approximately 9·4.

3.4.1. Copper sulphate solution: dissolve 25 g of copper sulphate A.R. $CuSO_4\ 5H_2O$, free from iron, in 100 ml of water.
3.4.2. Citric acid solution: dissolve 50 g of citric acid A.R. $C_6H_8O_7 \cdot H_2O$ in 50 ml of water.

3.4.3. Sodium carbonate solution: dissolve 143·8 g of anhydrous sodium carbonate A.R. in approximately 300 ml of warm water. Leave to cool.

3.5. Granulated pumice stone boiled in hydrochloric acid, washed in water and dried.
3.6. 30% solution (w/v) of sodium iodide.
3.7. Sulphuric acid 6 N.
3.8. Solution of sodium thiosulphate 0·1 N.
3.9. Starch solution: add a mixture of 5 g of soluble starch in 30 ml of water to 1 litre of boiling water. Boil for three minutes, leave to cool, and if necessary add 10 mg of mercuric iodide as a preservative.

4. **APPARATUS**
Water bath with thermostat set at 38-40 ºC.

5. **PROCEDURE**
Weigh 1 g of the sample to the nearest mg and place this portion of the sample in a 100 ml volumetric flask. Add 25 to 30 ml of water. Place the flask in a boiling water bath for thirty minutes and then cool to approximately 35 ºC. Add 5 ml of yeast suspension (3·1) and homogenise. Leave the flask to stand for two hours in a water bath, at a temperature of 38- 40 ºC. Cool to approximately 20 ºC.

Add 2·5 ml of Carrez solution I (3.2) and stir for thirty seconds, then add 2·5 ml of Carrez solution II (3.3) and again stir for thirty seconds. Make up to 100 ml with water, mix and filter. Using a pipette, remove an amount of filtrate which does not exceed 25 ml and which preferably contains from 40 to 80 mg of lactose and transfer it to a 300 ml Erlenmeyer flask. If necessary, make up to 25 ml with water.

Carry out a blank test in the same way with 5 ml of yeast suspension (3.1).

Determine the lactose content according to Luff-Schoorl, as follows: add exactly 25 ml of Luff-Schoorl reagent (3.4) and two granules of pumice stone (3.5). Stir by hand-while heating over a free flame of medium height and bring the liquid to the boil in approximately two minutes. Place the Erlenmeyer immediately on an asbestos-coated wire gauze with a hole approximately 6 cm in diameter under which a flame has been lit. The flame shall be regulated in such a way that only the base of the Erlenmeyer is heated. Fit a reflux condenser to the Erlenmeyer flask. Boil for exactly ten minutes. Cool immediately in cold water and after approximately five minutes titrate as follows:

Add 10 ml of potassium iodide solution (3.6) and immediately afterwards (carefully, because of the risk of abundant foaming) add 25 ml of sulphuric acid 6 N (3.7). Titrate with sodium thiosulphate solution 0·1 N (3.8) until a dull yellow colour appears, add the starch indicator (3.9) and complete titration.

Carry out the same titration on an accurately measured mixture of 25 ml of Luff-Schoorl reagent (3.4) and 25 ml of water, after adding 10 ml of potassium iodide solution (3.6) and 25 ml of sulphuric acid 6 N (3.7) without boiling.

6. **CALCULATION OF RESULTS**
Using the attached table, establish the amount of lactose in mg which corresponds to the difference between the results of the two titrations, expressed in ml of sodium thiosulphate 0·1 N.

Express the result as parts of anhydrous lactose as a percentage of the sample.

7. **OBSERVATION**
For products containing more than 40% of fermentable sugar, use more than 5 ml of yeast suspension (3.1).

Table of values for 25 ml of Luff-Schoorl reagent
ml of $Na_2 S_2 O_3$ 0·1 N, two minutes' heating, ten minutes' boiling

$Na_2 S_2 O_3$ 0·1 N	Glucose, fructose invert sugars $C_6 H_{12} O_6$		Lactose $G_{12} H_{22} O_{11}$		Maltose $C_{12} H_{22} O_{11}$		$Na_2 S_2 O_3$ 0·1 N
ml	mg	difference	mg	difference	mg	difference	ml
1	2.4	2.4	3.6	3.7	3.9	3.9	1
2	4.8	2.4	7.3	3.7	7.8	3.9	2
3	7.2	2.5	11.0	3.7	11.7	3.9	3
4	9.7	2.5	14.7	3.7	15.6	4.0	4
5	12.2	2.5	18.4	3.7	19.6	3.9	5
6	14.7	2.5	22.1	3.7	23.5	4.0	6
7	17.2	2.6	25.8	3.7	27.5	4.0	7
8	19.8	2.6	29.5	3.7	31.5	4.0	8
9	22.4	2.6	33.2	3.8	35.5	4.0	9
10	25.0	2.6	37.0	3.8	39.5	4.0	10
11	25.0	2.4	37.0	3.8	39.5	4.0	11
12	30.3	2.7	44.6	3.8	47.5	4.1	12
13	33.0	2.7	48.4	3.8	51.6	4.1	13
14	35.7	2.8	52.2	3.8	55.7	4.1	14
15	38.5	2.8	56.0	3.9	59.8	4.1	15
16	41.3	2.9	59.9	3.9	63.9	4.1	16
17	44.2	2.9	63.8	3.9	68.0	4.2	17
18	47.1	2.9	67.7	4.0	72.2	4.3	18
19	50.0	3.0	71.7	4.0	76.5	4.4	19
20	53.0	3.0	75.7	4.1	80.9	4.5	20
21	56.0	3.1	79.8	4.1	85.4	4.6	21
22	59.1	3.1	83.9	4.1	90.0	4.6	22
23	62.2		88.0		94.6		23

10. DETERMINATION OF POTASSIUM

1. PURPOSE AND SCOPE

This method makes it possible to determine the level of potassium in feeding-stuffs.

2. PRINCIPLE

The sample is ashed and the ash dissolved in hydrochloric acid. The potassium content of the solution is determined by flame photometry in the presence of caesium chloride and aluminium nitrate. The addition of these substances largely eliminates interference from disturbing elements.

3. REAGENTS

3.1. Hydrochloric acid A.R., d: 1.12.
3.2. Caesium chloride A.R.
3.3. Aluminium nitrate $Al(NO_3)_3 \cdot 9 H_2O$, general purpose reagent.
3.4. Potassium chloride A.R., anhydrous.
3.5. Loading agent: dissolve in water 50 g of caesium chloride (3.2) and 250 g of aluminium nitrate (3.3), make up to 1 litre with water and homogenise. Store in plastic bottles.
3.6. Standard solution of potassium: dissolve in water 1·907 g of potassium chloride (3.4), add 5 ml of hydrochloric acid (3.1), make up to 1 litre with water and homogenise. Store in plastic bottles. 1 ml of this solution contains 1·00 mg of potassium

4. APPARATUS

4.1. Platinum, silica or porcelain crucibles for ashing, provided if necessary with lids.
4.2. Electric muffle-furnace with thermostat.

4.3. Flame photometer.

5. **PROCEDURE**

5.1. *Analysis of sample*

As a general rule, weigh out 10 g of the sample to the nearest 10 mg, place in a crucible and ash at 450 ºC for three hours. After cooling transfer the ash quantitatively to a 500 ml graduated flask, using 250 to 300 ml of water and then 50 ml of hydrochloric acid (3.1). When all release of carbon dioxide has ceased, heat the solution and keep at a temperature of about 90 ºC for two hours, stirring occasionally. After cooling to room temperature, make up to the mark with water, shake and filter. Transfer to a 100 ml graduated flask an aliquot part of the filtrate containing a maximum of 1·0 mg of potassium, add 10·0 ml of loading agent (3.5), make up to the mark with water and homogenise. In the case of higher levels of potassium dilute the solution to be analysed in suitable proportions before adding the loading agent.

The table below is given as a guide for a sample of about 10 g.

Assumed potassium content of the sample (% K)	Dilution factor	Aliquot part in ml of the solution
up to 0·1	—	50
0·1 to 0·5	—	10
0·5 to 1·0	—	5
1·0 to 5·0	1: 10	10
5·0 to 10·0	1: 10	5
10·0 to 20·0	1: 20	5

Measure by flame photometry at a wavelength of 768 nm. Calculate the result by means of a calibration curve.

5.2. *Calibration curve*

Place exactly 10 ml of the standard solution (3.6) in a 250 ml graduated flask, make up to the mark with water and homogenise. Place in 100 ml graduated flasks exactly 5, 10, 15, 20 and 25 ml of this solution, corresponding respectively to amounts of potassium of 0·2, 0·4, 0·6, 0·8 and 1·0 mg. Complete the series with a blank flask containing no standard solution. Add 10 ml of loading agent (3.5) to each flask, make up to the mark with water and homogenise. Carry out the measurements as indicated in 5.1. The calibration curve is generally linear up to a potassium concentration of 1 mg in 100 ml of solution.

6. **CALCULATION OF RESULTS**

Express the result as a percentage of the sample.

7. **OBSERVATIONS**

It is not always necessary to add loading agent (3.5) in order to eliminate the interference of disturbing elements.

11. **DETERMINATION OF SODIUM**

1. **PURPOSE AND SCOPE**

This method makes it possible to determine the level of sodium in feedings stuffs.

2. **PRINCIPLE**

The sample is ashed and the ash dissolved in hydrochloric acid. The sodium content of the solution is determined by flame photometry in the presence of caesium chloride and aluminium nitrate. The addition of these substances largely eliminates interference from disturbing elements.

3. **REAGENTS**

3.1. Hydrochloric acid A.R., d: 1.12.

3.2. Caesium chloride A.R.

3.3. Aluminium nitrate Al $(NO_3)_3 \cdot 9\ H_2O$, general purpose reagent

3.4. Sodium chloride A.R., anhydrous.

3.5. Loading agent: dissolve in water 50 g of caesium chloride (3.2) and 250 g of aluminium nitrate (3.3), make up to 1 litre with water and homogenise. Store in plastic bottles.

3.6. Standard solution of sodium: dissolve in water 2·542 g of sodium chloride (3.4), add 5 ml of hydrochloric acid (3.1), make up to 1 litre with water and homogenise Store in plastic bottles, 1 ml of this solution contains 1·00 mg of sodium.

4. **APPARATUS**

4.1. Platinum, silica or porcelain crucibles for ashing, provided if necessary with lids.

4.2. Electric muffle-furnace with thermostat.

4.3. Flame photometer.

5. **PROCEDURE**

5.1. *Analysis of sample*

As a general rule, weigh out 10 g of the sample to the nearest 10 mg, place in a crucible (4.2) and ash at 450 ºC for three hours. Avoid overheating (ignition). After cooling transfer the ash quantitatively to a 500 ml graduated flask, using 250 to 300 ml of water and then 50 ml of hydrochloric acid (3.1). When all release of carbon dioxide has ceased, heat the solution and keep at a temperature of about 90 ºC for two hours, stirring occasionally. After cooling to room temperature, make up to the mark with water, shake and filter. Transfer to a 100 ml graduated flask an aliquot part of the filtrate containing a maximum of 1·0 mg of sodium, add 10·0 ml of loading agent (3.5), make up to the mark with water and homogenise. In the case of higher levels of sodium, dilute the solution to be analysed in suitable proportions before adding the loading agent.

The table below is given as a guide for a sample of about 10 g.

Assumed sodium content of the sample (% K)	Dilution factor	Aliquot part in ml of the solution
up to 0·1	—	50
0·1 to 0·5	—	10
0·5 to 1·0	—	5
1·0 to 5·0	1: 10	10
5·0 to 10·0	1: 10	5
10·0 to 20·0	1: 20	5

Measure by flame photometry at a wavelength of 589 nm. Calculate the result by means of a calibration curve.

5.2. *Calibration curve*

Place exactly 10 ml of the standard solution (3.6) in a 250 ml graduated flask, make up to the mark with water and homogenise. Place in 100 ml graduated flasks exactly 5, 10, 15, 20 and 25 ml of this solution, corresponding respectively to amounts of sodium of 0·2, 0·4, 0·6, 0·8 and 1·0 mg. Complete the series with a blank flask containing no standard solution. Add 10 ml of loading agent (3.5) to each flask, make up to the mark with water and homogenise. Carry out the measurements as indicated in 5.1. The calibration curve is generally linear up to a sodium concentration of 1 mg in 100 ml of solution.

6. **CALCULATION OF RESULTS**

Express the result as a percentage of the sample.

7. **Observations**

7.1. For products containing more than 4% of sodium, it is preferable to ash the substance for two hours in a crucible with a lid. After cooling, add water, bring the ash into suspension by means of a platinum wire, dry and ash again for two hours in the crucible with a lid.

7.2. If the sample consists solely of mineral substances, dissolve without prior ashing.

12. **DETERMINATION OF SUGAR**

1. **PURPOSE AND SCOPE**

This method makes it possible to determine the amount of reducing sugars and total sugars after inversion, expressed as glucose or where appropriate as sucrose, converting by the factor 0·95. It is applicable to compound feeding-stuffs. Special methods are provided for other feeding-stuffs. Where necessary, lactose should be measured separately and taken into account when calculating the results.

2. **PRINCIPLE**

The sugars are extracted in dilute ethanol; the solution is clarified with Carrez solutions I and II. After eliminating the ethanol, the quantities before and after inversion are determined by the Luff-Schoorl method.

3. **REAGENTS**

3.1. 40% ethanol (v/v) d: 0·948 at 20 ºC, neutralised to phenolphthalein.

3.2. Carrez solution I: dissolve in water 21·9 g of zinc acetate Zn $(CH_3COO)_2 \cdot 2H_2O$ and 3 g of glacial acetic acid. Make up to 100 ml with water.

3.3. Carrez solution II: dissolve in water 10·6 g of potassium ferrocyanide $K_4Fe(CN)_6 \cdot 3H_2O$. Make up to 100 ml with water.

3.4. 0·1% solution (w/v) of methyl orange.

3.5. Hydrochloric acid 4 N.

3.6. Hydrochloric acid 0·1 N.

3.7. Sodium hydroxide solution 0·1 N.

3.8. Luff-Schoorl reagent:

Stirring carefully, pour the citric acid solution (3.8.2) into the sodium carbonate solution (3.8.3). Add the copper sulphate solution (3.8.1) and make up to 1 litre with water. Leave to settle overnight and filter. Check the normality of the reagent thus obtained (Cu 0·1 N; Na_2CO_3 2 N). The solution's pH should be approximately 9·4.

3.8.1. Copper sulphate solution: dissolve 25 g of copper sulphate A.R., $CuSO_4 \cdot 5H_2O$, free from iron, in 100 ml of water.

3.8.2. Citric acid solution: dissolve 50 g of citric acid A.R., $C_6H_8O_7\ H_2O$ in 50 ml of water.

3.8.3. Sodium carbonate solution: dissolve 143·8 g of anhydrous sodium carbonate A.R. in approximately 300 ml of warm water. Leave to cool.

3.9. Sodium thiosulphate solution 0·1 N

3.10. Starch solution: add a mixture of 5 g of soluble starch in 30 ml of water to 1 litre of boiling water. Boil for three minutes, leave to cool and if necessary add 10 mg of mercuric iodide as a preservative.

3.11. Sulphuric acid 6 N.

3.12. 30% solution (w/v) of potassium iodide.

3.13. Granulated pumice stone boiled in hydrochloric acid, washed in water and dried.

3.14. 3-methylbutan-l-ol.

4. **APPARATUS**

Mixer (tumbler): approximately 35 to 40 rpm.

5. **PROCEDURE**

5.1. *Extraction of sample*

Weigh 2.5 g of the sample to the nearest mg and place in a 250 ml volumetric flask. Add 200 ml of ethanol (3.1) and mix in the tumbler for one hour. Add 5 ml of Carrez solution I (3.2) and stir for one minute. Add 5 ml of Carrez solution II (3.3) and again stir for one minute. Make up to volume with ethanol (3.1), homogenise and filter. Remove 200 ml of the filtrate and evaporate to approximately half volume in order to eliminate most of the ethanol. Transfer the evaporation residue quantitatively to a 200 ml volumetric flask using warm water, cool, bring up to volume with water, homogenise and filter if necessary. This solution will be used to determine the amount of reducing sugars and, after inversion, of total sugars.

5.2. *Determination of reducing sugars*

Using a pipette, remove not more than 25 ml of the solution containing less than 60 mg of reducing sugars expressed as glucose. If necessary, make up to 25 ml with distilled water and determine the content of reducing sugars by the Luff-Schoorl method. The result is expressed as the percentage content of glucose in the sample.

5.3. *Determination of total sugars after inversion*

Using a pipette take 50 ml of the solution and transfer to a 100 ml volumetric flask. Add a few drops of methyl orange solution (3.4) then, carefully and stirring continuously, add hydrochloric acid 4 N (3.5) until the liquid turns a definite red. Add 15 ml of hydrochloric acid 0·1 N (3.6), immerse the flask in a fast boiling water bath and keep there for thirty minutes. Cool rapidly to approximately 20 ºC and add 15 ml of sodium hydroxide solution 0·1 N (3.7). Make up to 100 ml with water and homogenise. Remove not more than 25 ml containing less than 60 mg of reducing sugars expressed as glucose. If necessary, make up to 25 ml with distilled water and determine the content of reducing sugars by the Luff-Schoorl method. The result is expressed as the percentage of glucose or, where appropriate, sucrose, by multiplying by the factor 0·95.

5.4. *Titration by the Luff-Schoorl method*

Using a pipette, take 25 ml of Luff-Schoorl reagent (3.8) and transfer to a 300 ml Erlenmeyer flask; add exactly 25 ml of the clarified sugar solution. Add 2 granules of pumice stone (3.13), heat, stirring by hand, over a free flame of medium height and bring the liquid to the boil in approximately two minutes. Place the Erlenmeyer immediately on an asbestos-coated wire gauze with a hole approximately 6 cm in diameter under which a flame has been lit. The flame shall be regulated in such a way that only the base of the Erlenmeyer is heated. Fit a reflux condenser to the Erlenmeyer flask, Boil for exactly ten minutes. Cool immediately in cold water and after approximately five minutes titrate as follows:

Add 10 ml of potassium iodide solution (3.12) and immediately afterwards (carefully, because of the risk of abundant foaming), add 25 ml of sulphuric acid 6 N (3.11). Titrate with sodium thiosulphate solution 0·1 N (3.9) until a dull yellow colour appears, add the starch indicator (3.10) and complete titration.

Carry out the same titration on an accurately measured mixture of 25 ml of Luff-Schoorl reagent (3.8) and 25 ml of water, after adding 10 ml of potassium iodide solution (3.12) and 25 ml of sulphuric acid 6 N (3.11) without boiling.

6. CALCULATION OF RESULTS

Using the table establish the amount of glucose in mg which corresponds to the difference between the values of the two titrations, expressed in mg of sodium thiosulphate 0·1 N.

Express the result as a percentage of the sample.

7. SPECIAL PROCEDURES

7.1. In the case of feeding-stuffs which are rich in molasses and other feeding-stuffs which are not particularly homogeneous, weigh out 20 g and place with 500 ml of water in a 1 litre volumetric flask. Mix for one hour in the tumbler. Clarify using Carrez 1 (3.2) and II (3.3) reagents as described under 5.1, this time however using four times the quantities of each reagent. Bring up to volume with 80% ethanol (v/v).

Homogenise and filter. Eliminate the ethanol as described under 5.1. If there is no dextrinised starch, bring up to volume with distilled water.

7.2. In the case of molasses and straight feeding-stuffs which are rich in sugar and almost starch-free (carobs, dried beetroot cossettes etc.), weigh out 5 g, place in a 250 ml volumetric flask, add 200 ml of distilled water and mix in the tumbler for one hour, or more if necessary. Clarify using Carrez I (3.2) and II (3.3) reagents as described under 5.1. Bring up to volume with cold water, homogenise and filter. In order to determine the amount of total sugars, continue as described under 5.3.

8. **OBSERVATIONS**

8.1. In order to prevent foaming it is advisable to add (irrespective of the volume) approximately 1 ml of 3-methylbutan-l-ol (3.14) before boiling with Luff-Schoorl reagent.

8.2. The difference between the content of total sugars after inversion, expressed as glucose, and the content of reducing sugars, expressed as glucose, multiplied by 0·95, gives the percentage content of sucrose.

8.3. In order to determine the content of reducing sugars, excluding lactose, two methods may be adopted:

8.3.1. for an approximate calculation, multiply by 0·675 the lactose content established by a different method of analysis and subtract the result obtained from the content of reducing sugars.

8.3.2. For an accurate calculation of reducing sugars, excluding lactose, the same sample must be used for the two final determinations. One of the analyses is carried out on part of the solution obtained under 5.1, the other on part of the solution obtained during the determination of lactose by the method laid down for that purpose (after fermenting the other types of sugar and clarifying).

In both cases the amount of sugar present is determined by the Luff-Schoorl method and calculated in mg of glucose. One of the values is subtracted from the other and the difference is expressed as a percentage of the sample.

Example

The two volumes taken correspond, for each determination, to a sample of 250 mg.

In the first case 17 ml of sodium thiosulphate solution 0·1 N corresponding to 44·2 mg of glucose is consumed; in the second, 11 ml, corresponding to 27·6 mg of glucose.

The difference is 16·6 mg of glucose.

The content of reducing sugars (excluding lactose), calculated as glucose, is therefore:

$$\frac{4 \times 16 \times 6}{10} = 6.64\%$$

Table of values for 25 ml of Luff Schoorl reagent

$Na_2 S_2 O_3$ 0·1 N	Glucose, fructose invert sugars $C_6 H_{12} O_6$		Lactose $G_{12} H_{22} O_{11}$		Maltose $C_{12} H_{22} O_{11}$		$Na_2 S_2 O_3$ 0·1 N
ml	mg	difference	mg	difference	mg	difference	ml
1	2.4	2.4	3.6	3.7	3.9	3.9	1
2	4.8	2.4	7.3	3.7	7.8	3.9	2
3	7.2	2.5	11.0	3.7	11.7	3.9	3
4	9.7	2.5	14.7	3.7	15.6	4.0	4
5	12.2	2.5	18.4	3.7	19.6	3.9	5
6	14.7	2.5	22.1	3.7	23.5	4.0	6
7	17.2	2.6	25.8	3.7	27.5	4.0	7
8	19.8	2.6	29.5	3.7	31.5	4.0	8
9	22.4	2.6	33.2	3.8	35.5	4.0	9
10	25.0	2.6	37.0	3.8	39.5	4.0	10
11	27.6	2.7	40.8	3.8	43.5	4.0	11
12	30.3	2.7	44.6	3.8	47.5	4.1	12
13	33.0	2.7	48.4	3.8	51.6	4.1	13
14	35.7	2.8	52.2	3.8	55.7	4.1	14
15	38.5	2.8	56.0	3.9	59.8	4.1	15
16	41.3	2.9	59.9	3.9	63.9	4.1	16
17	44.2	2.9	63.8	3.9	68.0	4.2	17
18	47.1	2.9	67.7	4.0	72.2	4.3	18
19	50.0	3.0	71.7	4.0	76.5	4.4	19
20	53.0	3.0	75.7	4.1	80.9	4.5	20
21	56.0	3.1	79.8	4.1	85.4	4.6	21
22	59.1	3.1	83.9	4.1	90.0	4.6	22
23	62.2		88.0		94.6		23

14. DETERMINATION OF UREA

1. PURPOSE AND SCOPE

This method makes it possible to determine the level of urea in feedingstuffs.

2. PRINCIPLE

The sample is suspended in water with a clarifying agent. The suspension is filtered. The urea content of the filtrate is determined after the addition of 4-dimethylaminobenzaldehyde (4-DMAB) by measuring the optical density at a wavelength of 420 nm,

3. REAGENTS

3.1. Solution of 4-dimethylaminobenzaldehyde: dissolve 1·6 g of 4-DMAB A.R. in 100 ml of 96% ethanol and add 10 ml of hydrochloric acid A.R. (d: 1·19). This reagent keeps for a maximum period of two weeks.

3.2. Carrez solution I: dissolve in water 21·9 g of zinc acetate $Zn (CH_3COO)_2 \cdot 2H_2O$ and 3 g of glacial acetic acid. Make up to 100 ml with water.

3.3. Carrez solution II: dissolve in water. 10·6 g of potassium ferrocyanide, $K_4 Fe (CN)_6 \cdot 3H_2O$. Make up to 100 ml with water.

3.4. Active carbon A.R. which does not absorb urea (to be checked).

3.5. 0·1% solution (w/v) of urea A.R.

4. APPARATUS

4.1. Mixer (tumbler): approximately 35 to 40 rpm.

4.2. Test tubes: 160 × 16 mm with ground-glass stoppers.

4.3. A spectrophotometer.

5. PROCEDURE

5.1. *Analysis of sample*

Weigh out 2 g of the sample to the nearest mg and place with 1 g of active carbon (3.4) in a 500 ml volumetric flask. Add 400 ml of water and 5 ml of Carrez solutions I (3.2) and II (3.3). Mix for thirty minutes in the tumbler. Make up to volume with water, shake and filter.

Remove 5 ml of the transparent colourless filtrates, place in test tubes with ground-glass stoppers, add 5 ml of 4-DMAB solution (3.1) and mix. Place the tubes in a hot-water bath at 20 ºC. After fifteen minutes measure the optical density of the sample solution with the spectrophotometer at 420 nm. Compare with the blank test solution of the reagents.

5.2. *Calibration Curve*

Remove volumes of 1, 2, 4, 5 and 10 ml of the urea solution (3.5), place in 100 ml volumetric flasks and make up the volume with water. Remove 5 ml from each solution, add 5 ml of 4-DMAB solution (3.1) to each of them, homogenise and measure the optical density as shown above in comparison with a control solution containing 5 ml of 4-DMAB and 5 ml of water free from urea. Plot the calibration curve.

6. **CALCULATION OF RESULTS**

Determine the amount of urea in the sample using the calibration curve.
Express the result as a percentage of the sample.

7. **OBSERVATIONS**

7.1. In the case of contents of urea exceeding 3%, reduce the sample to 1 g or dilute the original solution so that there are not more than 50 mg of urea in 500 ml.
7.2. In the case of low contents of urea, increase the sample as long as the filtrate remains transparent and colourless.
7.3. If the sample contains simple nitrogenous compounds such as amino acids, the optical density should be measured at 435 nm.

16. ESTIMATION OF THE UREASE ACTIVITY OF PRODUCTS DERIVED FROM SOYA

1. **PURPOSE AND SCOPE**

This test makes it possible estimate the urease activity of products derived from soya and to show whether these products have been cooked for a sufficient length of time.

2. **PRINCIPLE**

Urease activity is estimated by the amount of ammoniacal nitrogen liberated per 1 g of product per minute at 30 ºC from a solution of urea.

3. **REAGENTS**

3.1. Hydrochloric acid 0·1 N
3.2. Solution of sodium hydroxide 0·1 N.
3.3. 3.3. Loading agent of phosphate 0·05 M, containing, per 1000 ml, 4·45 g of disodium phosphate ($Na_2HPO_4 \cdot 2H_2O$) and 3·40 g of monopotassium phosphate ($KH_2 PO_4$).
3.4. Freshly-prepared urea loading agent containing 30·0 g of urea per 1000 ml of loading agent (3.3); pH 6·9-7·0.

4. **APPARATUS**

4.1. Potentiometric titration apparatus or high sensitivity pH-meter (0·02 pH) with magnetic stirrer.
4.2. Water bath fitted with thermostat set at 30 ºC exactly.
4.3. Test-tubes with ground-glass stoppers, 150 × 18 mm.

5. **PROCEDURE**

Crush about 10 g of the sample (for example in a coffee mill) so that it passes through a sieve with a mesh of 0·2 mm. Weigh out 0·2 g of the crushed sample to the nearest mg, place in a test tube with a ground-glass stopper and add 10 ml of urea loading agent (3.4). Stopper

immediately and shake vigorously. Place the tube in a water bath set at 30 ºC exactly and keep there for exactly thirty minutes. Immediately add 10 ml of 0·1 N hydrochloric acid (3.1), cool rapidly to 20 ºC and transfer the contents of the tube quantitatively to a titration vessel, rinsing twice with 5 ml of water. Using a glass electrode (4.1) titrate immediately and rapidly to pH 4·7 with the 0·1 N sodium hydroxide solution (3.2) by electrometry.

Carry out a blank test as follows:

Quickly place a sample of 0·2 g weighed to the nearest mg in a test tube with a ground-glass stopper, add 10 ml of 0·1 N hydrochloric acid (3.1) and then 10 ml of urea loading agent (3.4). Cool the tube immediately in ice-water and leave there for thirty minutes. Under the conditions indicated above, transfer the contents of the tube to the titration vessel using the 0·1 N sodium hydroxide solution (3.2) up to pH 4·7.

6. **CALCULATION**

The urease activity is calculated by using the formula:

$$\frac{\text{mg N}}{\text{g min}} \text{ AT } 30\ ^{\circ}\text{C} = \frac{.4\,(b - a)}{30\,.\,E}$$

where: a = ml of 0·1N sodium hydroxide solution consumed by the sample,
b = ml of 0·1N sodium hydroxide solution consumed in the blank test,
E = weight of sample in g.

7. **OBSERVATION**

7.1. This method is suitable for a urease activity of up to 1 mg of N/g/min at 30 ºC. For more active products, the size of the sample can be reduced to 50 mg.

7.2. Products containing more than 10% of crude fatty substance must first be defatted cold.

Nru. 1214

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikoli 22(ċ) u 25 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Metodi ta' Analiżi għall-Kontroll Uffiċjali ta' l-Oġġetti ta' l-Ikel.

Id-19 ta' Novembru, 2004

No. 1214

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority is hereby publishing the following draft rules in accordance with articles 22(c) and 25 of the Veterinary Services Act, to allow any person a period of four weeks to make representation to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed regulations are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Methods of Analysis for the Official Control of Feeding-Stuffs Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Undesirable Substances in Animal Feeds Rules, 2004

IN exercise of the powers conferred by article 10 of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment has made the following rules :

Title, scope and applicability.

1. (1) The title of these rules is the Undesirable Substances in Animal Feeds Rules, 2004

(2) These rules deal with undesirable substances in products intended for animal feed.

(3) The scope of these rules is to implement the provisions found under Directive 2002/32 EC of the European Parliament and of the Council of the 7th May 2002 on undesirable substances in animal feeds.

(4) These rules shall apply without prejudice to the provisions in:
(a) Order (70/524) concerning additives in feedingstuffs;
(b) Order (96/25)and Order (79/373) on the marketing of compound feedingstuffs;

(c) Orders relating to the fixing of maximum levels for pesticide residues, where these residues are not listed in Annex I to this Order;
(d) Veterinary legislation relating to public health and animal health;
(e) Order (82/471) concerning certain products used in animal nutrition;
(f) Order (93/74)on feedingstuffs intended for particular nutritional purposes.

Interpretation.

2. For the purposes of these rules:
"feedingstuffs" shall mean products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;
"feed materials" shall mean various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such or, after processing, in the preparation of compound feedingstuffs or as substrates for premixtures;
"additives" shall mean additives as defined in Article 2(a) of Council DirectiveOrder (70/524)/EEC;
"premixtures" shall mean mixtures of additives or mixtures of one or more additives with substances used as carriers, intended for the manufacture of feedingstuffs;
"compound feedingstuffs" shall mean mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;
"complementary feedingstuffs" shall mean mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if used in combination with other feedingstuffs;
"complete feedingstuffs" shall mean mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;
"products intended for animal feed" shall mean feed materials, premixtures, additives, feedingstuffs and all other products intended for use or used in animal feed;
"daily ration" shall mean the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age class and yield, to satisfy all its needs;
"animals" shall mean animals belonging to species normally fed and kept or consumed by man as well as animals living freely in the wild in cases where they are fed with feedingstuffs;
"putting into circulation" or "circulation" shall mean the holding of products intended for animal feed for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale or other forms of transfer themselves;
"undesirable substance" shall mean any substance or product, with the exception of pathogenic agents, which is present in and/or on the product intended for animal

feed and which presents a potential danger to animal or human health or to the environment or could adversely affect livestock production.
"The competent authority" shall mean the competent authority as mentioned in Article 2 (f) of Order (95/53) fixing the principles governing the organisation of official inspections in the field of animal nutrition.

Animal feed products.

3 (1) Products intended for animal feed may enter for use in the Community territory of Malta from third countries, be put into circulation and, or used in the Community territory only if they are sound, genuine and of merchantable quality. When correctly used such products do not represent any danger to human health, animal health or to the environment or could adversely affect livestock production.
(2) In particular, products intended for animal feed shall be deemed not to be in conformity with paragraph 1 if the level of undesirable substances they contain does not comply with the maximum levels laid down in Annex I.

Tolerance of undesirable substances.

4 (1) Undesirable substances listed in Annex I may be tolerated in products intended for animal feed only subject to the conditions laid down therein.
(2) In order to reduce or eliminate sources of undesirable substances of products intended for animal feed, the competent authority, in co-operation with economic operators, shall carry out investigations to identify the sources of undesirable substances, in cases where the maximum levels are exceeded and in cases where increased levels of such substances are detected, taking into account background levels. For a uniform approach in cases of increased levels it may be necessary to set action thresholds to trigger such investigations. These may be laid down in Annex II.

(3) The competent authority shall transmit to the Commission and to the relevant International Organisation and to the other Member States of the European Union all relevant information and findings of the source and the measures taken to reduce the level or elimination of the undesirable substances. This information shall be transmitted in the frame of the annual report to be transmitted to the Commission and to the relevant International Organisation according to the provisions of Article 22 of Directive (95/53)/EC except in those cases where the information is of immediate relevance for the other Member States. In this latter case, the information shall be transmitted immediately.

Products not to be mixed.

5. Products intended for animal feed containing levels of an undesirable substance that exceed the maximum level fixed in Annex I may not be mixed for dilution purposes with the same, or other, products intended for animal feed.

Complementary feedingstuffs.

6. In so far as there are no special provisions for complementary feedingstuffs, complementary feedingstuffs may not, taking into account the proportion prescribed for their use in a daily ration, contain levels of the undesirable substances listed in Annex I that exceed those fixed for complete feedingstuffs.

New information.

7. (1) Where the competent authority has grounds, based on new information or a reassessment of existing information made since the provisions in question were adopted, demonstrating that a maximum level fixed in Annex I, or an undesirable substance not listed therein, present a danger to animal or human health or to the environment, it may provisionally reduce the existing maximum level, fix a maximum level or prohibit the presence of that undesirable substance in products intended for animal feed. It shall immediately inform the other Member States and the Commission and to the relevant International Organisation thereof, stating the grounds for its decision.
(2) An immediate decision shall be taken, whether to amend Annexes I and II.
(3) Insofar as neither the Council nor the Commission and the relevant International Organisation has taken a decision, the competent authority may maintain the measures it has implemented. The competent authority must ensure that the decision taken is made public.

Adaptation of Annexes.

8. (1) In the light of developments in scientific and technical knowledge, Annexes I and II shall be adapted in agreement with decisions adopted by the relevant International Organisation.
(2) Furthermore, in accordance with the procedure laid down in Article 24, the Competent authority:
- shall periodically adopt consolidated versions of Annexes I and II incorporating any adaptations made pursuant to sub-rule (1);
- may define acceptability criteria for detoxification processes as a complement to the criteria provided for products intended for animal feed which have undergone such processes may be defined.
(3) Measures shall be taken to guarantee the correct application of any acceptable processes pursuant to sub-rule (2) and the conformity of the detoxified products intended for animal feed with the provisions of Annex I.

No other restrictions applicable.

9. Products intended for animal feed which comply with these rules shall not be subject to any other restrictions on circulation as regards the presence of undesirable substances other than those provided for in these rules and Directive (95/53)/EC.

Provisions that may be adopted.

10. Provisions that may have an effect upon public or animal health or on the environment shall be adopted after consultation with the relevant International Organisation.

ANNEX I

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
1. Arsenic	Feed materials with the exception of: - meal made from grass, from dried lucerne and from dried clover, and dried sugar beet pulp and dried molasses sugar beet pulp - phosphates and feedingstuffs obtained from the processing of fish or other marine animals Complete feedingstuffs with the exception of: - complete feedingstuffs for fish Complementary feedingstuffs with the exception of: - mineral feedingstuffs	2 4 10 2 4 4 12
2. Lead	Feed materials with the exception of: - green fodder - phosphates - yeasts Complete feedingstuffs Complementary feedingstuffs with the exception of: - mineral feedingstuffs	10 40 30 5 5 10 30

3. Fluorine	Feed materials with the exception of: - feedingstuffs of animal origin - phosphates Complete feedingstuffs with the exception of: - complete feedingstuffs for cattle, sheep and goats - in milk - other - complete feedingstuffs for pigs - complete feedingstuffs for poultry - complete feedingstuffs for chicks Mineral mixtures for cattle, sheep and goats Other complementary feedingstuffs	150 500 2 000 150 30 50 100 350 250 2 000 (1) 125 (2)
4. Mercury	Feed materials with the exception of: - feedingstuffs produced by the processing of fish or other marine animals Complete feedingstuffs with the exception of: - complete feedingstuffs for dogs and cats Complementary feedingstuffs except: - complementary feedingstuffs for dogs and cats	0,1 0,5 0,1 0,4 0,2
5. Nitrites	Fish meal Complete feedingstuffs excluding: - feedingstuffs intended for pets except birds and aquarium fish	60 (expressed as sodium nitrite) 15 (expressed as sodiumnitrite)
6. Cadmium	Feed materials of vegetable origin Feed materials of animal origin except: - feedingstuffs for pets Phosphates Complete feedingstuffs for cattle, sheep and goats except: - complete feedingstuffs for calves, lambs and kids Other complete feedingstuffs except: - feedingstuffs for pets Mineral feedingstuffs Other complementary feedingstuffs for cattle, sheep and goats	1 2 10 (3) 1 0,5 5 (4) 0,5

7. Aflatoxin B_1	Feed materials with the exception of: - groundnut, copra, palm-kernel, cotton seed, babassu, maize and products derived from the processing thereof Complete feedingstuffs for cattle, sheep and goats with the exception of: - dairy cattle - calves and lambs Complete feedingstuffs for pigs and poultry (except young animals) Other complete feedingstuffs Complementary feedingstuffs for cattle, sheep and goats (except complementary feedingstuffs for dairy animals, calves and lambs) Complementary feedingstuffs for pigs and poultry (except young animals) Other complementary feedingstuffs	0,05 0,02 0,05 0,005 0,01 0,02 0,01 0,05 0,03 0,005
8. Hydrocyanic acid	Feed materials with the exception of: - linseed - linseed cakes - manioc products and almond cakes Complete feedingstuffs with the exception of: - complete feedingstuffs for chicks	50 250 350 100 50 10
9. Free gossypol	Feed materials with the exception of: - cotton-seed cakes Complete feedingstuffs with the exception of: - complete feedingstuffs for cattle, sheep and goats - complete feedingstuffs for poultry (except laying hens) and calves - complete feedingstuffs for rabbits and pigs (except piglets)	20 1 200 20 500 100 60
10. Theobromine	Complete feedingstuffs with the exception of: - complete feedingstuffs for adult cattle	300 700

11. Volatile mustard oil	Feed materials with the exception of: - rape-seed cakes Complete feedingstuffs with the exception of: - complete feedingstuffs for cattle, sheep and goats (except young animals) - complete feedingstuffs for pigs (except piglets) and poultry	100 4 000 (expressed as allyl isothiocyanate) 150 (expressed as allylisothiocyanate) 1 000(expressed as allyl isothiocyanate) 500 (expressed as allylisothiocyanate)
12. Vinyl thiooxazolidone (Vinyloxazolidine thione)	Complete feedingstuffs for poultry with the exception of: - complete feedingstuffs for laying hens	1 000 500
13. Rye ergot (Claviceps purpurea)	All feedingstuffs containing unground cereals	1 000
14. Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination including (a) Lolium temulentum L., (b) Lolium remotum Schrank (c) Datura stramonium L.	All feedingstuffs	3 000 1 000 1 000 1 000
15. Castor oil plant - Ricinus communis L.	All feedingstuffs	10 (expressed in terms of castor-oil plant husks)
16. *Crotalaria* spp.	All feedingstuffs	100
17. Aldrin 18. Dieldrin } Singly or combined expressed as dieldrin	All feedingstuffs with the exception of: - fats	0,01 0,2 }
19. Camphechlor (toxaphene)	All feedingstuffs	0,1
20. Chlordane (sum of cis- and trans-isomers and of oxychlordane, expressed as chlordane)	All feedingstuffs with the exception of: - fats	0,02 0,05
21. DDT (sum of DDT-, TDE- and DDEisomers, expressed as DDT)	All feedingstuffs with the exception of: - fats	0,05 0,5
22. Endosulfan (sum of alpha- and betaisomers and of endosulfansulphate expressed as endo-sulfan)	All feedingstuffs with the exception of: - maize - oilseeds - complete feedingstuffs for fish	0,1 0,2 0,5 0,005
23. Endrin (sum of endrin and of delta-ketoiendrin, expressed as endrin)	All feedingstuffs with the exception of: - fats	0,01 0,05
24. Heptachlor (sum of heptachlor and of hepta-chlorepoxide, expressed as heptachlor)	All feedingstuffs with the exception of: - fats	0,01 0,2
25. Hexachlorobenzene (HCB)	All feedingstuffs with the exception of: - fats	0,01 0,2

26. Hexachlorocyclo-hexane (HCH) 26.1. alpha-isomers 20.2. beta-isomers 26.3. gamma-isomers	 All feedingstuffs with the exception of: - fats Compound feedingstuffs with the exception of: - feedingstuffs for dairy cattle Feed materials with the exception of: - fats All feedingstuffs with the exception of: - fats	 0,02 0,2 0,01 0,005 0,01 0,1 0,2 2,0
27. Dioxin (sum of PCDD and PCDF), expressed in international toxic equivalents	Citrus pulp **AMENDED BY DIR 2003/57/EC**	500 pg I-TEQ/kg (upper bound detection limit)
28. Apricots - *Prunus armeniaca* L. 29. Bitter almond - *Prunus dulcis* (Mill.) D.A.m Webb var. *amara* (DC.) Focke (= *Prunus amygdalus Batsch* var. *amara* (DC.) Focke) 30. Unhusked beech mast - *Fagus silvatica* L. 31. Camelina - *Camelina sativa* (L.) Crantz 32. *Mowrah, Bassia, Madhuca* - *Madhuca longifolia* (L.) Macbr. (= *Bassia longifolia* L. = *Illipe malabrorum* Engl.) *Madhuca indica* Gmelin (= *Bassia latifolia* Roxb.) = *Illipe latifolia* (Roscb.) F. Mueller) 33. Purghera - *Jatropha curcas* L. 34. Croton - *Croton tiglium* L. 35. Indian mustard - *Brassica juncea* (L.) Czern. and Coss. ssp. *integrifolia* (West.) Thell. 36. Sareptian mustard - *Brassica juncea* (L.) Czern. and Coss. ssp. *juncea* 37. Chinese mustard - *Brassica juncea* (L.) Czern. and Coss. ssp. *juncea* var. *lutea* Batalin 38. Black mustard - *Brassica nigra* (L.) Koch 39. Ethiopian mustard - *Brassica carinata* A. Braun	All feedingstuffs	Seeds and fruit of the plant species listed opposite as well as their processed derivatives may only be present in feedingstuffs in trace amounts not quantitavely determinable

(1) Member StatesCompetent authority may also prescribe a maximum fluorine content of 1,25 % of the phosphate content.
(2) Fluorine content per 1 % phosphorus.
(3) Member States Competent authority may also prescribe a maximum cadmium content of 0,5 mg per 1 % phosphorus.
(4) Member States Competent authority may also prescribe a maximum cadmium content of 0,75 mg per 1 % phosphorus.
(5) Upper bound concentrations are calculated assuming that all values of the different congeners less than the limit of detection are equal to the limit of detection.

ANNEX II

Undesirable substances	Products intended for animal feed	Action threshold in mg/kg (ppm) relative to a product intended for animal feed with a moisture content of 12 %	Comments and additional information (e.g. nature of investigation to be performed)

Nru. 1215

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu10 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar il-Kondizzjonijiet ta' Saħħa għall-Produzzjoni u t-Tqegħid fis-Suq tal-Prodotti tas-Sajd.

Id-19 ta' Novembru, 2004

No. 1215

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 10 of the Veterinary Services Act to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

The Health Conditions for the Production and the Placing on the Market of Fishery Products Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

The Health Conditions for the Production and the Placing on the Market of Fishery Products Rules, 2004

IN exercise of the powers conferred by article 10 of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment has, after consultation with the Minister of Health, the Elderly and Community Care, made the following regulations :

Title and Scope

1. (1) The title of these regulations is the Health Conditions for the Production and the Placing on the Market of Fishery Products Rules, 2004

(2) The scope of these rules is to implement the provisions found under European Union Council Directive 91/493/EEC of the 22nd July, 1991 laying down the health conditions for the production and the placing on the market of fishery products.

(3) These rules lay down the health conditions for the production and the placing on the market of fishery products for human consumption.

Definitions.

2. For the purposes of these rules –

'fishery products' means all seawater or freshwater animals or parts thereof, including their roes, excluding aquatic mammals, frogs and aquatic animals covered by other European Community acts;

'aquaculture products' means all fishery products born and raised in controlled conditions until placed on the market as a foodstuff. However seawater or freshwater fish or crustaceans caught in their natural environment when juvenile and kept until they reach the desired commercial size for human consumption are also considered to be aquaculture products. Fish and crustaceans of commercial size caught in their natural environment and kept alive to be sold at a later date are not considered to be aquaculture products if they are merely kept alive without any attempt being made to increase their size or weight;

'chilling' means the process of cooling fishery products to a temperature approaching that of melting ice;

'fresh products' means any fishery product whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, which have not undergone any treatment to ensure preservation other than chilling;

'prepared products' means any fishery product which has undergone an operation affecting its anatomical wholeness, such as gutting, heading, slicing, filleting, chopping, etc.;

'processed products' means any fishery product which has undergone a chemical or physical process such as the heating, smoking, salting, dehydration or marinating, etc., of chilled or frozen products, whether or not associated with other foodstuffs, or a combination of these various processes;

'preserve' means the process whereby products are packaged in hermetically sealed containers and subjected to heat treatment to the extent that any micro-organisms that might proliferate are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;

'frozen products' means any fishery product which has undergone a freezing process to reach a core temperature of 18°C or lower after temperature stabilisation;

'packaging' means the procedure of protecting fishery products by a wrapper, a container or any other suitable device;

'batch' means the quantity of fishery products obtained under practically identical circumstances;

'consignment' means the quantity of fishery products bound for one or more customers in the country of destination and conveyed by one means of transport only;

'means of transport' means those parts set aside for goods in automobile vehicles, rail vehicles and aircraft, the holds of vessels, and containers for transport by land, sea or air;

'competent authority' means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence; for Malta, the competent authority is the Veterinary Services;

'establishment' means any premises where fishery products are prepared, processed, chilled, frozen, packaged or stored. Auction and wholesale markets in which only display and sale by wholesale takes place are not deemed to be establishments;

'placing on the market' means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market in the European Community, excluding retail sales and direct transfers on local markets of small quantities by fishermen to retailers or consumers, which must be subject to the health checks laid down by other European Community rules or, if not yet established, national rules for checking the retail trade;

'importation' means the introduction into the territory of the European Community of fishery products from third countries;

'clean seawater' means seawater or briny water which is free from microbiological contamination, harmful substances and/or toxic marine plankton in such quantities as may affect the health quality of fishery products and which is used under the conditions laid down in these regulations;

'factory vessel' means any vessel on which fishery products undergo one or more of the following operations followed by packaging: filleting, slicing, skinning, mincing, freezing or processing. The following are not deemed to be 'factory vessels':
(a) fishing vessels in which only shrimps and molluscs are cooked on board;
(b) fishing vessels on board which only freezing is carried out.

Placing on the market of fishery products.

3. (1) The placing on the market of fishery products caught in their natural environment shall be subject to the following conditions:
(a) they must have:
(i) been caught and where appropriate handled for bleeding, heading, gutting and the removal of fins, chilled or frozen, on board vessels in accordance with hygiene rules to be established in accordance with requirements of European Community and according to the procedure laid down in Article 10 of the Veterinary Services Act;

(ii) where appropriate, been handled in factory vessels approved in accordance with Article 7, and in accordance with the requirements of Chapter I of the Annex. The cooking of shrimps and molluscs on board must comply with the provisions of Chapter III, section I (5) and Chapter IV, section IV (7), of the Annex. Such vessels shall be specifically registered by the Veterinary Services;
(b) during and after landing they must have been handled in accordance with Chapter II of the Annex;
(c) they must have been handled and, where appropriate, packaged, prepared, processed, frozen, defrosted or stored hygienically in establishments approved in accordance with Article 7, in compliance with the requirements of Chapters III and IV of the Annex. The competent authority may, notwithstanding Chapter II, section 2 of the Annex, authorise the transfer of fishery products ex quay into containers for immediate delivery to an approved establishment or registered auction or wholesale market to be checked there;
(d) they must have undergone a health check in accordance with Chapter V of the Annex;
(e) they must have been appropriately packaged in accordance with Chapter VI of the Annex;
(f) they must have been given an identification mark in accordance with Chapter VII of the Annex;
(g) they must have been stored and transported under satisfactory conditions of hygiene, in accordance with Chapter VIII of the Annex.

(2) Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed.

(3) The placing on the market of aquaculture products shall be subject to the following conditions:
(a) they must have been slaughtered under appropriate conditions of hygiene. They must not be soiled with earth, slime or faeces. If not processed immediately after having been slaughtered, they must be kept chilled;
(b) they must, in addition, comply with the requirements laid down under sub-rule (1) (c) to (g) hereof.

(4) (a) The placing on the market of live bivalve molluscs shall be subject to the requirements laid down in Council Directive 91/492/EEC of 15 July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs.
(b) When processed, bivalve molluscs must, in addition to the requirements in sub-rule (3) (a) hereof, satisfy those of sub-rule (1) (c) to (g) hereof.

Suitable survival conditions.

4. Fishery products to be placed on the market alive shall at all times be kept under the most suitable survival conditions.

5. The placing on the market of the following products shall be forbidden:

- poisonous fish of the following families: Tetraodontidae, Molidae, Diodontidae, Canthigasteridae,
- fishery products containing biotoxins such as ciguatera toxins or muscle paralysing toxins. Detailed requirements concerning the species covered by this Article and concerning methods of analysis shall be laid down in accordance with requirements of European Community and in accordance with the procedure prescribed in article 10 of the Veterinary Services Act.

Compliance with Rules.

6. (1) Veterinary Services shall ensure that persons responsible for establishment take all necessary measures, so that, at all stages of the production of fishery products, the specifications of these rules are complied with. To that end, the said persons responsible must carry out their own checks based on the following principles;
(a) identification of critical points in their establishment on the basis of the manufacturing processes used;
(b) establishment and implementation of methods for monitoring and checking such critical points;
(c) taking samples for analysis in an approved laboratory by the competent authority for the purpose of checking cleaning and disinfection methods and for the purpose of checking compliance with the standards established by these rules;
(d) keeping a written record or a record registered in an indelible fashion of the preceding points with a view to submitting them to the competent authority. The results of the different checks and tests will in particular be kept for a period of at least two years.

(2) If the results of own checks or any information at the disposal of the persons responsible referred to in paragraph 1 reveal the risk of a health risk or suggest one might exist and without prejudice to the measures laid down in the fourth subparagraph of Article 3 (1) of Council Directive 89/662/EEC, the appropriate measures shall be taken, under official supervision.

(3) Rules for the application of the second subparagraph of paragraph 1 shall be established in accordance with requirements of European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

Approval of Establishments.

7. (1) The Veterinary Services shall approve establishments once they have verified that these establishments meet the requirements of these rules, with regard to the nature of the activities they carry out. The approval must be renewed if an establishment decides to carry out activities other than those for which it has received approval. The Veterinary Services shall take the necessary measures if the requirements cease to be met. To this end, they shall take particular account of the conclusions of any check carried out in accordance with Article 8. The competent authority shall register those auction and wholesale markets which are not subject

to approval after verifying that such installations comply with the provisions of these rules.

(2) The Veterinary Services shall draw up a list of their approved establishments, each of which shall have an official number. Veterinary Services shall notify the European Commission of its list of approved establishments and of any subsequent amendment thereof.

(3) The inspection and monitoring of establishments shall be carried out regularly under the responsibility of the competent authority, which shall at all times have free access to all parts of establishments, in order to ensure compliance with the requirements of these rules. If such inspections and monitoring reveal that the requirements of these rules are not being met, the competent authority shall take appropriate action.

(4) Sub-rules (1),(2) and (3) shall also apply in respect of factory vessels.

(5) Sub-rules (2) and (3) shall also apply to wholesale and auction markets.

Spot-checks.

8 (1) Experts from the European Commission may, in co-operation with the Veterinary Services or any other relevant authority of Malta, make on-the-spot checks insofar as this is necessary to ensure the uniform application of these rules and the proper implementation of Council Directive 91/493/EEC. These experts may in particular verify whether establishments are in effect complying with the requirements of these rules.
(2) All persons responsible under the provisions of these rules and of Council Direcive 91/493/EEC shall ensure that experts are given free access to the establishment owned or directly or indirectly controlled by them, and that all the staff of the establishment co-operate with the experts at all times and that they allow the same experts access to all manual and electronic data found within the establishment.

Applicable provisions.

9. Provisions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of European Community products. Fishery products caught in their natural environment by a fishing vessel flying the flag of a third country must undergo the checks laid down in Article 19 (2) of Directive 97/78/EEC.

Third Countries.

10. (1) For any third country or group of third countries, fishery products must fulfil the specific import conditions fixed by decision of the European Commission, depending on the health situation in the third country concerned.

(2) For the purpose of allowing the import conditions to be fixed, and in order to verify the conditions of production, storage and dispatch of fishery products for consignment to the Community, experts from the European Commission or experts from the Member States appointed by the Commission for such purpose, shall have the right to carry out inspections. These inspections shall be made on behalf of the Community, which shall bear any expenditure incurred..

(3) When fixing the import conditions of fishery products referred to in sub-rule (1), particular account shall be taken of:

(a) the legislation of the third country;
(b) the organisation of the competent authority of the third country and of its inspection services, the powers of such services and the supervision to which they are subject, as well as their facilities for effectively verifying the implementation of their legislation in force;
(c) the actual health conditions during the production, storage and dispatch of fishery products intended for the European Community;
(d) the assurances which a third country can give on the compliance with the standards laid down in Chapter V of the Annex.

(4) The import conditions referred to in sub-rule (1) shall include:

(a) the procedure for obtaining a health certificate which must accompany consignments when forwarded to the European Community;
(b) the placing of a mark identifying the fishery products, in particular with the approval number of the establishment of origin, except in the case of frozen fishery products, landed immediately for canning and bearing the certificate provided for under paragraph (a) hereof;
(c) drawing up a list of approved establishments and auction or wholesale markets registered and approved by the European Commission; For that purpose, one or more lists of such establishments shall draw up on the basis of a communication from the competent authorities of the third country to the European Commission. An establishment may not appear on a list unless it is officially approved by the competent authority of the third country exporting to the European Community. Such approval shall be subject to observance of the following requirements:

(i) compliance with requirements equivalent to those laid down in the Council Directive 91/493/EEC,
(ii)monitoring by an official inspection service of the third country.

(5) The conditions referred to in sub-rule (4) (a) and (b) may be modified by the European Commission. The list referred to in sub-rule (4) (c) may be amended by the European Commission, in accordance with the rules established by Commission Decision 90/13/EEC.

(6) To deal with specific situations , imports may be authorised by the European Commission direct from an establishment or factory vessel of a third country where

the latter is unable to provide the guarantees laid down in sub-rule (3), provided that the establishment or factory vessel in question has received special approval following an inspection carried out in accordance with sub-rule (2).
The authorisation decision shall fix the specific import conditions to be followed for products coming from that establishment or factory vessel.

(7) Pending the fixing of the import conditions referred to in paragraph 1, the Veterinary Services of Malta shall ensure that the conditions applied to imports of fishery products from third countries shall be at least equivalent to those governing the production and placing on the market of European Community products.

Applicable rules.

11. The rules and principles laid down by Council Directive 97/78/EC shall apply, notably as regards the organisation of and follow up to the inspections to be carried out by the Member States, and in particular for Malta by the Veterinary Services when fishery products are introduced into the European Community via the territory of Malta.

ANNEX

CHAPTER I

Conditions applicable to factory vessels

I. Conditions concerning design and equipment

1. The minimum requirements for factory vessels are as follows:

(a) a reception area set aside for taking fishery products on board, designed and arranged into pounds or pens that are large enough to allow each successive catch to be separated. The reception area and its movable parts must be easy to clean. It must be designed in such a way as to protect the products from the sun or the elements and from any source of dirt or contamination;
(b) a system for conveying fishery products from the reception area to the work area that conforms with rules of hygiene;
(c) work areas that are large enough for the preparation and processing of fishery products in proper conditions of hygiene. They must be designed and arranged in such a way as to prevent any contamination of the products;
(d) storage areas for the finished products that are large enough and designed so that they are easy to clean. If a waste-processing unit operates on board, a separate hold must be designated for the storage of these by-products;
(e) a place for storing packaging materials that is separate from the product preparation and processing areas;
(f) special equipment for pumping waste or fishery products that are unfit for human consumption either directly into the sea or, where circumstances so require,

into a watertight tank reserved for that purpose. If waste is stored and processed on board with a view to cleaning, separate areas must be allocated for that purpose;
(g) equipment providing a supply of potable water within the meaning of Community rules relating to the quality of water intended for human consumption or pressurised clean seawater. The seawater intake must be situated in a position where it is not possible for the water being taken in to be affected by discharges into the sea of waste water, waste and engine coolant outlets;
(h) a suitable number of changing rooms, wash basins and toilets, the latter not opening directly onto areas where fishery products are prepared, processed or stored. The wash basins must be equipped with appliances for washing and drying the hands that comply with hygiene requirements; the washbasin taps must not be hand-operable.
2. Areas used for the preparation and processing or freezing/quick-freezing of fishery products must have:
(a) a non-slip floor that is also easy to clean and disinfect and equipped for easy drainage of water. Structures and fixtures must have limber holds that are large enough not to be obstructed by fish waste and to allow water to drain freely;
(b) walls and ceilings that are easy to clean, particularly where there are pipes, chains or electricity conduits;
(c) the hydraulic circuits must be arranged or protected in such a way as to ensure that it is not possible for any leakage of oil to contaminate fishery products;
(d) adequate ventilation and, where necessary, proper vapour extraction;
(e) adequate lighting;
(f) appliances for cleaning and disinfecting tools, equipment and fittings;
(g) appliances for cleaning and disinfecting the hands with taps that are not hand-operable and with single use towels.
3. Equipment and tools such as cutting benches, containers, conveyors, gutting or filleting machines, must be resistant to seawater corrosion, easy to clean and disinfect and well maintained.
4. Factory vessels which freeze fishery products must have:
(a) a refrigeration plant sufficiently powerful to lower the temperature rapidly so as to achieve a core temperature that complies with the specifications of these rules ;
(b) refrigeration plants sufficiently powerful to keep fishery products in the storage holds at a temperature that complies with the specifications of these rules. The storage holds must be equipped with a temperature recording system placed so that it can easily be consulted.

II. Conditions of hygiene relating to onboard handling and storage of fishery products

1. A qualified person on board the factory vessel must be responsible for applying good fishery products manufacturing practices. That person shall have the authority to ensure that the provisions of these rules are applied and shall make available to inspectors the program for inspecting and checking critical points as applied on board, a register containing that person's comments and the temperature recordings that may be required.
2. The general conditions of hygiene applicable to areas and equipment shall be those laid down in Chapter III, section II (A), of this Annex.

3. The general conditions of hygiene applicable to staff shall be those laid down in Chapter III, section II (B), of this Annex.
4. Heading, gutting and filleting must be carried out under the conditions of hygiene laid down in Chapter IV, section I (2), (3) and (4) of this Annex.
5. Onboard processing of fishery products must be carried out under the conditions of hygiene laid down in Section II, points 2 and 3, Section IV and Section V of Chapter IV of this Annex.'
6. Fishery products must be wrapped and packaged under the conditions of hygiene laid down in Chapter VI of this Annex.
7. Onboard storage of fishery products must be carried out under the conditions of hygiene laid down in Chapter VIII, points 1 and 2, of this Annex.

CHAPTER II

Requirements during and after landing

1. Unloading and landing equipment must be constructed of material which is easy to clean and disinfect and must be kept in a good state of repair and cleanliness.
2. During unloading and landing, contamination of fishery products must be avoided. It must in particular be ensured that:
- unloading and landing operations proceed rapidly;
- fishery products are placed without unnecessary delay in a protected environment at the temperature required on the basis of the nature of the product and, where necessary, in ice in transport, storage or market facilities, or in an establishment;
- equipment and handling practices that cause unnecessary damage to the edible parts of the fishery products are not authorised.
3. Parts of auction or wholesale markets where fishery products are displayed for sale must:
(a) be covered and have walls which are easy to clean;
(b) have waterproof flooring which is easy to wash and disinfect and laid in such a way as to facilitate the drainage of water and have a hygienic waste water disposal system;
(c) be equipped with sanitary facilities with an appropriate number of wash basins and flush lavatories. Wash basins shall be supplied with materials for cleaning the hands and single use hand towels;
(d) be well lit to facilitate the inspection of fishery products provided for in Chapter V of this Annex;
(e) when they are used for display or storage of fishery products, not be used for other purposes; vehicles emitting exhaust fumes which may impair the quality of the fishery products not be admitted to markets; undesirable animals must not be admitted;
(f) be cleaned regularly and at least after each sale; crates must, after each sale, be cleaned and rinsed inside and outside with drinking water or clean seawater; where required, they must be disinfected;
(g) have displayed in a prominent position signs prohibiting smoking, spitting, eating and drinking;
(h) be closeable and be kept closed when the Veterinary Services considers it necessary;

(i) have facilities to provide adequate water supplies satisfying the conditions laid down in Chapter III, section I, point 7 of this Annex;
(j) have special watertight receptacles made of corrosion-resistant materials for fishery products which are unfit for human consumption;
(k) insofar as they do not have their own premises on-the-spot or in the immediate vicinity on the basis of the quantities displayed for sale, have, for the purposes of the Veterinary Services, an adequately equipped lockable room and the equipment necessary for carrying out inspections.
4. After landing or, where appropriate, after first sale, fishery products must be transported without delay, under the conditions laid down in Chapter VIII, of this Annex, to their place of destination.
5. However, if the conditions laid down in point 4 are not fulfilled, the markets in which fishery products may be stored before being displayed for sale or after being sold and pending transport to their place of destination must have sufficiently large cold rooms which satisfy the conditions laid down in Chapter III, section I, point 3 of this Annex. In such cases, fishery products must be stored at a temperature approaching that of melting ice.
6. The general conditions of hygiene laid down in Chapter III, section II with the exception of point B 1 (a) of this Annex shall apply mutatis mutandis to the markets in which fishery products are displayed for sale or stored.
7. The wholesale markets in which fishery products are displayed for sale or stored shall be subject to the same conditions as those laid down in points 3 and 5 of this Chapter and to those set out in points 4, 10 and 11 of Chapter III, section I of this Annex. The general conditions of hygiene laid down in Chapter III, section II of this Annex shall apply mutatis mutandis to wholesale markets.

CHAPTER III

General conditions for establishments on land

I. General conditions relating to premises and equipment Establishment shall afford at least the following facilities:
1. working areas of sufficient size for work to be carried out under adequate hygienic conditions. Their design and layout shall be such as to preclude contamination of the product and keep quite separate the clean and contaminated parts of the building;
2. in areas where products are handled, prepared and processed:
(a) waterproof flooring which is easy to clean and disinfect and laid down in such a way as to facilitate the drainage of the water or provided with equipment to remove water;
(b) walls which have smooth surfaces and are easy to clean, durable and impermeable;
(c) ceilings or roof linings which are easy to clean;
(d) doors in durable materials which are easy to clean;
(e) adequate ventilation and, where necessary, good steam and watervapour extraction facilities;
(f) adequate natural or artificial lighting;

(g) an adequate number of facilities for cleaning and disinfecting hands. In work rooms and lavatories taps must not be hand-operable. These facilities must be provided with single use hand towels;
(h) facilities for cleaning plant, equipment and utensils;
3. in cold rooms where fishery products are stored:
- the provisions set out under point 2 (a), (b), (c), (d) and (f) ;
- where necessary, a sufficiently powerful refrigeration plant to keep products at temperatures prescribed in these rules;
4. appropriate facilities for protection against pests such as insects, rodents, birds, etc.;
5. instruments and working equipment such as cutting tables, containers, conveyor belts and knives made of corrosion-resistant materials, easy to clean and disinfect;
6. special watertight, corrosion-resistant containers for fishery products not intended for human consumption and premises for the storage of such containers if they are not emptied at least at the end of each working day;
7. facilities to provide adequate supplies of drinking water within the meaning of Community rules, or alternatively of clean seawater or seawater treated by an appropriate system, under pressure and in sufficient quantity. However, by way of exception, a supply of non-drinking water is permissible for the production of steam, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products. Non-drinking water pipes must be clearly distinguished from those used for drinking water or clean seawater;
8. hygienic waste water disposal system;
9. an adequate number of changing rooms with smooth, waterproof, washable walls and floors, wash basins and flush lavatories. The latter may not open directly onto the work rooms. The wash basins must have materials for cleaning the hands and disposable towels; the wash basin taps must not be hand-operable;
10. if the volume of products treated requires regular or permanent presence an adequately equipped lockable room for the exclusive use of the inspection service;
11. adequate facilities for cleaning and disinfecting means of transport. However, such facilities are not compulsory if there is a requirement for the means of transport to be cleaned and disinfected at facilities officially authorised by the Veterinary Services;
12. establishments keeping live animals such as crustaceans and fish must have appropriate fittings ensuring the best survival conditions provided with water of a quality such that no harmful organisms or substances are transferred to the animals.

II. General conditions of hygiene

A. General conditions of hygiene applicable to premises and equipment
1. Floors, walls and partitions, ceilings or roof linings, equipment and instruments used for working on fishery products must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the products.
2. Rodents, insects and any other vermin must be systematically exterminated in the premises or on the equipment; rodenticides, insecticides, disinfectants and any

other potentially toxic substances must be stored in premises or cupboards which can be locked; their use must not present any risk of contamination of the products.
3. Working areas, instruments and working equipment must be used only for work on fishery products. However, following authorisation by the Veterinary Services they may be used at the same time or other times for work on other foodstuffs.
4. Drinking water, within the meaning of Community rules, or clean seawater must be used for all purposes. However, by way of an exception, non-drinking waster may be used for steam production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for the purpose preclude the use of such water for other purposes and present no risk of contamination of the products.
5. Detergents, disinfectants and similar substances must be approved by the Veterinary Services and used in such a way that they do not have adverse effects on the machinery, equipment and products.
B. General conditions of hygiene applicable to staff
1. The highest possible standard of cleanliness is required of staff. More specifically:
(a) staff must wear suitable clean working clothes and headgear which completely encloses the hair. This applies particularly to persons handling exposed fishery products;
(b) staff assigned to the handling and preparation of fishery products must be required to wash their hand at least each time work is resumed; wounds to the hands must be covered by a waterproof dressing;
(c) smoking, spitting, eating and drinking in work and storage premises of fishery products must be prohibited.
2. The employer shall take all the requisite measures to prevent persons liable to contaminate fishery products from working on and handling them, until there is evidence that such persons can do so without risk. When recruited, any person working on and handling fishery products shall be required to prove, by a medical certificate, that there is no impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in Malta or in the case of third countries by specific guarantees to be fixed by the European Commission.

CHAPTER IV

Special conditions for handling fishery products on shore

I. Conditions for fresh products

1. Where chilled, unpacked products are not dispatched, prepared or processed immediately after reaching the establishment, they must be stored or displayed under ice in the establishment's cold room. Re-icing must be carried out as often as is necessary; the ice used, with or without salt, must be made from drinking water or clean seawater and be stored under hygienic conditions in receptacles provided for the purpose; such receptacles must be kept clean and in a good state of repair.
Pre-packed fresh products must be chilled with ice or mechanical refrigeration plant creating similar temperature conditions.

2. If they are not carried out on board, operations such as heading and gutting must be carried out hygienically. The products must be washed thoroughly with drinking water or clean seawater immediately after such operations.
3. Operations such as filleting and slicing must be carried out in such a way as to avoid the contamination or spoilage of fillets and slices, and in a place other than that used for heading and gutting operations 'Fillets and slices must not remain on work tables any longer than is necessary for their preparation and must be protected from contamination by appropriate packaging.' Fillets and slices to be sold fresh must be chilled as quickly as possible after preparation.
4. Guts and parts that may constitute a danger to public health must be separated from and removed from the vicinity of products intended for human consumption.
5. Containers used for the dispatch or storage of fresh fishery products must be designed in such a way as to ensure both their protection from contamination and their preservation under sufficiently hygienic conditions and, more particularly, they must provide adequate drainage of melt water.
6. Unless special facilities are provided for the continuous disposal of waste, the latter must be placed in leak-proof, covered containers which are easy to clean and disinfect. Waste must not be allowed to accumulate in working areas. It must be removed either continuously or as soon as the containers are full and at least at the end of each working day in the containers or to the premises referred to in Chapter III, section I, paragraph 6 of this Annex. The containers, receptacles and/or premises set aside for waste must always be thoroughly cleaned and, if appropriate, disinfected after use. Waste stored there must not constitute a source of contamination for the establishment or of pollution of its surroundings.

II. Conditions for frozen products

1. Plants must have:
(a) freezing equipment sufficiently powerful to achieve a rapid reduction in the temperature so that the temperatures laid down to in these rules can be obtained in the product;
(b) freezing equipment sufficiently powerful to keep products in storage rooms at a temperature not exceeding those laid down in these rules, whatever the ambient temperature may be. However, for technical reasons related to the method of freezing and to the handling of such products, for whole fish frozen in brine and intended for canning, higher temperatures than those laid down in these rules are acceptable although they may not exceed -9 °C.
2. Fresh products to be frozen or quick-frozen must comply with the requirements of section I of this Chapter.
3. Storage rooms must have a temperature-recording device in a place where it can easily be read. The temperature sensor of the recorder must be located in the area furthest away from the cold source, i.e. where the temperature in the storage room is the highest. Temperature charts must be available for inspection by the supervisory authorities at least during the period in which the products are stored.

III. Conditions for thawing products

Establishments that carry out thawing operations must comply with the following requirements:

1. fishery products must be thawed under hygienic conditions; their contamination must be avoided and there must be adequate drainage for any melt water produced. During thawing, the temperature of the products must not increase excessively;

2. after thawing, fishery products must be handled in accordance with the requirements of these rules. When they are prepared or processed, these operations must be carried out without delay. If they are put directly onto the market, particulars as to the thawed state of the fish must be clearly marked on the packaging in accordance with Article 5 (3) of Council Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

IV. Conditions for processed products

1. Fresh, frozen and thawed products used for processing must comply with the requirements set out in I, II or III of this Chapter.

2. Where the processing treatment is carried out to inhibit the development of pathogenic micro organisms, or if it is a significant factor in the preservation of the product, the treatment must be scientifically recognised by the law in force, or in the case of a treatment of products referred to in Chapter I Section 1 (b) and (c) of Directive 91/492/EEC which have not been relayed or purified, such treatment must be approved in accordance with requirements of European Community and in accordance with the procedure laid down in Chapter 437 Veterinary Services Act, Article 10. The person responsible for an establishment must keep a register of the processing carried out. Depending on the type of process employed, heating time and temperature, salt content, pH, water content, etc., must be monitored and controlled. Records must be kept at least for the expected storage life of the products and be available to the Veterinary Services.

3. For products which are preserved for a limited period by a treatment such as salting, smoking, drying or marinating, the appropriate conditions for storage must be clearly marked on the packaging, in accordance with Council Directive 2000/13/EC. In addition, the following conditions shall be complied with.

4. Canning

In the case of fishery products which have been subjected to sterilisation in hermetically sealed containers:

(a) the water used for the preparation of cans must be drinking water;

(b) the process used for the heat treatment must be appropriate, having regard to such major criteria as the heating time, temperature, filling, size of containers, etc., a record of which must be kept; the heat treatment must be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms. The heating equipment must be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment. Drinking water must be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and containers;

(c) further checks must be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment, viz.:
- incubation tests: incubation must be carried out at 37 °C for seven days or at 35 °C for ten days, or at any other equivalent combination;
- microbiological examination of contents and containers in the establishment's laboratory or in another approved laboratory;
(d) samples must be taken of production each day at predetermined intervals to ensure the efficacy of sealing or of any other method of hermetic closure.' For that purpose, appropriate equipment must be available for the examination of cross-sections of the canseams;
(e) checks are carried out in order to ensure that containers are not damaged;
(f) all containers which have undergone heat treatment under practically identical conditions must be given a batch identification mark, in accordance with Council Directive 89/396/EEC of 14 June 1989 on indications or marks identifying the lot to which a foodstuff belongs.
5. Smoking
Smoking must be carried out in separate premises or a special place equipped, if necessary, with a ventilation system to prevent the smoke and heat from the combustion from affecting other premises or places where fishery products are prepared, processed or stored.
(a) Materials used to produce smoke for the smoking of fish must be stored away from the place of smoking and must be used in such a way that they do not contaminate the products.
(b) Materials used to produce smoke by burning wood that has been painted, varnished, glued or has undergone any chemical preservation treatment must be prohibited.
(c) After smoking, products must be cooled rapidly to the temperature required for their preservation before being packaged.
6. Salting
(a) Salting operations must take place in different premises and sufficiently removed from the premises where the other operations are carried out.
(b) Salt used in the treatment of fishery products must be clean and stored in such a way as to preclude contamination. It must not be reused. (c) Any container used for salting or brining must be constructed in such a way as to preclude contamination during the salting or brining process. (d) Containers or areas used for salting or brining must be cleaned before use.
7. Cooked crustacean and molluscan shellfish products Crustaceans and molluscan shellfish must be cooked as follows:
(a) any cooking must be followed by rapid cooling. Water used for this purpose must be drinking water or clean seawater. If no other method of preservation is used, cooling must continue until the temperature approaching that of melting ice is reached;
(b) shelling or shucking must be carried out under hygienic conditions avoiding the contamination of the product. Where such operations are done by hand, workers must pay particular attention to the washing of their hands and all working surfaces must be cleaned thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected after each working day. After shelling or shucking, cooked

products must immediately be frozen or kept chilled at a temperature which will preclude the growth of pathogens, and be stored in appropriate premises;
(c) every manufacturer must carry out microbiological checks on his production at regular intervals, complying with the standards to be fixed in accordance with Chapter V, Section 4 of this Annex.
8. Mechanically recovered fish flesh The mechanical recovery of fish flesh must be carried out under the following conditions:
(a) mechanical recovery of gutted fish must take place without undue delay after filleting, using raw materials free of guts. Where whole fish are used, they must be gutted and washed beforehand;
(b) the machinery must be cleaned at frequent intervals and at least every two hours;
(c) after recovery, mechanically recovered flesh must be frozen as quickly as possible or incorporated in a product intended for freezing or stabilising treatment.

V. Conditions concerning parasites

1. During production and before they are released for human consumption, fish and fish products must be subject to a visual inspection for the purpose of detecting and removing any parasites that are visible. Fish or parts of fish which are obviously infested with parasites, and which are removed, must not be placed on the market for human consumption. The detailed rules for this inspection shall be adopted in accordance with requirements of European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act.
2. The fish and fish products referred to in point 3 which are to be consumed as they are must, in addition, be subjected to freezing at a temperature of not more than 20° C in all parts of the product for not less than 24 hours. Products subjected to this freezing process must be either raw or finished.
3. Fish and products subject to the conditions in point 2:
(a) fish to be consumed raw or almost raw, e.g. raw herring 'maatje';
(b) the following species, if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60°C:
- herring,
- mackerel,
- sprat,
- (wild) Atlantic and Pacific salmon;
(c) marinated and/or salted herring where this process is insufficient to kill the larvae of nematodes.
This list may be amended, in the light of scientific data, in accordance with requirements of European Community and in accordance with the procedure laid down in Chapter 437 Veterinary Services Act, Article 10. In accordance with the same procedure, criteria will be laid down which must enable the processes which are deemed sufficient or insufficient to destroy nematodes to be defined.
4. Manufacturers must ensure that fish and fish products listed in point 3 or the raw materials for use in their manufacture are subjected to the treatment described in point 2, prior to their release for consumption.

5. The fishery products listed in point 3 must, when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone.

CHAPTER V

Health control and monitoring of production conditions

I. General monitoring

Arrangements for checking and monitoring must be made by the competent authorities in order to establish whether the requirements laid down in these rules are complied with such arrangements will include, in particular:
1. a check on the fishing vessels, on the understanding that such a check may be carried out during the stay in port;
2. a check on the conditions of landing and first sale;
3. an inspection at regular intervals of establishments to check, in particular:
(a) whether the conditions for approval are still fulfilled;
(b) whether the fishery products are handled correctly;
(c) the cleanliness of the premises, facilities and instruments and staff hygiene;
(d) whether identification marks are put on correctly;
4. an inspection of the wholesale and auction markets;
5. a check on storage and transport conditions.

II. Special checks

1. Organoleptic checks
Without prejudice to the derogation provided for by Council Regulation (EC) No 2406/96 of the 26th November 1996 laying down common marketing standards for certain fishery products, each batch of fishery products must be submitted for inspection by the Veterinary Services at the time of landing or before first sale to check whether they are fit for human consumption. This inspection comprises an organoleptic check carried out by sampling.
Fishery products complying, as far as the freshness criteria are concerned, with the common marketing standards already laid down pursuant to Article 2 of Regulation (EEC) No 3796/81 are considered to fulfil the organoleptic requirements necessary for compliance with the provisions of these rules. Specific organoleptic requirements for fishery products not harmonised under Regulation (EC) No 104/2000 of the 17th December 1999 on the common organisation of the markets in fishery and aquaculture products may, where necessary be applied according to European Commission Decision.
The organoleptic examination must be repeated after the first sale of fishery products, if it is found that the requirements of these rules have not been complied with or when considered necessary. After the first sale, fishery products must at least comply with the minimum freshness requirements of the aforementioned Regulation.
If the organoleptic examination reveals that the fishery products are not fit for human consumption, measures must be taken to withdraw them from the market

and denature in such a way that they cannot be reused for human consumption. If the organoleptic examination reveals any doubt as to the freshness of the fishery products, use may be made of chemical checks or microbiological analyses.

2. Parasite checks

Before they are released for human consumption, fish and fish products must be subject to a visual inspection, by way of sample, for the purpose of detecting any parasites that are visible. Fish or parts of fish which are obviously infested with parasites, and which are removed, must not be placed on the market for human consumption. The detailed rules for this inspection shall be established in accordance with requirements of European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

3. Chemicals checks

A. Samples must be taken and subjected to laboratory analysis for the control of the following parameters:

(a) TVBN (Total Volatile Basic Nitrogen) and TMAN (TrimethylamineNitrogen) The levels of these parameters must be specified for each category of species , in accordance with requirements of European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

(b) Histamine Nine samples must be taken from each batch. These must fulfil the following requirements:

- the mean value must not exceed 100 ppm;
- two samples may have a value of more than 100 ppm but less than 200 ppm;
- no sample may have a value exceeding 200 ppm. These limits apply only to fish species of the following families:

scombridae, clupeidae, engraulidae and coryphaenidae.

However, fish belonging to these families which have undergone enzyme ripening treatment in brine may have higher histamine levels but not more than twice the above values. Examinations must be carried out in accordance with reliable, scientifically recognised methods, such as high-performance liquid chromatography (HPLC).

B. In accordance with requirements of European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act, the following shall be decided on:

(a) the methods of analysis to be used to check the chemical parameters, as well as the sampling plans;

(b) the acceptable levels for the chemical parameters.

4. Microbiological analyses:

In accordance with requirements of European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act, microbiological criteria, including sampling plans and methods of analysis, may be laid down when there is a need to protect public health.

CHAPTER VI

Packaging

1. Packaging must be carried out under satisfactory conditions of hygiene, to preclude contamination of the fishery products.
2. Packaging materials and products liable to enter into contact with fishery products must comply with all the rules of hygiene, and in particular:
- they must not be such as to impair the organoleptic characteristics of the fishery products;
- they must not be capable of transmitting to the fishery products substances harmful to human health;
- they must be strong enough to protect the fishery products adequately.
3. With the exception of certain containers made of impervious, smooth and corrosion-resistant material which are easy to clean and disinfect, which may be reused after cleaning and disinfecting, packaging materials may not be reused. Packaging materials used for fresh products held under ice must provide adequate drainage for melt water.
4. Unused packaging materials must be stored in premises away from the production area and be protected from dust and contamination.

CHAPTER VII

Identification marks

Without prejudice to the provisions of Council Directive 2000/13/EC, it must be possible to trace for inspection purposes the establishment of dispatch of consignments of fishery products, by means either of labelling or of the accompanying documents. For that purpose, the following information must appear on the packaging or, in the case of a non-packaged product, in the accompanying documents:
- the country of dispatch, which may be written out in full or shown as an abbreviation, using capital letters, for Malta : **MT**,
- identification of the establishment or factory vessel by its official approval number or, in the case of marketing from a freezer vessel covered by point 7 of Annex II to Council Directive 92/48/EEC, the identification number of the vessel, or, in the case of separate registering of auction or wholesale markets as laid down in the third subparagraph of Article 7 (1) of these rules, the registration number of the auction or wholesale market,
- the following abbreviations:
KEE. All the letters and figures must be fully legible and grouped together on the packaging in a place where they are visible from the outside without any need to open the said packaging..

CHAPTER VIII

Storage and transport

1. Fishery products must, during storage and transport, be kept at the temperatures laid down in these rules and in particular:
- fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products must be kept at the temperature of melting ice;
- frozen fishery products, with the exception of frozen fish in brine intended for the manufacture of canned foods, must be kept at an even temperature of 18 °C or less in all parts of the product, allowing for the possibility of brief upward fluctuations of not more than 3° C, during transport;
- processed products must be kept at the temperatures specified by the manufacturer, when the circumstances so require, prescribed in accordance with requirements of European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act.
2. Where frozen fishery products are transported from a cold-storage plant to an approved establishment to be thawed on arrival for the purposes of preparation and/or processing and where the distance to be covered is short, not exceeding 50 km or one hour's journey, the Veterinary Services may grant a derogation from the conditions laid down in point 1, second indent.
3. Products may not be stored or transported with other products, which may contaminate them or affect their hygiene, unless they are packaged in such a way as to provide satisfactory protection.
4. Vehicles used for the transport of fishery products must be constructed and equipped in such a way that the temperatures laid down in these rules can be maintained throughout the period of transport. If ice is used to chill the products, adequate drainage must be provided in order to ensure that water from melted ice does not stay in contact with the products. The inside surfaces of the means of transport must be finished in such a way that they do not adversely affect the fishery products. They must be smooth and easy to clean and disinfect.
5. Means of transport used for fishery products may not be used for transporting other products likely to impair or contaminate fishery products, except where the fishery products can be guaranteed uncontaminated as a result of such transport being thoroughly cleaned and disinfected.
6. Fishery products may not be transported in a vehicle or container which is not clean or which should have been disinfected.
7. The transport conditions of fishery products to be placed on the market alive must not adversely affect the products.

CHAPTER IX

Points of annex i which may be subject to derogation and possible conditions applicable in the case of derogation

Re Chapter I Part I of the Annex

1. Point 1 (a)

provided products are sheltered from the sun and the elements and from any source of dirt or contamination.
2. Point 1 (c)
provided any contamination of the products is prevented.
3. Point 1 (d), first sentence
provided the finished products are stored on board at the required temperature.
4. Point 1 (g), last sentence
provided products cannot be contaminated by waste water, waste or engine coolant.
5. Point 1 (h)
provided staff handling fishery products can wash their hands after using the toilet.
6. Point 2 (a)
provided floors are properly cleaned and disinfected.
7. Point 2 (b), (c) and (d)
8. Point 2 (g) on taps and towels
9. Point 3
provided equipment and tools are well maintained.

Re Chapter II of the Annex

10. Point 3 (a)
provided the walls are kept clean.
11. Point 3 (b)
provided the flooring is kept clean after every sale.
12. Point 3 (c), first sentence
13. Point 3 (e): vehicles emitting exhaust fumes
provided products contaminated by exhaust fumes are withdrawn from the market.
14. Point 3 (j)
provided that products which are not fit for human consumption cannot contaminate or be mixed with fishery products.
15. Point 3 (k)
16. Point 7
insofar as it refers to point 3 of the same Chapter and point 10 of Chapter III, section I.

Re Chapter III Part I of the Annex

17. Point 1
provided finished products cannot be contaminated by raw materials or waste.
18. Point 2 (a)
provided the flooring is cleaned and disinfected accordingly.
19. Point 2 (b)
provided the walls are kept clean.
20. Point 2 (c)
provided the ceiling is not a source of contamination.
21. Point 2 (d)
22. Point 2 (e)
provided products cannot be spoilt or contaminated by the steam.
23. Point 2 (g)
provided there are facilities available for staff to wash their hands.

24. Point 3
25. Point 5
insofar as it relates to corrosion-resistant materials provided instruments and working equipment are kept clean.
26. Point 6
provided products cannot be contaminated by waste or leakage therefrom.
27. Point 10

Re Chapter IV of the Annex

28. Part I, point 1
in respect of the requirement for products being held over to be put in the establishment's cold room provided the products are re-iced as often as necessary during a period not in excess of 12 hours or that a nearby cold room not belonging to the establishment can be used.
29. Part I, point 6
in respect of the requirement for waste to be put in leakproof covered containers provided products cannot be contaminated by waste or leakage therefrom.
30. Part IV, point 5, first paragraph
provided that every precaution is taken to prevent fishery products that are being prepared or stored from being affected by the smoke.
31. Part IV, point 6 (a)
provided fishery products that are being prepared or stored are not affected by salting operations

Nru. 1216

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikoli10, 11 u 12 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regolamenti ta' l-2004 dwar ir-Rekwiżiti tas-Saħħa ta' l-Annimali u s-Saħħa Pubblika li jirregolaw il-Kummerċ u l-Importazzjoni fil-Komunità Ewropea ta' Prodotti mhux soġġetti għar-Rekwiżiti msemmija stipulati f'regoli veterinarji speċifiċi oħra.

Id-19 ta' Novembru, 2004

No. 1216

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 10, 11, 12 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

The animal health and public health requirements governing trade in and imports into the European Community of products not subject to the said requirements laid down in other specific veterinary rules Regulations, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

The animal health and public health requirements governing trade in and imports into the European Community of products not subject to the said requirements laid down in other specific veterinary rules Regulations, 2004

IN exercise of the powers conferred by articles 10, 11 and 12 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment after consultation with the Minister of Health, the Elderly and Community Care, has made the following rules :

Title and Scope

1. (1) The title of these rules is the animal health and public health requirements governing trade in and imports into the European Community of products not subject to the said requirements laid down in other specific veterinary requirements rules, 2004

(2) These rules implement the provisions found under European Union Council Directive 92/118/EEC of the 17th December, 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC.

Health requirements

2. (1) These rules lay down the animal health and public health requirements governing trade in and imports into the European Community of products of animal origin (including trade samples taken from such products) not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogenic agents, to Directive 90/425/EEC.

(2) These Rules shall be without prejudice to the adoption of more detailed rules on animal health in the framework of the aforesaid specific rules nor the maintenance of restrictions on trade or imports of products covered by the specific rules referred to in sub-rule (1) hererof based on the rules of public health.

Interpretation

3. For the purposes of these Rules-

"trade" means trade as defined by Article 2 (2) of Directive 89/662/EEC);

"trade sample" means a sample of no commercial value, taken on behalf of the owner or the person responsible for an establishment, which is representative of a given product of animal origin produced by that establishment, or constitutes a specimen of a product of animal origin the manufacture of which is contemplated, and which, for the purposes of subsequent examination, must bear a reference to the type of product, its composition and the species of animal from which it was obtained;

"serious transmissible" disease means all diseases covered by the second schedule in the Veterinary Services Act;

"pathogenic agents" means any collection or culture of organisms or any derivative, present either alone or in the form of a manipulated combination of such a collection or culture of organisms capable of causing disease in any living being (other than man) and any modified derivatives of these organisms, which can carry or transmit an animal pathogen, or the tissue, cell culture, secretions or excreta by which or by means of which an animal pathogen can be carried or transmitted; this definition does not include the immunological veterinary medicinal products authorised pursuant to Directive 2001/82/EC of the European Parliament and of the Council 2001/82/EC of 6 November 2001 on the Community code relating to veterinary medicinal products;

processed animal protein intended for human consumption means greaves, meat-meal and porkrind powder referred to in Article 2 (b) of Council Directive (77/99);

(2) In addition, the definitions contained in Article 2 of Directives 89/662, 90/425 and 97/78 shall apply mutatis mutandis.

Duties of Veterinary Services

4. Veterinary Services shall ensure that:

(a) trade in and imports of products of animal origin referred to in regulation 2 are not prohibited or restricted for animal health or public health reasons other than those arising from the application of these rules or from European Community legislation, and in particular any safeguard measures taken,

(b)any new product of animal origin intended for human consumption whose placing on the market in a Malta or another Member State is authorised after the date provided for in Article 20 of the European Union Council Directive 92/118/EEC may not be the subject of trade or importation until a decision has been taken by the European Community, after evaluation of the real risk of the spread of serious transmissible diseases which could result from movement of the product, not only for the species from which the product originates but also for other species which could carry the disease, become a focus of disease or a risk to human health,

(c) the other products of animal origin referred to in Article 2 (b) of Council Directive (77/99) may not be the subject of trade or importation from third countries unless they meet the requirements of that Council Directive and the relevant requirements of these rules

Checks at Origin

5. Veterinary services shall take the necessary measures to ensure that, for the purposes of applying Article 4 (1) of Directive 89/662/EEC and Article 4 (1) (a) of Directive 90/425/EEC concerning checks at origin, the products of animal origin referred to in Annexes I and II and sub-rules 4(b)(c) of these rules may, without prejudice to the particular provisions to be adopted in implementation of Articles 10 (3) and 11, be the subject of trade only if they satisfy the following requirements:

1. they must meet the requirements of Article 5 and the specific requirements laid down in Annex I as regards animal health aspects and Annex II as regards public health aspects,
2. they must come from establishments which:

(a) undertake, in the light of the specific requirements laid down in Annexes I and II for the products the establishment produces, to:

(i)comply with the specific production requirements set out in this Legal Notice,

(ii) establish and implement methods of monitoring and checking the critical points on the basis of the processes used,

(iii) depending on the products, take samples for analysis in a laboratory recognised by the Veterinary services for the purpose of checking compliance with the standards established by this Legal Notice,

(iv) keep a record, whether written or otherwise recorded, of the information obtained pursuant to the preceding indents for presentation to the Veterinary Services. The results of the various checks and tests in particular shall be kept for at least two years,

(v) guarantee the administration of marking and labelling,

(vi) should the result of the laboratory examination or any other information available to them reveal the existence of a serious animal health or public health hazard, inform the competent authority,

(vii)consign, for purposes of trade, only products accompanied by a commercial document indicating the nature of the product, the name and, where appropriate, the veterinary approval number of the establishment of production;

(b) they are under supervision by the Veterinary Services to ensure that the operator or manager of the establishment complies with the requirements of this Legal Notice;

(c) they were registered by the competent authority on the basis of assurances from the establishment guaranteeing compliance with the requirements of this Legal Notice.

Guarantee about Products

6. Veterinary Services shall ensure that every necessary measure is taken to guarantee that products of animal origin referred to in Annexes I and II are not dispatched for purposes of trade from any holding, situated in a zone subject to restrictions because of the occurrence of a disease to which the species from which the product is derived is susceptible or from any establishment or zone from which movements or trade would constitute a risk to the animal health status of the Member States except where products are heat-treated in accordance with European Community legislation. Particular assurances permitting, by way of derogation from the first paragraph, the movement of certain products may be adopted by the Director in conformity with European Community requirements within the framework of safeguard measures.

Pathogenic Agents

7. Veterinary Services shall ensure that trade in pathogenic agents is subject to strict rules to be defined in accordance with requirements of European

Community and under the procedure laid down in Articles 10 and 11 Veterinary Services Act.

Follow up of Checks

8. (1) The rules on checks established by Council Directive 89/662/EEC and, as regards pathogenic agents, by Council Directive 90/425/EEC shall apply, in particular as regards the organisation of and follow-up to the checks to be carried out, to the products covered by these Rules.

(2) Article 10 of Council Directive 90/425/EEC shall apply to the products covered by these rules.

(3) For the purposes of trade, the provisions of Article 12 of Council Directive 90/425/EEC shall be extended to establishments supplying products of animal origin covered by these Rules.

(4) Without prejudice to the specific provisions of this Legal Notice, the Veterinary Services shall carry out any checks it may deem appropriate where it is suspected that these Rules is not being complied with.

(5) Veterinary Services shall take the appropriate administrative or penal measures to penalise any infringement of this Legal Notice, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the products referred to in Annexes I and II, or that the products in question do not satisfy the requirements of these Rules or have not undergone the checks provided for therein.

Applicable requirements

9. The requirements applicable to imports of products covered by these Rules must offer at least the guarantees provided for in Chapter II, including those established in implementation of Article 6, and those laid down in the sub-rules 4(b)(c).

10 (1) For the purposes of application of rule 8, the provisions in the following sub-rules shall apply.

(2) The products referred to in Annexes I and II and in the sub-rules 4(b)(c) may be imported into the European Community only if they satisfy the following requirements:

(a) unless otherwise specified in Annexes I and II, they must come from a third country or part of a third country on a list drawn up and updated by the European Community;

(b) unless otherwise specified in Annex II, products must come from establishments on a Community list drawn up by the European Community;

(c) in the cases specifically provided for in Annexes I and II and in sub-rules 4(b)(c), they must be accompanied by an animal health or public health certificate corresponding to a specimen drawn up by the European Community, certifying that the products meet the additional conditions or offer the equivalent guarantees referred to in sub-rule 3 (a) and come from establishments offering such guarantees, and signed by an official veterinarian or, as appropriate, by any other competent authority recognised. by the European Community

(3) Veterinary services and operators shall follow the provisions of the European Community legislation concerning:

(a) specific requirements established - in particular for the protection of the European Community from certain exotic diseases - or diseases transmissible to man - or guarantees equivalent to those conditions. The specific requirements and equivalent guarantees established for third countries may not be more favourable than those laid
down in Annexes I and II and in the sub-rules 4(b)(c) of Article 3:

Provided that pending the fixing of the detailed rules of application provided for in the fourth and fifth indents of Chapter 2 of Annex II, Veterinary Services shall ensure that imports of products referred to therein are subject to compliance with the minimum guarantees laid down in the said subrules.

(b) the nature of any treatment or the measures to be taken to avoid recontamination of animal casings, eggs and egg products.

(4) To implement the provisions of paragraphs 2 and 3 the Veterinary services shall take due account of the evaluation by the European Commission of the real risk of the spread of serious transmissible diseases or of diseases transmissible to man which could result from movement of the product, not only for the species from which the product originates but also for other species which could carry the disease or become a focus of disease or a risk to public health.

(5)(a) Where experts from the European Commission and the Member States carry out on the spot inspections to verify whether the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the European Community, experts from Malta may be authorised by the Director and at the request of the European Commission to participate to these inspections.

(b) These inspections shall be made on behalf of the European Community. Pending organisation of the inspections referred to in the first subparagraph, national rules applicable to inspection in third countries shall continue to apply, subject to notification, to the European commission and to the other Member

States, of any failure to comply with the guarantees offered in accordance with paragraph 3 found during these inspections.

(6) Pending compilation of the lists provided for in sub-rules 2 (a) and (b) of this rule, the Veterinary Services shall apply the border controls provided for by Council Directive 97/78/EC .

Specific Animal Health requierments

11. The Veterinary Services shall use the specific animal health requirements stipulated by the European Community for imports into the European Community and the nature and content of accompanying documents for products referred to in Annex I intended for experimental laboratories.

Organisation of Inspections

12. The principles and rules laid down in Council Directives 97/78/EC and 91/496/EEC shall apply, with particular reference to the organisation of and follow-up to the inspections to be carried out by the Veterinary Services and the safeguard measures to be implemented. However, for certain types of product of animal origin, derogation may be used in accordance with whose adopted by the European Community requirements, from the physical check provided for in Article 4 (4) (b) of Directive 97/78/EC.

13 (1) Veterinary Services may, by issuing an appropriate licence, permit the importation from third countries of products of animal origin referred to in Annexes I and II in the form of trade samples.

(2) The licence mentioned in sub-rule (1) must accompany the consignment and contain full details of the specific conditions under which the consignment may be imported, including any derogation from the checks provided for by Council Directive 97/78/EC.

(3) Where the consignment enters Malta for onward transmission to a second Member State, Veterinary Services shall ensure that the consignment is accompanied by the appropriate licence. Movement shall take place in accordance with the provisions of Council Directive 97/78/EEC. The responsibility for ensuring that the consignment complies with the conditions of the licence (and whether entry into its territory should be permitted) shall rest with the Member State which issues the licence.

14 (1) Veterinary Services shall be authorised to make the entry into the territory of Malta of products of animal origin referred to in Annexes I and II and in the sub-rules 4(b)(c) which were produced in the territory of a Member State and have passed through the territory of a third country, subject to production of an animal health or public health certificate certifying compliance with the requirements of the Council Directive 92/118/EEC.

(2) Where Veterinary Services have recourse to the possibility laid down in sub-rule (1) they shall so inform the European Commission and the other Member States.

ANNEX I

SPECIFIC ANIMAL HEALTH REQUIREMENTS

CHAPTER 1
Milk, milk products and colostrum not intended for human consumption

Trade with Member States and imports of milk, milk products and colostrum not intended for human consumption are subject to the following conditions:
1. any container in which the product is transported must be marked to indicate the nature of the product;
2. each consignment must be accompanied by, as appropriate, a commercial document as referred to in the last indent of Article 4 (2) (a) or the health certificate referred to in Article 10 (2) (c), bearing the name and registration number of the processing or treatment plant; the document or certificate must be retained by the consignee for at least one year;
3. the documents and certificates referred to in paragraph 2 must show:
(a) in the case of raw milk or colostrum, that it has been produced under conditions offering adequate guarantees as regards animal health. Such conditions must be established in accordance with the procedure laid down in Article 11 (1) of the Veterinary Framework Act concerning trade with Member States and with article12 (1) of the Veterinary Framework Act concerning import from third countries.
(b) in the case of milk or treated or processed milk products, the milk or milk product has been subjected to a heat treatment of at least 72°C for at least 15 seconds or any combination of temperature and time having at least an equivalent heat effect and producing a negative reaction to the phosphatase test, followed by
(i) in the case of dried milk or dried milk products, a drying process
(ii) in the case of an acidified milk product, a process by which the pH is reduced and kept for at least one hour at a level below 6, 0
(c) in the case of dried milk and dried milk products, the following requirements have been met:
(i) after completion of the drying process, every precaution has been taken to prevent contamination of the product;
(ii) the final product was packed in new containers;
(d) in the case of bulk containers, before the liquid milk, dried milk, or dried-milk product was loaded in any vehicle or container for conveyance to its destination, the said vehicle or container was disinfected using a product approved by the Veterinary Services.
In addition to the requirements set out in points 1, 2 and 3, imports of milk, milk products and colostrum.
Furthermore, imports of liquid milk, dried milk and dried-milk not intended for human consumption may be authorised only from third countries or parts of third countries included on the lists provided for in Order (92/46) and meeting the conditions set out in that Order. Where a risk of introduction of an exotic disease or any other risk to animal health is identified, additional conditions for the protection of animal health may be established in accordance with the procedure laid down in Article 11 (1) of the Veterinary Framework Act concerning trade with member States and with article12 (1) of the Veterinary Framework Act concerning import from third countries.

CHAPTER 1
Animal casings

A. Trade
Trade in animal casings is subject to production of a document specifying the plant of origin which must be:
- where the casings are salted or dried at the point of origin and where salted or dried casings are subsequently handled for other purposes, a plant approved by the Veterinary Services,

- in other cases, a plant approved in accordance with Council Directive 64/433/EEC, provided the casings are transported in such a way as to avoid contamination.
B. Imports from third countries
Imports of animal casings from any third country are subject to production of the certificate referred to in Article 9 (2) (c), issued and signed by an official veterinarian of the exporting third country, stating that:
(i) the casings come from plants approved by the competent authority of the exporting country;
(ii) the casings have been cleaned, scraped and then either salted or bleached (or as an alternative to salting or bleaching, that they have been dried after scraping) ;
(iii) after the treatment in (ii), effective steps were taken to prevent the recontamination of the casings.

CHAPTER 3

Hides and skins of ungulates ("hides and skins of ungulates" means the integument of ungulates) not covered by Order (64/433) or (72/462) and which have not undergone certain tanning processes

I. A. The provisions of this chapter do not apply to:
- hides or skins of ungulates covered by Order (64/433) or (72/462),
- hides or skins having undergone the complete process of tanning,
- "wet blue",
- "pickled pelts",
- "limed hides" (treated with lime and in brine at a pH of 12 to 13 for at least eight hours).
B. Within the scope defined in A, the provisions of this chapter apply to fresh, chilled and treated hides and skins. For the purpose of this decision, "treated hides and skins" means hides and skins which have been:
- dried, or
- dry-salted or wet-salted for at least 14 days prior to dispatch, or
- salted for seven days in sea salt with the addition of sodium carbonate to 2 %, or
- drying for 42 days at a temperature of at least 20°C, or
- preserved by a process other than tanning, to be determined in accordance with the procedure laid down in Article 10 (1) (c) of the Veterinary Framework Act.
II. Trade with Member States.
A. trade in fresh or chilled hides and skins is subject to the same animal health conditions as those applicable to fresh meat pursuant to Order (72/461).
B. Trade in treated hides and skins is authorised on condition that each consignment is accompanied by a commercial document as provided for in the last indent of Article 4 (2) (a) certifying that:
- the hides and skins have been treated in accordance with point I.B, and
- the consignment has not been in contact with any other animal product or live animals presenting a risk of spreading a serious transmissible disease.
III. Importation
A. Fresh or chilled hides and skins may only be imported from third countries or a part of a third country from which imports of all categories of fresh meat of the corresponding species are authorised pursuant to the legislation of the Republic of Malta.
B. Imports of fresh or chilled hides and skins must meet animal health conditions to be determined in accordance with the procedure laid down in Article 12 (1) of the Veterinary Framework Act and must be accompanied by an animal health certificate as provided for in Article 10 (2) (c).
C. Imports of treated hides or skins from the third countries listed in the list established with the procedure laid down in Article 12 (2) (a) of the Veterinary Framework Act for fresh meat, fresh meat wild and live animals of the species concerned and meat products, are authorised on condition that each consignment is accompanied by a certificate of a model to be determined in accordance with the procedure laid down in article 12 (2) (c) of the Veterinary Framework Act, to the effect that:
(a) either where the hides or skins come from animals originating in a region of a third country or in a third country not subject to restrictions as a result of an outbreak of a serious transmissible disease to which the animals of the species concerned are susceptible, they have been treated in accordance with point I.B;

or
where the hides or skins come from other regions of a third country or other third countries, they are treated as laid down in point I.B, third and fourth indents;
and
(b) the consignment has not been in contact with any other animal product or with live animals presenting a risk of spreading a serious transmissible disease.
D. However, in the case of imports from any third country of hides or skins of ruminants treated in accordance with point I.B and which have been kept separate for 21 days or have undergone transport for 21 uninterrupted days, the certificate provided for in point C is replaced by a declaration to the effect that or proving that those requirements have been met, of a model to be determined in accordance with the procedure laid down in Article 12 (2) (c) of the Veterinary Framework Act.

CHAPTER 4

Pet food containing low-risk materials within the meaning of Order (90/667)

1. Each consignment of pet-food in hermetically sealed containers must be accompanied by a certificate issued and signed by an official veterinarian of the country of origin or of the Veterinary Services from the Republic of Malta stating that the product has been subjected to heat treatment to a minimum Fc value of 3,0.
2. Each consignment of semimoist petfood must be accompanied either by the commercial document or by the certificate provided for in Article 13 (2) (b) of Order (90/667) stating that:
(i) the raw materials of animal origin from which the pet-food was manufactured were obtained solely from healthy slaughtered animals, the meat from which had been passed as fit for human consumption;
(ii) the ingredients of animal origin have been subjected to a heat treatment of at least 90°C throughout their substance;
(iii) after processing, effective steps were taken to ensure that the consignment was not exposed to recontamination.
3. Dried pet-food must satisfy the following requirements:
(a) the raw materials from which the pet-food was manufactured were low-risk materials in accordance with Articles 2, 5 and 17 of Order (90/667);
(b) each consignment is accompanied by a commercial document or certificate provided for in Article 13 (2) (b) of Order (90/667) stating that:
(i) the dried pet-food consisted of products of slaughtered animals heat-treated so as to achieve a temperature throughout their substance of at least 90°C, on the understanding that the treatment was not necessary for finished products the ingredients of which had undergone such treatment;
(ii) after heat treatment, every precaution was taken to ensure that the product was not contaminated in any way prior to shipment;
(iii) the product is packed in new containers (bags or sacks) ;
(iv) the production process has been tested, with satisfactory results, in accordance with Chapter III (2) of Annex II to Order (90/667).
4. Each consignment of products manufactured from processed hides must be accompanied by a commercial document or certificate provided for in Article 13 (2) (b) of Order (90/667) stating that the products have been subjected to a heat treatment during processing sufficient to destroy pathogenic organisms (including salmonella) and that effective steps were taken after processing to prevent contamination of the products.

CHAPTER 2

Bones and bone products (excluding bone meal), horns and horn products (excluding horn meal) and hooves and hoof products (excluding hoof meal) intend for human consumption

Trade in and imports of the products in question are subject to the following conditions:
1. where trade is concerned, bones, horns and hooves are subject to the animal health requirements laid down in Council Directive 72/461/EEC;

2. where trade is concerned, bone products, horn products and hoof products are subject to the animal health requirements provided for in Council Directive 80/215/EEC;
3. where imports are concerned, bones, bone products, horns, horn products, hooves and hoof products are subject to the requirements of Directive 72/462/EEC;

CHAPTER 3

Processed animal protein

I. Without prejudice to any restrictions imposed as regards BSE or to the restrictions on the feedings of ruminant protein to ruminants, trade in and imports of processed animal protein are subject:
A. as regards trade to the production of the document or certificate provided for in council Directive 77/99/EEC stating that the requirements of that Directive have been complied with;
B. as regards imports:
1. to production of a health certificate as provided for in Article 9 (2) (c), signed by the official veterinarian of the country of origin and stating that:
(a) the product fulfils the requirements of Council Directive 80/215/EEC;
(b) every precaution has been taken after treatment to prevent contamination of the product treated;
(c) samples have been taken and tested for salmonella when the consignment left the country of origin;
(d) the results of these tests are negative;
2. following document checks of the certificate referred to in 1, to sampling by the competent authority at the border inspection post without prejudice to point II.:
(i) of each consignment of products submitted in bulk;
(ii) at random of consignments of products packaged in the manufacturing plant;
3. for release for free circulation in European Community territory of consignments of processed animal protein, to prove that the results of the sampling carried out pursuant to B (1) (c) have proved negative, if necessary after reprocessing;
C. Rules concerning the requirements applicable as regards BSE and scrapie for animal proteins shall be conform to European Community decision on the type of heat treatment capable of destroying the agent responsible.
Trade in and imports of meat meal and bone meal remain subject to Article 5 (2) of Council Directive 89/662/EEC and of Council Directive 97/78/EC.
II. Veterinary Services may carry out random sampling of bulk consignments originating in a third country from which the last six consecutive tests have proved negative. Where during one of these checks a result has proved positive, the competent authority of the country of origin must be informed so that it can take appropriate measures to remedy the situation. These measures must be brought to the attention of the Veterinary services responsible for the import checks. In the event of a further positive result from the same source, further tests must be carried out on all consignments from the same source until the requirements laid down in the first sentence are again satisfied.
III. Veterinary Services must keep records of the results of sampling carried out on all consignments which have undergone sampling.
IV. In accordance with Article 3 (3) of Council Directive 89/662/EEC, transhipment of consignments is permitted only through ports which have been approved by the European Community, provided that a bilateral agreement has been reached with Member States to allow checking of the consignments to be deferred until they reach the border inspection post of the Member State of final destination.
V. Where a consignment proves to be positive for salmonella, it is either:
(a) re-exported from the European Community;
(b) used for purposes other than animal feeds. In this case, the consignment may leave the port or storage depot only on condition that it is not incorporated into animal feedingstuffs;
(c) reprocessed in a treatment plant approved pursuant to Regulation of the European Parliament and of the Council (EC) No 1774/2002 of 3 October2002 laying down health rules concerning animal by-products not intended for human consumption or any plant approved for decontamination. Movement from the port or storage depot shall be controlled by permit from the competent authority and the consignment shall not be released until it has been treated, tested for

salmonella by the competent authority in accordance with the relevant requirements of Regulation (EC) No 1774/2002 and a negative result obtained.

CHAPTER 4

Blood and blood products of ungulates and poultry (with the exception of serum from equidae)

I. Fresh blood and blood products intended for human consumption

A. Trade
1. Trade in fresh blood of ungulates and poultry intended for human consumption is subject to the animal health conditions applicable to trade in fresh meat pursuant to Council Directives 72/461/EEC, 91/494/EEC or 91/495/EEC.
2. Trade in blood products intended for human consumption is subject to the animal health conditions laid down in Chapter 11 of these rules.
B. Imports
1. Imports of fresh blood of domestic ungulates intended for human consumption are prohibited pursuant to Council Directive 72/462/EEC.
- Imports of fresh blood of domestic poultry intended for human consumption are subject to the animal health conditions laid down in Council Directive 91/494/EEC.
- Imports of fresh blood of reared game intended for human consumption are subject to the animal health conditions laid down in Chapter 11 of this Annex.
2. Imports of blood products for human consumption, including those referred to in Council Directive 77/99/EEC, are subject to the animal health conditions applicable to meat products pursuant to Council Directive 72/462/EEC and these rules, without prejudice to the rules on blood-based processed animal protein products referred to in Chapter 6 of this Annex.

II. General provisions

For the application of this Chapter, Veterinary Services shall follow the detailed rules adopted, where necessary, by the European Community.

CHAPTER 5

Lard and rendered fats

1. Veterinary services shall authorise the importation into the European Community of lard and rendered fats from third countries appearing on the list annexed to Council Decision 79/542/EEC from which the importation of fresh meat of the species concerned is permitted.
2. Where there has been an outbreak of a serious transmissible disease in the previous 12 months before export in a country mentioned in paragraph 1, each consignment of lard or rendered fats must be accompanied by a certificate referred to in Article 9 (2) of these rules stating that:
A. the lard or rendered fats have been subjected to one of the following heat treatment processes:
(i) at least 70°C for at least 30 minutes;
or
(ii) at least 90°C for at least 15 minutes;
or.
(iii) a minimum temperature of 80°C in a continuous rendering system;
B. where the lard of rendered fats are packaged, they have been packed in new containers and all precautions have been taken to prevent their recontamination;
C. where bulk transport of the product is intended, the pipes, pumps and bulk tank and any other bulk container tanks or bulk road tanker used in the transportation of the products from the manufacturing plant either directly on to the ship or into shore tanks or direct to establishments were inspected and found to be clean before use.

CHAPTER 6

Rabbit meat and farmed game meat

Veterinary Services shall ensure that rabbit meat and farmed game meat are imported only if:
(a) they come from third countries included:
(i) for furred farm game, on the list of countries from which fresh meat of the corresponding species may be imported pursuant to Council Directive 72/462/EEC;
(ii) for feather farmed game, on the list of countries from which fresh poultrymeat may be imported pursuant to Council Directive 91/494/EEC;
(iii) for rabbit meat, on a list drawn up by the European Community;
(b) they satisfy at least the requirements laid down in Chapters II and III respectively of council Directive 91/495/EEC;
(c) they come from establishments offering the guarantees provided for in (b) and recognised under the procedure provided for in Article 18 or, pending the list referred to in (a) (iii), from establishments approved by the competent authorities;
(d) each batch of meat is accompanied by the health certificate provided for in Article 9 (2) (c).

ANNEX II

SPECIFIC PUBLIC HEALTH CONDITIONS

CHAPTER 1

Imports from third countries of meat products obtained from poultry-meat, farmed game meat, wild game meat and rabbit meat

Veterinary Services shall ensure that meat products obtained from poultry-meat, farmed game meat, wild game meat and rabbit meat are not imported unless:
a) - either they come from a third country listed in accordance with:
(i) Article 9 of Council Directive 91/494/EEC for poultry-meat;
(ii) Article 16 of Council Directive 92/45/EEC for wild game meat;
(iii) Chapter 2 of Annex I to this Legal Notice for rabbit meat and farmed-game meat
- either they come from a third country listed in the Annex, Part I of Council Decision 79/542/EEC. In this case they must have undergone a heat treatment in a sealed container, the Fo value being equal or over 3, 00. However, for meat products made from species other than swine, this treatment may be replaced by a heat treatment which brings the internal temperature to at least 70°C
(b) the fresh meat used meets the appropriate requirements of Article 14 of Council Directive 71/118/EEC for poultry-meat, Article 16 of Council Directive 92/45/EEC for wild game meat, Article 3 of Directive Council 91/495/EEC for rabbit meat and Article 6 of that Directive for farmed-game meat;
(c) they come from an establishment offering the same guarantees as those referred to in Council Directive 77/99/EEC and approved by the European Community;
(d) they are prepared, checked and handled in accordance with the appropriate requirements provided for in Council Directive 77/99/EEC;
(e) each consignment of meat products is accompanied by a health certificate established by the European Community.

CHAPTER 2

The health conditions applicable to the following shall be implemented by the Veterinary Services according to the requirements established by the European Community:
- putting on the market in and imports of eggs and imports of egg products intended for human consumption, without prejudice to the rules laid down within the framework of the common organisation of the market,
In respect of salmonella, special rules shall apply for eggs intended for Finland and Sweden and consignments of eggs shall be subject to additional general or limited guarantees defined by the

European Commission; these guarantees shall or be carried out for eggs originating in an establishment subject to a program recognised by the European Community as equivalent to the operational program approved by the European Commission for Finland and Sweden.
- trade in and import of honey, intended for human consumption.
- trade in and imports of milk and milk-based products intended for human consumption, obtained from species not covered by Council Directive 92/46/EEC; depending on the species, Veterinary Services shall implement specific requirements laid down by European community as regards:
- animal health and, the health status of dairy herds, in particular with regard to tuberculosis and brucellosis
- hygiene in respect of
- milking,
- the collection, transport, treatment and processing of milk,
- staff,
- testing for residues of pharmacologically and/or hormonally active substances, antibiotics, pesticides or other harmful substances in milk or milk products,
- criteria applicable to raw milk as a raw material,
- microbiological criteria applicable to finished products,
- the production, placing on the market and importation of meat of species not covered by specific requirements, and in particular reptile meat and products thereof, intended for human consumption. Depending on the species, Veterinary Services shall implement specific requirements e laid down by the European Community as regards:
- microbiological and parasitological criteria,
- hygiene during slaughter,
- testing for residues.

CHAPTER 3

I. Specific public health conditions applicable to trade in and imports of snails intended for human consumption

A. Without prejudice to European Community, national or international provisions on the protection of wildlife, for the purpose of this Chapter, 'snails` means terrestrial gastropods of the species Helix pomatia Linné, Helix aspersa Muller, Helix lucorum and species of the family of Achatinidae.
B. Veterinary services must ensure that shelled, cooked and prepared or preserved snails are traded for human consumption only if they meet the following conditions:
(1) They must come from establishments:
- which meet the requirements of Article 4 (2) of these rules,
- which are approved by the competent authority in accordance with the requirements of Chapters III and IV of the Annex to Council Directive 91/493/EEC,
- which undergo monitoring by the competent authority of production conditions and health checks in accordance with Chapter V (I) (3) and (5) and (II), (3) and (4) of Council Directive 91/493/EEC,
- which conduct own checks in accordance with the provisions of European Commission Decision 94/356/EC.
(2) They must be subjected to organoleptic checks carried out by sampling. If the organoleptic examination reveals that the snails are not fit for human consumption, measures must be taken to withdraw them from the market and denature in such a way that they cannot be reused for human consumption.
(3) For the preparation of shelled snail-meat,
(a) depending on the scale of the operation, establishments must set aside special rooms or areas for:
- the storage of packaging and wrapping materials,
- the reception and storage of live snails,
- washing, blanching or boiling, shelling and trimming,
- the storage and, where necessary, cleaning and treatment of shells, - the heat treatment of the snail-meat, where necessary,
- the wrapping or packaging of the snail-meat,
- the storage of the finished product in cold stores;
(b) the snails must be checked before being boiled. Dead snails must not be prepared for human consumption;

(c) following shelling, the hepatopancreas removed during trimming must not be used for human consumption.

(4) Canned snails

Establishments must satisfy the conditions laid down in Chapter IV (IV) (4) of the Annex to Council Directive 91/493/EEC.

(5) Cooked and prepared snails

(a) Depending on the scale of the operation, establishments must set aside special rooms or areas for:

- the storage of shelled snail-meat in cold stores,
- the storage of clean shells,
- the storage of breading products,
- the preparation of stuffing,
- cooking and cooling,
- the filling of the shells with snail-meat and stuffing, and packaging in a controlled temperature room,
- where applicable, freezing,
- the storage of finished products in cold stores;

Products must satisfy the relevant conditions set out in Chapter IX of Annex B to Council Directive 77/99/EEC.

(b) Snail-meat used to fill shells prior to cooking must satisfy the conditions laid down in respect of shelled snail-meat.

(6) Veterinary services shall implement, microbiological criteria, including sampling plans and methods of analysis, laid down by the European Community when there is a need to protect public health.

(7) The snails must be put up, packaged, stored and transported under the appropriate hygiene conditions laid down in Chapters VI and VIII of the Annex to Council Directive 91/493/EEC.

(8) The packaging and wrapping of snails must bear an identification mark containing the following particulars:

- the name of the consigning country in capitals or the initial letter or letters of the consigning country in printed capitals, for Malta:

MT, followed by the approval number of the establishment, and the following sets of initials: **KEE**.

C. For imports:

(1) the packaging and wrapping of shelled, cooked and prepared or preserved snails must carry the name or ISO code of the country of origin and the approval number of the production establishment in indelible print;

(2) the following is an example of the specimen health certificate laid down in Article 9 (2) (c) of these rules , which must accompany every consignment of shelled, cooked and prepared or preserved snails originating in third countries.

SPECIMEN HEALTH CERTIFICATE
FOR SHELLED, COOKED, PREPARED OR PRESERVED SNAILS ORIGINATING IN THIRD COUNTRIES AND INTENDED FOR THE EUROPEAN COMMUNITY

Note to the importer: this certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection point.

Reference No: . .....

Country of dispatch: ……..……..……..……...
Competent authority:. ……..……..……..…….

I. Identification of snails

Description of product:.....……...
- species (scientific names) :.....……..
- state ([1]) and nature of treatment:.....……...
Code No (as appropriate) :.....……..
Type of packaging Number of packages:.....……...
Net weight:...……
Required storage and transportation temperature:.....……..

II. Origin of snails

Name (s) and official approval number (s) of establishment (s) approved by the competent authority for export to the European
Community:.....….....
……...……...……...……...……...…….
……...……...……...……...……...……

III. Destination of products

The snails are dispatched from:.....……
(place of dispatch)

to:.....……..……..……..…….
(country and place of destination)

by the following means of transport ([2]) :.....……
Name and address of consignor:.....…….....
Name of consignee and address of the place of destination:.....
……...……...……...…….....

IV. Health attestation

The undersigned official inspector hereby certifies that the snails described above:
(1) have been handled and, where appropriate, shelled, cooked, prepared, preserved, frozen, packaged and stored in a hygienic manner in accordance with the requirements of Chapter 3 (I) of Annex II to Directive 92/118/EEC;
(2) have been the subject of an own check program drawn up and implemented by the person responsible for the establishment in accordance with Directive 94/356/EC;
(3) have undergone an official health check in accordance with Chapter V of the Annex to Directive 91/493/EEC.
The undersigned official inspector hereby declares that he is aware of the provisions of Chapter 3, Part I, of Annex II to Council Directive 92/118/EEC, of the provisions of Chapters III, IV, V, VI and VII of Directive 91/493/EEC of the provisions of Chapter IX of Annex B to Directive 77/99/EEC and of the provisions of Decision 94/356/EC.

Done at.....……, on…….....
(place) (date)

Official stamp

stamp ([3])

.....
(Name in capital letters signature of the official veterinarian) (3)

([1]) Chilled, frozen, shelled, cooked, prepared, preserved.
([2]) Registration number of lorries, railway wagons or container, flight number or name of ship.
([3]) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

II. Specific public health conditions applicable to trade in and imports of frogs' legs intended for human consumption

A. Without prejudice to European Community, national or international provisions on the protection of wildlife, for the purposes of this Chapter, 'Frogs' legs` means the back part of the body divided by a transversal cut behind the front limbs, eviscerated and skinned, of the species Rana spp. (family Ranidae), presented fresh, frozen or processed.

B. Veterinary Services must ensure that frogs' legs are traded for human consumption only if they meet the following conditions:

(1) The frogs must have been slaughtered, bled, prepared and, where appropriate, chilled, frozen, processed, packaged and stored in establishments which:

- meet the requirements of Article 4, point 2 of these rules,
- are approved by the competent authority in accordance with the requirements of Chapters III and IV of the Annex to Council Directive 91/493/EEC,
- undergo monitoring by the competent authority of production conditions and health checks in accordance with Chapter V (I) (3) and (5) and (II) (3) and (4) of the Annex to Council Directive 91/493/EEC,
- conduct own checks in accordance with the provisions of Decision 94/356/EC.

(2) The frogs legs must be subjected to organoleptic checks carried out by sampling. If the organoleptic examination reveals that the frogs legs are not fit for human consumption, measures must be taken to withdraw them from the market and denature in such a way that they cannot be reused for human consumption.

(3) In addition, a special room must be set aside for the storage and washing of live frogs, and for their slaughter and bleeding. The death of frogs must only be carried out by slaughter in an approved establishment. Frogs which are found to be dead prior to slaughter must not be prepared for human consumption. The special room must meet the requirements of Chapter III, paragraph I, point 2 of the Annex to Council Directive 91/493/EEC and must be physically separated from the preparation room.

(4) Immediately following preparation, the frogs' legs must be washed very fully in running drinking water and immediately chilled at the temperature of melting ice, frozen at a temperature of at least 18°C or processed.

(5) Where the frogs' legs are processed, this must be carried out in accordance with the rules laid down in Chapter IV of the Annex to Council Directive 91/493/EEC.

(6) Microbiological controls

Veterinary Services shall implement microbiological criteria, including sampling plans and methods of analysis, in accordance with requirements laid down by the European Community when there is a need to protect public health.

(7) The frogs' legs must be put up, packaged, stored and transported under the appropriate hygiene conditions laid down in Chapters VI and VIII of Community Directive 91/493/EEC.

(8) The packaging and containers of frogs' legs must bear an identification mark containing the following particulars:

The name of the consigning country in capitals, or the initial letter or letters of the consigning country in printed capitals, for Malta : **MT** followed by the approval number of the establishment, and, the following sets of initials: **KEE**.

C. For imports:

(1) The packaging and wrapping of frogs' legs must carry the name or ISO code of the country of origin and the approval number of the production establishment in indelible print.

(2) The following is an example of the specimen health certificate laid down in Article 9(2) (c) of this Legal Notice, which must accompany every consignment of frogs' legs originating in third countries:

SPECIMEN HEALTH CERTIFICATE FOR CHILLED, FROZEN OR PREPARED FROGS' LEGS ORIGINATING IN THIRD COUNTRIES AND INTENDED FOR THE EUROPEAN COMMUNITY

Note to the importer: This certificate is for veterinary purposes only and must accompany the consignment until it reaches the border inspection point.

Reference No:.....

Country of dispatch:..……

Competent authority:.. ..……

I. Identification of frogs legs

Description of product:.....……
- species (scientific names) :.....……
- state ([1]) and nature of treatment:.....…….
Code No (as appropriate) :.....……...
Type of packaging Number of packages:.....……....
Net weight:..... ..…….....
Required storage and transportation temperature:.....…….....

II. Origin of frogs legs

Name (s) and official approval number (s) of establishment (s) approved by the competent authority for export to the European Community:

.....…….....
.....
.....

III. Destination of products

The frogs' legs are dispatched from:.....……..
(Place of dispatch)

to:.....……..……
(Country and place of destination).

by the following means of transport ([2]) :.....……
Name and address of consignor:.....……..
..…….
Name of consignee and address of the place of destination:.....…….
..…….

IV. Health attestation

The undersigned official inspector hereby certifies that the frogs' legs described above:
(1) originate from frogs that have been bled, prepared and, where appropriate, chilled, frozen or processed, packaged and stored in a hygienic manner in accordance with the requirements of Chapter 3 (II) of Annex II to Directive 92/118/EEC;
(2) have been the subject of an own check program drawn up and implemented by the person responsible for the establishment in accordance with Decision 94/356/EC;
(3) have undergone an official health check in accordance with the relevant provisions of Chapter V of the Annex to Directive 91/493/EEC. The undersigned official inspector hereby declares that he is aware of the provisions of Chapter 3,
Part II, of Annex II to Directive 92/118/EEC, of the provisions of Chapters II, IV, V, VI and VII of Directive 91/493/EEC and of the provisions of Decision 94/356/EC.

Done at……....., on…….....
(place) (date)

Official stamp([3])

…….....
(Name in capital letters signature of the official veterinarian) (3)

([1]) Chilled, frozen, processed.
([2]) Registration number of lorries, railway wagons or container, flight number or name of ship.
([3]) The colour of the stamp and signature must be different from that of the other particulars in the

CHAPTER 4

Section A
Specific health conditions for the gelatine intended for human consumption

This chapter lays down the health conditions applicable to putting on the market and for imports of gelatine intended for human consumption, but excluding gelatine destined to pharmaceutical, cosmetic or other technical use and medical devices.

For the purpose of this chapter, the following definitions apply:
-gelatine: natural, soluble protein, gelling or non-gelling, obtained by the partial hydrolysis of collagen produced from bones, hides and skins, tendons and sinews of animals (including fish and poultry),
-hides and skins: all cutaneous and subcutaneous tissues,
-tanning: the hardening of hides, using vegetable tanning agents, chromium salts or other substances such as aluminium salts, ferric salts, silicic salts, aldehydes and quinones, or other synthetic hardening agents,
-category 1 country or region: country or region classified as BSE free in accordance with European Community legislation,
-category 2 country or region: country or region classified as provisionally BSE free with accordance to European Community legislation,
-category 3 country or region: country or region classified as low BSE risk in accordance with European Community legislation,
-category 4 country or region: country or region classified as high BSE risk in accordance with European Community legislation.

Gelatine intended for human consumption shall comply with the following conditions:

I. ***Conditions for establishments producing gelatine***:

Gelatine intended for human consumption shall come from establishments which:
1.comply with the conditions laid down in Chapters I, II, V, VI, VII, VIII, IX and X of the Annex to Council Directive 93/43/EEC;
2.are authorised and registered in accordance with Article 11 of Council Directive 77/99/EEC;
3.are subject to supervision of production conditions by the competent authority in accordance with Chapter IV of Annex B to Council Directive 77/99/EEC as appropriate;
4.carry out an own checks program in accordance with Article 7 (1) and (3) of Council Directive 77/99/EEC;
5.keep records for two years on the sources of all incoming raw material and on all outgoing products;
6.introduce and implement a system that makes it possible to link each production batch dispatched, the incoming raw material consignments the production conditions and the time of production.

II. Requirements for raw materials to be used for the production of gelatine

1.For the production of gelatine intended for human consumption, the following raw materials may be used:
-bones,
-hides and skins of farmed ruminant animals,
-pig skins,
-poultry skin,
-tendons and sinews,
-wild game hides and skins,
-fish skin and bones.
2.The use of bones obtained from ruminant animals born, reared or slaughtered in category 4 countries or regions is prohibited.
3.The use of hides and skins submitted to tanning processes is prohibited.

4.Raw materials listed in the first five indents of paragraph 1 shall be derived from animals which have been slaughtered in a slaughterhouse and whose carcasses have been found fit for human consumption following ante and post mortem inspection.
5.Raw material listed in the sixth indent of paragraph 1 shall be derived from killed animals whose carcasses have been found fit for human consumption following the inspections laid down in Article 3 of Council Directive 92/45/EEC.
6.Raw materials listed in the first six indents of paragraph 1 shall come from slaughterhouses, cutting plants, meat processing establishments, wild game processing plants, bone degreasing plants, tanneries, collection centres, retail shops, or premises adjacent to sales points where the cutting and the storage of meat and poultry-meat is performed for the sole purpose of supplying the final consumer directly.
7.Raw material listed in the last indent of paragraph 1 shall come from plants manufacturing fish products for human consumption approved or registered in accordance with Council Directive 91/493/EEC.
8.The collection centres and tanneries which intend to supply raw material for the production of gelatine intended for human consumption shall be specifically authorised for this purpose and registered by the competent authorities and fulfil the following requirements:
(a) they must have storage rooms with hard floors and smooth walls which are easy to clean and disinfect;
(b) where appropriate, they must be provided with refrigeration facilities;
(c) the storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials;
(d) if raw material not in conformity to this part is stored and/or processed in these premises, it must be segregated throughout the period of receipt, storage, processing and dispatch from raw material in conformity to this part;
(e) they must be inspected by the competent authority at regular intervals in order to ensure that this chapter is being complied with and to check accounting documents and/or health certificates which enable the origin of the raw material to be traced.
9.Imports into the Community of raw material destined to the production of gelatine intended for human consumption are subject to the following provisions:
- Veterinary Services shall authorise the importation of this raw material only from third countries which appear on the list laid down in Council Decision 79/542/EEC or in Commission Decision 94/85/EC or in Commission Decision 97/296/EC or in Decision 94/86/EC, as appropriate,
-each consignment is accompanied by a certificate that conforms to the model laid down in accordance with the procedure provided for in Article 18 of these rules .

III. Transport and storage of raw materials

1.Transports of raw materials destined to the production of gelatine must be carried out under clean conditions using appropriate means of transport. During transportation, at the time of delivery in the collection centre and in the tannery and in the gelatine processing establishment, raw materials must be accompanied by a commercial document in conformity with the model laid down in Part VIII of this chapter.
2.Raw materials must be transported and stored chilled or frozen, unless they are processed within 24 hours after their departure. By way of derogation from the preceding subparagraph, degreased and dried bones or ossein salted, dried and limed hides and skins and hides and skins treated with alkali or acid may be transported and stored at ambient temperature.
3.The storage rooms must be kept in a satisfactory state of cleanliness and repair, so that they do not constitute a source of contamination for the raw materials.

IV. Conditions to be complied with for the manufacture of gelatine

1.Gelatine must be produced by a process which ensures that:
-all ruminant bone material which is derived from animals born, reared and slaughtered in category 3 countries or regions is subjected to a process which ensures that all bone material is finely crushed and degreased with hot water and treated with dilute hydrochloric acid (at minimum concentration of 4 %and pH <1, 5) over a period of at least two days, followed by an alkaline treatment of saturated lime solution (pH >12, 5) for a period of at least 20 days with a sterilisation step of 138140°C during four seconds or by an equivalent process approved by the European Commission,

-other raw material is subjected to a treatment with acid or alkali, followed by one or more rinses. The pH must be adjusted subsequently. Gelatine must be extracted by heating one or several times in succession, followed by purification by means of filtration and sterilisation.
2.After having been subjected to the processes listed in paragraph 1, gelatine may undergo a drying process and, where appropriate, a process of pulverisation or lamination.
3.The use of preservatives, other than sulphur dioxide and hydrogen peroxide, is prohibited.
4.Provided the requirements for gelatine not intended for human consumption are exactly the same as for gelatine intended for human consumption, production and storage may be undertaken in the same establishment.

V. Requirements for finished products

Each production batch of gelatine shall be subjected to tests to ensure that it meets the following criteria:

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ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu10 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar il-Metodi tal-Komunità għall-Analiżi u Kontroll Uffiċjali ta' l-Oġġetti ta' l-Ikel.

Id-19 ta' Novembru, 2004

No. 1217

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 10 of the Veterinary Services Act to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Community Methods for the Analysis and Official Control of Feedingstuffs Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

IN exercise of the powers conferred by article 10 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has, after consultation with the Minister of Health, the Elderly and Community Care, made the following rules:-

Title and scope

1. (1) The title to these rules is Community Methods for the Analysis and Official Control of feedingstuffs Rules, 2004.

(2) The scope of these rules is to implement the provisions found under European Union Council Directive 73/46/EEC regarding official controls of feedingstuffs as regards moisture contents of animal and vegetable fats and oils and magnesium and crude fibre contents of feeding stuffs in accordance with the methods described in the Schedule to these rules and in accordance with article 22 (c) of the Veterinary Services Act.

SCHEDULE
(Rule 2)

Chapter I

Determination of Moisture in Animal and Vegetable Fats and Oils

1. **Purpose and Scope**

This method makes it possible to determine the water and volatile substances content of animal and vegetable fats and oils.

2. **Principle**

The sample is dried to constant weight at 103 ºC. The loss in mass is determined by weighing.

3. **Apparatus**

3.1. Flat-bottomed dish, of a corrosion-resistant material, 8 to 9 cm in diameter and approximately 3 cm high.
3.2. Mercury thermometer with a strengthened bulb and expansion tube at the top end, graduated from approximately 80 ºC to at least 110 ºC, and approximately 10 cm in length.
3.3. Sand bath or electric hot-plate.
3.4. Desiccator, containing an efficient drying agent.
3.5. Analytical balance.

4. **Procedure**

Weigh out to the nearest mg approximately 20 g of the homogenized sample into the dry, weighed dish (3.1) containing the thermometer (3.2). Heat on the sand bath or hot-plate (3.3), stirring continuously with the thermometer, so that the temperature reaches 90 ºC in about 7 minutes.
Reduce the heat, watching the frequency with which bubbles rise from the bottom of the dish. The temperature must not exceed 105 ºC. Continue to stir, scraping the bottom of the dish, until bubbles stop forming.
In order to ensure complete elimination of moisture, reheat several times to 103 ºC ± 2 ºC, cooling to 93 ºC between successive heatings. Then leave to cool to room temperature in the desiccator (3.4) and weigh. Repeat this operation until the loss in mass between two successive weighings no longer exceeds 2 mg.
N.B. An increase in the mass of the sample after repeated heating indicates an oxidation of the fat, in which case calculate the result from the weighing carried out immediately before the mass began to increase.

5. **Calculation of results**

The moisture content, as a percentage of the sample, is given by the following formula:

$$(M1 - M2) \cdot \frac{100}{Mo}$$

where:
Mo = mass, in grammes, of the test sample;
M1 = mass, in grammes, of the dish with its contents before heating;
M2 = mass, in grammes, of the dish with its contents after heating.
Results lower than 0·05 % must be recorded as 'lower than 0·05 %'.
Repeatability
The difference in moisture between the results of two parallel determinations carried out on the same sample must not exceed 0·05 %, in absolute value.

Chapter II

Determination of Magnesium
— by atomic absorption spectrophotometry —

1. **Purpose and Scope**

This method makes it possible to determine the quantity of magnesium in feeding stuffs. It is particularly appropriate for determining magnesium contents lower than 5 %.

2. **Principle**

The sample is ashed and dissolved in dilute hydrochloric acid. If it contains no organic substances, it is dissolved directly in dilute hydrochloric acid. The solution is diluted and the magnesium content determined by atomic absorption spectrophotometry at 285·2 nm, by comparison with standard solutions.

3. **Reagents**

3.1. Hydrochloric acid a.p. d: 1·16.
3.2. Concentrated hydrochloric acid a.p. d: 1·19.
3.3. Magnesium ribbon or wire, or magnesium sulphate heptahydrate, dried at room temperature.
3.4. Strontium salt solution (chloride or nitrate) at 2·5 % (w/v) strontium
(= 76·08 g SrC12 · 6H2O a.p., or 60·38 g Sr (NO3)2 a.p.).
3.5. Standard magnesium solution: weigh out to the nearest mg 1 g magnesium (3.3) which has previously had its oxide coating carefully removed, or the corresponding quantity (10·143 g) of magnesium sulphate heptahydrate (3.3). Place ina 1 000 ml graduated flask, add 80 ml hydrochloric acid (3.1), leave to dissolve and make up to 1 000 ml with water. 1 ml of this solution contains 1·000 mg magnesium.

4. **Apparatus**

4.1. Platinum, silica or porcelain ashing crucibles.
4.2. Thermostatically controlled electric muffle furnace.
4.3. Atomic absorption spectrophotometer.

5. **Procedure**

5.1. *Preparation of the sample solution*
5.1.1. *Feeding stuffs composed exclusively of mineral substances*
Weigh out to the nearest mg 5 g of the sample into a 500 ml graduated flask with 250 to 300 ml water. Add 40 ml hydrochloric acid (3.1), bring to the boil and keep the liquid gently boiling for 30 minutes. Leave to cool, make up to volume with water, mix and filter into a dry beaker through a dry pleated filter. Discard the first 30 ml of the filtrate. In the presence of silica, treat 5 g of sample with a sufficient quantity (15—30 ml) of hydrochloric acid (3.2), evaporate to dryness on a water bath and transfer to an oven at 105 ºC for one hour. Proceed as from the third sentence of 5.1.2.
5.1.2. *Feeding stuffs composed predominantly of mineral substances*
Weigh out to the nearest mg 5 g of the sample into a crucible and ash at 550 ºC in the muffle furnace until an ash which is free from carbonaceous particles is obtained, and leave to cool. In order to eliminate silica, add to the ash a sufficient quantity (15—30 ml) of hydrochloric acid (3.2), evaporate to dryness on a water bath and transfer to an oven at 105 ºC for one hour. Treat the residue with 10 ml hydrochloric acid (3.1) and transfer to a 500 ml graduated flask using warm water. Leave to cool and make to volume with water. Mix and filter into a dry beaker through a dry pleated filter. Discard the first 30 ml of the filtrate.
5.1.3. *Feedingstuffs composed predominantly of organic substances*
Weigh out to the nearest mg 5 g of the sample into a crucible and ash at 550 ºC in the muffle furnace until an ash which is free from carbonaceous particles is obtained. Treat the ash with 5 ml hydrochloric acid (3.2), evaporate to dryness on a water bath and then dry for one hour in the oven

at 105 ºC in order to render the silica insoluble. Treat the ash with 5 ml hydrochloric acid (3.1), transfer to a 250 ml graduated flask using warm water, bring to the boil, leave to cool and make up to volume with water. Mix and filter into a dry beaker through a dry pleated filter. Discard the first 30 ml of the filtrate.

5.2. *Measurement by atomic absorption*

By diluting the standard solution (3.5) with water, prepare at least 5 reference solutions of increasing concentration, corresponding to the optimal measuring range of the spectrophotometer. Add to each solution 10 ml strontium salt solution (3.4) and then make up the volume to 100 ml with water. Dilute with water one aliquot part of the filtrate obtained from 5.1.1, 5.1.2 or 5.1.3, so as to obtain a magnesium concentration which is within the limits of concentration of the reference solutions. The hydrochloric acid concentration of this solution must not exceed 0·4 N. Add 10 ml strontium salt solution (3.4) and then make up the volume to 100 ml with water. Measure the absorption of the solution to be determined and of the reference solutions at 285·2 nm.

6. **Calculation of results**

Calculate the quantity of magnesium in the sample by relation to the reference solutions. Express the result as a percentage of the sample.

Repeatability

The difference between the results of two parallel determinations carried out on the same sample must not exceed 5 %, in relative value.

Chapter III

Determination of Crude Fibre

1. Purpose and scope

This method makes it possible to determine fat-free organic substances in feeding stuffs which are insoluble in acid and alkaline media and are conventionally described as crude fibre.

2. Principle

The sample, defatted where necessary, is treated successively with boiling solutions of sulphuric acid and potassium hydroxide of specified concentrations. The residue is separated by filtration on a sintered-glass filter washed, dried, weighed and ashed within a range of 475 to 500 ºC. The loss of weight resulting from ashing corresponds to the crude fibre present in the test sample.

3. **Reagents**

3.1. Sulphuric acid, c = 0,13 mol/l.
3.2. Anti-foaming agent (e.g. n-octanol).
3.3. Filter aid (Celite 545 or equivalent), heated at 500 ºC for four hours
(8.6).
3.4. Acetone.
3.5. Light petroleum boiling-range 40 to 60 ºC.
3.6. Hydrochloric acid, c = 0,5 mol/l.
3.7. Potassium hydroxide solution, c = 0,23 mol/l.

4. Apparatus

4.1. Heating unit for digestion with sulphuric acid or potassium hydroxide solution, equipped with a support for the filter crucible (4.2) and provided with an outlet tube with a tap to the liquid outlet and vacuum, possibly with compressed air. Before use each day preheat the unit with boiling water for five minutes.
4.2. Glass filter crucible with fused sintered glass filter plate pore size 40-90 μm. Before first use, heat to 500 ºC for a few minutes and cool (8.6).
4.3. Cylinder of at least 270 ml with a reflux condenser, suitable for boiling.

4.4. Drying oven with thermostat.
4.5. Muffle furnace with thermostat.
4.6. Extraction unit consisting of a support plate for the filter crucible (4.2.) and with a discharge pipe with a tap to the vacuum and liquid outlet.
4.7. Connecting rings to assemble the heating unit (4.1), crucible (4.2) and cylinder (4.3) and to connect the cold extraction unit (4.6) and crucible.

5. Procedure

Weigh out to the nearest 0,001 g, 1 g of the prepared sample and place it in the crucible (4.2), (see observations 8.1, 8.2 and 8.3) and add 1 g of filter aid (3.3).
Assemble the heating unit (4.1) and the filter crucible (4.2), then attach the cylinder (4.3) to the crucible. Pour 150 ml of boiling sulphuric acid (3.1) into the assembled cylinder and crucible and if necessary add a few drops of antifoaming agent (3.2).
Bring the liquid to the boil within 5 ± 2 minutes and boil vigorously for exactly 30 minutes. Open the tap to the discharge pipe (4.1) and, under vacuum, filter the sulphuric acid through the filter crucible and wash the residue with three consecutive 30 ml portions of boiling water, ensuring that the residue is filtered dry after each washing. Close the outlet tap and pour 150 ml boiling potassium hydroxide solution (3.7) to the assembled cylinder and crucible and add a few drops of antifoaming agent (3.2). Bring the liquid to boiling point within 5 ± 2 minutes and boil vigorously for exactly 30 minutes. Filter and repeat the washing procedure used for the sulphuric acid step. After the final washing and drying, disconnect the crucible and its contents and reconnect it to the cold extraction unit (4.6). Apply the vacuum and wash the residue in the crucible with three consecutive 25 ml portions of acetone (3.4) ensuring that the residue is filtered dry after each washing.
Dry the crucible to constant weight in the oven at 130 ºC. After each drying cool in the desiccator and weigh rapidly. Place the crucible in a muffle furnace and ash to constant weight at 475 ºC to 500 ºC for at least 30 minutes. After each heating cool first in the furnace and then in the desiccator before weighing.
Carry out a blank test without the sample. Loss of weight resulting from ashing must not exceed 4 mg.

6. Calculation of results

The crude fibre content as a percentage of the sample is given by the expression:

$$\frac{(b-c) \times 100}{a}$$

where
a = mass of sample in g;
b = loss of mass after ashing during the determination, in g;
c = loss of mass after ashing during the blank test, in g.

7. Repeatability

The difference between two parallel determinations carried out on the same sample must not exceed:
— 0,3 in absolute value for crude fibre contents lower than 10 %,
— 3 % relative to the higher result, for crude fibre contents equal to or greater than10 %.

8. Observations

8.1. Feedingstuffs containing more than 10 % crude fat must be defatted prior to analysis with light petroleum (3.5). Connect the filter crucible (4.2) and its contents to the cold extraction unit (4.6) and apply vacuum and wash the residue with three consecutive 30 ml portions of light petroleum, ensuring that the residue is dry. Connect the crucible and its contents to the heating unit (4.1) and continue as described under 5.

8.2. Feedingstuffs containing fats which cannot be extracted directly with light petroleum (3.5) must be defatted as shown in 8.1 and defatted once more after boiling with acid. After boiling with acid and the subsequent washing connect the crucible and its contents to the cold extraction unit (4.6) and wash three times with 30 ml acetone followed by three further washings with 30 ml portions of light petroleum. Filter under vacuum until dry and continue the analysis as described under 5, beginning with potassium hydroxide treatment.

8.3. If the feeding stuffs contain over 5 % of carbonates, expressed as calcium carbonate, connect the crucible (4.2) with the weighed sample to the heating unit (4.1). Wash the sample three times with 30 ml hydrochloric acid (3.6). After each addition let the sample stand for about one minute before filtering. Wash once with 30 ml water and then continue as described under 5.

8.4. If an apparatus in the form of a stand is used (several crucibles attached to the same heating unit) no two individual determinations on the same sample for analysis may be carried out in the same series.

8.5. If after boiling it is difficult to filter the acidic and basic solutions, use compressed air through the discharge pipe of the heating unit and then continue filtering.

8.6. The temperature for ashing should not be higher than 500 ºC in order to extend the lifetime of the glass filter crucibles. Care must be taken to avoid excessive thermal shock during heating and cooling cycles.

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IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu 5(1) ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar il-Marda ta' l-Ilsien u d-Dwiefer (Miżuri ta' Kontroll).

Id-19 ta' Novembru, 2004

No. 1218

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 5(1) of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Foot-and-Mouth Disease (Control Measures) Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Foot-and-Mouth Disease (Control Measures) Rules, 2004

IN exercise of the powers conferred by article 5(1) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title and scope.

1. (1) The title of these rules is Foot-and-Mouth Disease (Control Measures) Rules, 2004.

(2) The scope of these rules is to define the Community control measures to be applied in the event of outbreaks of foot and mouth disease, whatever the type of virus concerned, in accordance with Council Directive 85/511/EEC of the 18th November, 1985.

Interpretation.

2. For the purposes of these rules, the following definitions shall apply.

'animal of a susceptible species' means any domestic or wild ruminant or swine present on a holding;

'receptive animal' means any animal of a susceptible species which is not vaccinated, or which is vaccinated but whose immunisation cover is considered to be inadequate by the competent authority;

'infected animal' means any animal of a susceptible species:

- in which clinical symptoms or post-mortem lesions which may arise from foot-

and-mouth disease have been ascertained, or

- in which the presence of foot-and-mouth disease has been officially ascertained following a laboratory examination;

'animal suspected of being infected' means any animal of a susceptible species showing clinical symptoms or post-mortem lesions which are such that the presence of foot-and-mouth disease may reasonably be suspected;

'animal suspected of being contaminated' means any animal of a susceptible species which may according to the epizootiological information collected have been directly or indirectly exposed to the foot-and-mouth virus.

'holding' means an agricultural establishment or officially supervised dealer's premises situated in the territory of a Member State, in which animals for breeding, production or slaughter are regularly kept or bred;

'animal for slaughter' means a bovine animal or swine intended to be taken on arrival in the country of destination direct to a slaughterhouse, or to a market adjoining a slaughterhouse under whose rules all animals may be removed, in particular after the market, only to a slaughterhouse approved for this purpose by the competent central authority. In the latter case, the animals must be slaughtered at that slaughterhouse not later than seventy-two hours after arriving at the market;

'animals for breeding or production' means bovine animals and swine other than those referred to in 'animal for slaughter', including those intended for breeding, milk or meat production, or draft purposes;

'tuberculosis-free bovine animal' means a bovine animal which satisfies the conditions laid down in Annex A (I) (1) of Directive 64/432/EEC;

'officially tuberculosis-free bovine herd' means a bovine herd which satisfies the conditions laid down in Annex A (I) (2) of Directive 64/432/EEC;

'brucellosis-free bovine animal' means a bovine animal which satisfies the conditions laid down in Annex A (II) (1) of Directive 64/432/EEC;

'officially brucellosis-free bovine herd' means a bovine herd which satisfies the conditions laid down in Annex A (II) (A) (2) of Directive 64/432/EEC;

'brucellosis-free bovine herd' means a bovine herd which satisfies the conditions laid down in Annex A (II) (A) (3) of Directive 64/432/EEC;

'brucellosis-free swine' means swine which satisfy the conditions laid down in Annex A (II) (B) (1) of Directive 64/432/EEC;

'officially brucellosis-free swine herd' means a swine herd which satisfies the conditions laid down in Annex A (II) (B) (2) of Directive 64/432/EEC;

'epizootic free area' means an area 20 km in diameter in which, according to official findings, for at least thirty days prior to loading there has been: (i) no incidence of foot-and-mouth disease, in the case of bovine animals; (ii) no incidence of foot-and-mouth disease, swine fever or contagious swine paralysis (Teschen disease) in the case of swine;

'compulsorily notifiable diseases' means the diseases listed in Annex E of Directive 64/432/EEC;

'official veterinarian' means the veterinarian designated by the competent central authority of the Member State;

'exporting country' means the Member State from which bovine animals and swine are sent to another Member State;

'country of destination' means the Member State to which bovine animals and swine are sent from another Member State.

Notification to the competent authority.

3. The Veterinary Services shall take all the necessary provisions to ensure that the presence, or suspected presence, of foot-and-mouth disease is compulsorily and immediately notifiable to the competent authority, in accordance with Directive 82/894/EEC.

Suspected infected holdings.

4. (1) The Veterinary Services shall take all the necessary provisions to ensure that, where a holding contains one or more animals suspected of being infected or of being contaminated with foot-and-mouth disease, official means of investigation to confirm or rule out the presence of the disease are set in motion immediately and, in particular, that the official veterinarian takes the necessary samples, or has them taken, for laboratory examination. As soon as the suspected infection is notified, the competent authority shall have the holding placed under official surveillance and shall in particular order that:

- a census be made of all categories of animals of susceptible species and that, in respect of each of these categories, the number of animals already dead, infected or liable to be infected or contaminated be recorded; the census must be kept up to date to take account of animals born or dying during the period of suspicion; the information in the census must be produced on request and may be checked at each visit;
- all animals of susceptible species on the holding be kept in their living quarters or some other place where they can be isolated;
- no animals of susceptible species enter or leave the holding;
- no animals of other species enter or leave the holding without the authorisation of the competent authority;
- all movement from the holding of meat or carcasses of animals of susceptible species or of animal feed, utensils, objects or other substance, such as wool or waste or rejected matter, liable to transmit foot-and-mouth disease be prohibited, unless authorised by the competent authority;
- the movement of milk from the holding be prohibited;

in the event of difficulties in storing the milk on the holding, the competent authority may authorise the milk to be moved from the holding under veterinary supervision to a treatment establishment in order that it may be given heat treatment ensuring the destruction of the foot-and-mouth virus;

- the movement of persons to or from the holding be made subject to authorisation by the competent authority;
- the entry or exit of vehicles to or from the holding be made subject to authorisation by the competent authority which shall lay down the conditions necessary in order to avoid propagation of the foot-and-mouth virus;
- appropriate means of disinfection be used at the entrances and exits of buildings housing animals of susceptible species and of the holding itself;
- an epizootiological inquiry be carried out in accordance with rules 7 and 8 hereof.

(2) The competent authority may extend the measures provided for in sub-rule (1) hereof to adjoining holdings should their location, their configuration, or contacts with animals from the holding where the disease is suspected, give reason to suspect possible contamination.

(3) The measures referred to in sub-rules (1) and (2) shall not be withdrawn until the suspicion of foot-and-mouth disease has been officially ruled out.

Measures to be introduced on infected holdings.

5. As soon as it has been confirmed that one or more of the animals defined in rule 2 (c) are on a holding, the competent authority shall introduce the following measures:

(1) the official veterinarian shall take adequate samples or has them taken for examination by the laboratory referred to in Schedule A, where these samples and examinations have not been taken or carried out during the period of suspicion in accordance with sub-rule 4 (1) hereof;

(2) in addition to the measures listed in sub-rule 4 (1) , the following measures are taken without delay:

- all animals of susceptible species on the holding shall be slaughtered on the spot under official supervision in such a way as to avoid all risk of spreading the foot-and-mouth virus;
- after being slaughtered, the aforementioned animals shall be destroyed under official supervision in such a way that there is no risk of spreading the foot-and-mouth virus;
- meat of animals of susceptible species coming from the holding and slaughtered during the period between the probable introduction of the disease to the holding and the implementation of official measures shall, wherever possible, be traced and destroyed under official supervision in such a way as to avoid any risk of spreading the foot-and-mouth virus;
- the carcasses of animals of susceptible species which have died on the holding shall be destroyed under official supervision in such a way as to avoid any risk of spreading the foot-and-mouth virus;
- any substance referred to in sub-rule 4 (1), fifth indent, shall be destroyed or treated in such a way as to ensure the destruction of any foot-and-mouth virus present; all treatment must be carried out in accordance with the instructions of the official veterinarian;
- milk and milk products shall be destroyed in such a way as to avoid any risk of spreading the foot-and-mouth virus;
- after elimination of the animals of susceptible species and of the substances referred to in sub-rule 4 (1) , fifth indent, the buildings used for housing, their surroundings and the vehicles used for their transport and all equipment likely to be contaminated shall be cleaned and disinfected in accordance with rule 10;.
- no animals of susceptible species shall be reintroduced to the holding until at least 21 days after completion of the cleaning and disinfection operations carried out in accordance with rule 10 hereof;
- an epizootiological inquiry shall be carried out in accordance with rules 7 and 8 hereof;

(3) the provisions of paragraph (1) hereof shall not apply in the case of appearance of a secondary source which is linked epidemiologically with a primary source for which

samples have already been taken;

(4) the competent authority may extend the measures provided for in paragraph (1) to adjoining holdings should their location, their configuration, or contacts with animals from the holding where the disease has been recorded give reason to suspect possible contamination.

Holdings consisting of two or more units.

6. (1) (a) In the case of holdings which consist of two or more separate production units, the competent authority may derogate from the requirements of sub-rule 5 (2), first and second indents as regards healthy production units of a holding which is infected, provided that the official veterinarian has confirmed that the structure and size of these units and the operations carried out there are such that they are completely separate as regards housing, keeping and feeding, so that the virus cannot spread from one to another.

(b) The same measures and the possibility of derogating from the requirements of the sixth indent of sub-rule 5 (2) may be extended to holdings producing milk, provided that, in addition, milking in each unit is carried out quite separately.

(2) (a) Where recourse is had to the provisions of sub-rule (1), the competent authority shall ensure that the rules they apply include, at least, the following:

- the derogation available in sub-rule 6 (1) shall only be granted following an individual assessment of the holding in question carried out by an official veterinarian at the time of the official investigation to confirm or rule out the presence of foot-and-mouth disease,
- this assessment shall take into account all conditions and situations pertaining to the possible spread of foot-and-mouth disease.

(b) (i) In granting the derogation referred to in paragraph (a), the competent authority shall take all the necessary provisions to ensure that there is no more risk of foot-and-mouth disease virus spreading between separate production units on a holding than of it spreading between separate holdings.

(ii) Intensively managed production units containing healthy animals shall conform to the following requirements:

- they shall be constructionally separate from those which contained infected animals with no communication or common air space between them,
- they shall have separate stores for equipment, fodder, effluent and, where appropriate, milk,
- they shall have individual disinfection facilities at entrances and exits,
- they shall have their own personnel,
- further, there shall have been no exchange of farm machinery or other equipment between infected and healthy units nor shall there have been an exchange of animals, animal products, animal feed, utensils, objects or other substances such as wool or waste or rejected matter liable to transmit foot-and-mouth disease from infected to healthy units.

(c) The conditions laid down in paragraph (b) hereof shall have been in place, to the satisfaction of the official veterinarian, prior to the date on which one or more infected animals as defined in sub-rule (2) (c) were present on the holding, taking into account the

likely incubation period of the disease.

Epizootiological inquiry.

7. The epizootiological inquiry shall deal with:

- the length of time during which the foot-and-mouth disease may have existed on the holding before being notified or suspected;. the possible origin of the foot-and-mouth disease on the holding and the identification of other holdings on which there are animals of susceptible species which may have become infected or contaminated from the same source;
- the movement of persons, vehicles and substances referred to in sub-rule 4 (1), fifth indent, likely to have carried the foot-and-mouth virus to or from the holdings in question.

Cross-holding infections.

8. (1) (a) Where the official veterinarian finds, or considers on the basis of confirmed data, that foot-and-mouth disease could have been introduced from other holdings on to the holding referred to in rule 4, or from the latter holding on to other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with rule 4 and this surveillance shall not be lifted until the suspected presence of foot-and-mouth disease on the holding referred to in rule 4 has been officially ruled out.

(b) Where the official veterinarian finds, or considers on the basis of confirmed data, that foot-and-mouth disease could have been introduced on to the holding referred to in rule 5 from other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall be placed under official surveillance in accordance with rule 4.

(c) Where the official veterinarian finds, or considers on the basis of confirmed data, that foot-and-mouth disease could have been introduced from the holding referred to in rule 5 on to other holdings as a result of the movement of persons, animals or vehicles or in any other way, those other holdings shall become subject to the provisions of rule 4.

(2) When a holding has been subject to the provisions of sub-rule (1), the competent authority shall prohibit removal of animals from the holding other than for transport directly to a slaughterhouse under official supervision for the purpose of emergency slaughter during a 15-day period in the case of holdings referred to in sub-rule (1) (a) and (b) and a 21-day period in the case of holdings referred to in sub-rule (1) (c) respectively. Prior to granting such authorisation, the official veterinarian must have carried out an examination of the herd and confirmed that none of the animals is suspected of being infected.

(3) Where it considers that conditions permit, the competent authority may limit the measures provided for in sub-rule (1) (a) and (b) to a part of the holding and the animals contained therein, provided that the animals there have been housed, kept and fed completely separately.

Protection zone.

9. (1) (a) The Veterinary Services shall take all the necessary provisions to ensure that, once the diagnosis of foot-and-mouth disease has been officially confirmed, a protection zone based on a minimum radius of 3 kilometres and a surveillance zone based on a minimum radius of 10 kilometres is established around the infected holding.

(b) The definition of zones shall take account of natural boundaries, supervision facilities and technological progress which makes it possible to foresee the possible dispersion of the virus by air or any other means and will have to be reviewed, if necessary, in the light of such elements.

(2) (a) the following measures shall be applied in the protection zones:
- a census of all the holdings with animals of susceptible species must be carried out,
- holdings which are the subject of such a census must periodically undergo a veterinary inspection,
- animals of susceptible species may not be removed during the first 15 days from the holding on which they are kept except to be transported directly under official supervision for the purpose of emergency slaughter to a slaughterhouse located in that zone or, if that zone has no slaughterhouse under veterinary supervision, to a slaughterhouse designated by the competent authority. Such movement may be authorised by the competent authority only after examination by the official veterinarian of all the animals of susceptible species on the holding has ruled out the presence of suspected animals;
- itinerant service for breeding shall be prohibited;
- artificial insemination shall be prohibited during the first 15 days except where it is carried out by the farmer with sperm that is on the farm or with sperm delivered directly by an insemination centre;
- fairs, markets, shows or other gatherings of susceptible animals, including collection and distribution, shall be prohibited;
- without prejudice to the case provided for in the second sentence of the third indent, the transport of animals of susceptible species shall be prohibited, except for transit by major highways or mainline railways.

(b) the measures applied in the protection zone shall be maintained for at least 15 days after elimination of all the animals referred to in rule 5 from the holding and the carrying out on that holding of preliminary cleaning and disinfection operations in accordance with regulation 10. However, the measures described in sub-rule (3) hereof for the surveillance zone shall remain in force in the protection zone for the period provided for in sub-rule (3) (b) hereof.

(3) (a) The following measures shall be applied in the surveillance zone:
- a census shall be taken of all holdings having animals of susceptible species;
- the movement of animals of susceptible species on public roads shall be prohibited except for the purpose of leading them to pasture;
- the transport of animals of susceptible species within the surveillance zone shall be subject to the authorisation of the competent authority;
- the animals may not be removed from the surveillance zone during the first 15 days. Between the 15th day and the 30th day, the animals may not be removed from the said zone except to be transported under official supervision directly to a slaughterhouse for the

purpose of emergency slaughter. Such transport may be authorised by the competent authority only after the official veterinarian has carried out an examination of all the animals concerned and confirmed that none of the animals is suspected of being infected;
- itinerant service for breeding shall be prohibited;
- fairs, markets, shows and other gatherings of susceptible animals shall be prohibited.

(b) the measures in the surveillance zone shall be kept in force for at least 30 days after the elimination of all the animals referred to in rule 5 from the holding and the carrying out on that holding of preliminary cleaning and disinfection operations in accordance with rule 10.

Cleaning and disinfection operations.

10. (1) The disinfectants to be used and their concentrations are officially approved by the competent authority;
(2) The cleaning and disinfection operations are carried out under official supervision, in accordance with the instructions given by the official veterinarian.

Testing in laboratory.

11. (1) Laboratory testing to detect the presence of foot-and-mouth disease are carried out by the national laboratory indicated in Schedule B. This laboratory testing should, if necessary and especially on the first appearance of the disease, show the type, subtype or, where appropriate, the variant of the relevant virus which may be confirmed, if necessary, by a reference laboratory designated by the community;

(2) The national laboratories referred to in the first indent liase with a reference laboratory designated by the European Community.

Provisions to be taken by Veterinary Services.

12. The Veterinary Services shall take the necessary provisions to ensure that:

(1) when animals of susceptible species are moved out of the holding on which they are kept, they are identified in such a way as to enable their holding of origin, or the holding from which they have come, and their movements to be traced rapidly. However, for certain categories of animals and without prejudice to measures concerning tracing of pigs for the control of classical swine fever, the competent authority may, in certain circumstances and having regard to the health situation, authorise other ways of rapidly tracing their holding of origin, or the holding from which they have come, and their movements. The arrangements for identifying the animals or for tracing the holding of origin shall be determined by the competent authority;

(2) the owner or keeper of the animals is required to supply the competent authority, on request by that authority, with information concerning animals entering or leaving his holding;

(3) all persons engaged in the transport or marketing of animals of susceptible species are able to supply the competent authority with information concerning the movements of animals which they have transported or marketed and to furnish all the details concerning such information.

Foot-and-mouth vaccines.

13. (1) (a) The use of foot-and-mouth vaccines, the manipulation of foot-and-mouth virus for research, diagnosis and, or manufacture of vaccines is prohibited in Malta,

(b) The storage, supply, distribution and sale of foot-and-mouth vaccines on the territory of Malta shall be carried out under official control.

(2) Notwithstanding the provisions of sub-rule (1) concerning the use of foot-and-mouth disease vaccine, it may be decided, when foot-and-mouth disease has been confirmed and threatens to become extensive, that emergency vaccination using technical procedures guaranteeing the animals total immunity may be introduced provided that basic community interests are not endangered. In this case, the measures to be taken shall include:
- the extent of the geographical area in which emergency vaccination is to be carried out,
- the species and the age of the animals to be vaccinated,
- the duration of the vaccination campaign,
- a specific standstill of vaccinated animals and their products,
- the special identification and special registration of the vaccinated animals,
- other matters appropriate to the emergency situation. The decision to introduce emergency vaccination shall be taken in collaboration with the Member States. This decision shall have particular regard to the degree of concentration of animals in certain regions and the need to protect special breeds.

SCHEDULE A

Commercial laboratory authorised to handle live foot-and-mouth disease virus for vaccine production intended for Malta

Rhônemerieux, Pirbright laboratory, Ash Road, Pirbright, Woking, Surrey.

SCHEDULE B

National laboratory authorised to handle for Malta live foot-and-mouth disease virus

Institute for Animal Health, Pirbright,
Woking, Surrey.

Nru. 1219

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu 10 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Kundizzjonijiet ta' Saħħa għall-Produzzjoni u t-Tqegħid fis-Suq ta' Molluski Bivalvolari Hajjin.

Id-19 ta' Novembru, 2004

No. 1219

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 10 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Health Conditions for the Production and the Placing on the Market of Live Bivalve Molluscs.

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Health Conditions for the Production and the Placing on the Market of Live Bivalve Molluscs Rules, 2004

IN exercise of the powers conferred by article 10 of the Veterinary Services Act 2003, the Minister for Rural Affairs and the Environment, after consultation with the Minister of Health, the Elderly and Community Care, has made the following rules:-

Title and scope.

1. (1) The title of these rules is 'Health Conditions for the Production and the Placing on the Market of Live Bivalve Molluscs': Rules, 2004.

(2) The scope of these rules is to implement the provisions found under European Union Council Directive 91/492/EEC of the 15th July, 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs which are intended for immediate human consumption or for further processing before consumption.

With the exception of the provisions on purification, these rules apply to echinoderms, tunicates and marine gastropods.

CHAPTER I

Definitions.

2. For the purposes of these rules, the following definitions shall apply:

'bivalve molluscs' means filterfeeding lamellibranch molluscs;
'marine biotoxins' means poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxin;
'clean sea water' means sea water or brackish water which is to be used under the conditions laid down in these rules and which is free from microbiological contamination and toxic and objectionable substances occurring naturally or after discharge in the environment such as those listed in the Annex to Council Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, in such quantities as may adversely affect the health quality of bivalve molluscs or to impair their taste;
'competent authority' means the central authority of a Member State competent to carry out veterinary checks or any authority to which it has delegated that competence; for Malta, the competent authority is the Veterinary Services;
'conditioning' means the storage of live bivalve molluscs, whose quality does not indicate the need for relaying or treatment in a purification plant, in tanks or any other installation containing clean sea water or in natural sites to remove sand, mud or slime;
'gatherer' means any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market;
'production area' means any sea, estuarine or lagoon area containing natural deposits of bivalve molluscs or sites used for cultivation of bivalve molluscs from which live bivalve molluscs are taken;
'relaying area' means any sea, estuarine or lagoon area approved by the competent authority, with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs;
'dispatch centre' means any approved onshore or offshore installation for the reception, conditioning, washing, cleaning, grading and wrapping of live bivalve molluscs fit for human consumption;
'purification centre' means an approved establishment with tanks fed by naturally clean sea water or sea water that has been cleaned by appropriate treatment, in which live bivalve molluscs are placed for the time necessary to remove microbiological contamination, so making them fit for human consumption;
'relaying' means an operation whereby live bivalve molluscs are transferred to approved sea or lagoon areas or approved estuarine areas under the supervision of the Veterinary Services for the time necessary to remove contamination. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening;
'means of transport' means those parts set aside for goods in automobile vehicles, rail vehicles and aircraft, the holds of vessels and containers for transport by land, sea or air;
'wrapping' means an operation whereby live bivalve molluscs are placed in packaging material adequate for the purpose;
'consignment' means a quantity of live bivalve molluscs handled in a dispatch centre or treated in a purification centre and subsequently intended for one or more customers;
'batch' means a quantity of live bivalve molluscs collected from a production area and subsequently intended for delivery to an approved dispatch centre, purification centre,

relaying area or processing plant as appropriate;
'placing on the market' means the holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market of live bivalve molluscs for human consumption either raw or for the purpose of processing in the European Community, excluding the direct transfer on the local market in small quantities by the coastal fisherman to the retailer or the consumer which must be subject to the health checks laid down by national rules for checking on retail business; these rules shall be established under the procedure laid down in article 10 of the Veterinary Services Act;
'importation' means the introduction of live bivalve molluscs into the territory of the European Community from third countries;
'faecal coliform' means facultative, aerobic, gramnegative, non-sporeforming, cytochrome oxidase negative, rod-shaped bacteria that are able to ferment lactose with gas production in the presence of bile salts, or other surface active agents with similar growth-inhibiting properties, at 44°C ± 0, 2°C within 24 hours at least;
'E. coli' means faecal coliforms which also form indole from tryptophan at 44°C ± 0, 2°C within 24 hours.

CHAPTER II

Provisions for European Community production.

3. (1) The placing on the market of live bivalve molluscs for immediate human consumption shall be subject to the following conditions:

(a) they must originate from production areas which comply with the requirements laid down in Chapter I of the Schedule; however, in the case of pectinidae, this provision shall apply only to aquaculture products as defined in Article 2 (2) of Council Directive 91/493/EEC of the 22nd July, 1991 laying down the health conditions for the production and placing on the market of fishery products;

(b) they must have been harvested and transported from the production area to a dispatch centre, purification centre, relaying area or processing plant under the conditions laid down in Chapter II of the Schedule;

(c) where provided for in these rules, they must have been relaid in suitable areas approved for that purpose and complying with the conditions laid down in Chapter III of the Schedule;

(d) they must have been handled hygienically, and where appropriate, they must have been purified in establishments approved for that purpose and complying with the requirements of Chapter IV of the Schedule;

(e) they must comply with the criteria set out in Chapter V of the Schedule;

(f) health controls must have been carried out in accordance with Chapter VI of the Schedule;.

(g) they must have been appropriately wrapped in accordance with Chapter VII of the Schedule;

(h) they must have been stored and transported under satisfactory conditions of hygiene in accordance with Chapters VIII and IX of the Schedule;

(i) they must bear a health mark as provided for in Chapter X of the Schedule.

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(2) Live bivalve molluscs intended for further processing must comply with the relevant requirements of sub-rule (1) and be processed in accordance with the requirements of Council Directive 91/493/EEC.

Compliance with rules.

4. Member States shall ensure that persons handling live bivalve molluscs during their production and placing on the market shall adopt all measures necessary to comply with the requirements of these rules. Persons responsible for dispatch and purification centres shall in particular ensure that:

(a) representative numbers of samples for laboratory examination are regularly taken and analysed in order to establish an historical record on the basis of the areas where batches come from and of the health quality of the live bivalve molluscs both before and after handling at a dispatch centre or purification centre.

(b) a register is kept for the permanent record of the results of the various checks and kept for presentation to the Veterinary Services.

Approval by Veterinary Services.

5. (1) (a) The Veterinary Services shall approve dispatch centres and purification centres once it is satisfied that they meet the requirements of these rules. The Veterinary Services shall take the necessary measures if the requirements cease to be met. In so doing, it shall take account of, in particular, the outcome of any check carried out in accordance with regulation 6 (1).

In the territory of Malta, the operators shall obtain an authorisation of the Veterinary Services previous to create or re-open dispatch and purification centres. Such authorisation may be granted only to establishments, which have submitted a duly substantiated application for authorisation to the Veterinary Services. This application must be accompanied by a work plan and program indicating the period within which it would be possible for the establishments to comply with the conditions of the approval set out in the above-mentioned Chapter. Only requests in respect of projects complying with the requirements of these rules can be accepted.

The Veterinary Services shall draw up a list of approved dispatch centres and purification centres, each of which shall have an official number.

The list of approved dispatch centres and purification centres, and any subsequent amendments thereto, must be communicated by the Veterinary Services to the European Commission.

(b) The inspection and monitoring of these centres shall be carried out regularly under the responsibility of the Veterinary Services, which shall have free access to all parts of the centres, in order to ensure compliance with the provisions of these rules. If such inspections and monitoring reveal that the requirements of these rules are not being met, the Veterinary Services shall take appropriate action.

(2) (a) The Veterinary Services shall establish a list of production and re-laying areas, with an indication of their location and boundaries, from which live bivalve molluscs may be taken in accordance with the requirements of these rules and, in particular, with Chapter I of the Schedule. This list must be communicated to those affected by these rules, such as gatherers and operators of purification centres and dispatch centres.

(b) The monitoring of the production and relaying areas shall be carried out under the responsibility of the Veterinary Services in accordance with the requirements of these rules.

If such monitoring reveals that the requirements of these rules are no longer being met, the Veterinary Services shall close the production or relaying area concerned until the situation has been restored to normal.

(3) The Veterinary Services may prohibit any production and harvesting of bivalve molluscs in areas considered unsuitable for these activities for health reasons.

Spot checks.

6. (1) Experts from the European Commission may, in co-operation with the Veterinary Services and, if necessary, the other authorities of Malta involved, make on-the-spot checks insofar as is necessary to ensure the uniform application of the Council Directive 91/492/EEC. They may, in particular, check whether centres, production and relaying areas are in effect complying with the requirements of that Directive. The Veterinary Services and, if necessary, the other authorities of Malta involved shall give all necessary assistance to the experts in carrying out their duties. In particular, access on the same basis as officials of the competent authority shall be given to all concerned persons, information and documentation as well as access to places, establishments, installations and means of transport in order for the checks to be carried out.

(2) The Competent authority and the operators shall follow the recommendations containing guidelines on good manufacturing practices drawn up by the European Commission, applicable at the different stages of production and placing on the market.

Checks and safeguard measures.

7. The rules laid down in Council Directive 89/662/EEC as regards live bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption, shall apply, in particular as regards the organisation of, and the action to be taken following, the checks to be carried out at destination, and the safeguard measures to be implemented.

CHAPTER III

Imports from third countries.

8. Provisions applied to imports of live bivalve molluscs from third countries shall be at least equivalent to those governing the production and placing on the market of European Community products.

Uniform application of requirement.

9. In order to ensure the uniform application of the requirement imposed in rule 8, the following procedure shall apply:

(1) (a) European Commission and the Member States carry out on the spot inspections by experts from the Commission and the Member States to verify whether the conditions of production and placing on the market can be considered as being equivalent to those applied in the Community;

(b) These inspections shall be made on behalf of the Community and the frequency and

the procedure for these inspections shall be determined by the European Commission. At the request of the European Commission, experts from Malta may be authorised by the Director to participate to inspections carried out on the spot by experts from the European Commission and the Member States;

(2) in deciding whether the conditions of production and placing on the market of live bivalve molluscs in a third country can be deemed equivalent to those of the European Community, particular account shall be taken of:

(a) the legislation of the third country;

(b) the organisation of the competent authority of the third country and of its inspection services, the powers of such services and the supervision to which they are subject, as well as their facilities for monitoring the implementation of their legislation in force;

(c) the actual health conditions during the production and placing on the market of live bivalve molluscs and in particular the monitoring of production areas in relation to microbiological and environmental contamination, and to the presence of marine biotoxins;

(d) the regularity and the rapidity of the information provided by the third country on the presence of plankton containing toxin in the production areas and, in particular, of species not occurring in European Community waters, and risks that such presence may signify for the European Community;

(e) the assurances which a third country can give on the compliance with the standards laid down in Chapter V of the Schedule;

(3) the Veterinary Services shall apply the relevant requirements decided on by the European Commission:

(a) the list of third countries fulfilling the conditions of equivalence referred to in paragraph 2 hereof;

(b) for each third country, the specific conditions for the importation of live bivalve molluscs. These conditions must include:

(i) the procedure for obtaining a health certificate which must accompany consignments when forwarded to the European Community;

(ii) the demarcation of the production areas from which live bivalve molluscs may be harvested and imported;

(iii) the obligation to notify the European Community of any possible change in the approval of production areas;

(iv) any purification after arrival in the territory of the European Community;

(c) a list of establishments from which the importation of live bivalve molluscs is authorised. For that purpose, one or more lists of such establishments shall be established. An establishment may not appear on a list unless it is officially approved by the competent authority of the third country exporting to the Community. Such approval shall be subject to observance of the following requirements:

(i) compliance with requirements equivalent to those laid down in these rules;

(ii)monitoring by an official inspection service of the third country;

(4) the Veterinary Services shall apply the amendment to decisions referred to in paragraph (3) hereof decided on by the European Commission. These decisions and the amendments thereto shall be published in the Gazette according to article 12(2) of the Veterinary Services Act;

(5) pending the decisions referred to in paragraph (3) hereof, the conditions which Malta

shall apply to imports of live bivalve molluscs from third countries shall be at least equivalent to those governing the production and placing on the market of European Community products.

Applicability of Directive.

10. Rules and principles laid down in Council Directive 97/78/EC shall apply, with particular reference to the organisation of and follow up to the inspections to be carried out by the Veterinary Services and the safeguard measures to be implemented.

Designation of laboratory for monitoring marine biotoxins.

11. (1) The laboratory "……." is hereby designated as national reference laboratory for the monitoring of marine biotoxins in Malta.

(2) This national reference laboratory shall be responsible for the following tasks:

(a) coordinating the activities of the national laboratories responsible for analyses of marine biotoxins in Malta;

(b) assisting the Veterinary services to organise the system for monitoring marine biotoxins;

(c) organising comparative tests between the various laboratories responsible for analysing marine biotoxins;

(d) ensuring that the information supplied by the European Community reference laboratory is disseminated to the Veterinary Services in Malta and to the laboratories responsible for analysing marine biotoxins.

(3) The national reference laboratories shall collaborate with the `Laboratorio de biotoxinas marinas del Area de Sanidad` in Vigo designated by the European Community as the European Community reference laboratory for the monitoring of marine biotoxins.

Designation of laboratory for monitoring bivalve molluscs.

12. (1) The laboratory "....." is hereby designated as national reference laboratory for monitoring viral and bacteriological contamination of bivalve molluscs in Malta.

(2) This national reference laboratory shall be responsible for:

(a) coordinating the activities of the other laboratories responsible for viral and bacteriological analyses of bivalve molluscs in Malta;

(b) assisting the Veterinary Services to organise a system for monitoring viral and bacteriological contamination of bivalve molluscs;

(c) organising on a regular basis comparative tests between the various other laboratories responsible for the said analyses;

(d) disseminating the information provided by the European Community reference laboratory for monitoring viral and bacteriological contamination of bivalve molluscs to the Veterinary Services and other laboratories responsible for the said analyses.

(3) The national reference laboratory and the other laboratories shall collaborate with the "laboratory of the Centre for Environment, Fisheries and Aquaculture Science at Weymouth in the United Kingdom" designated as the European Community reference laboratory for monitoring the viral and bacteriological contamination of bivalve molluscs.

SCHEDULE

CHAPTER I

CONDITIONS FOR PRODUCTION AREAS

1. The location and the boundaries of production areas must be fixed by the Veterinary Services in such a way as to identify the areas from which live bivalve molluscs:
(a) can be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the requirements set out in Chapter V of these rules;
(b) can be collected but only placed on the market for human consumption after treatment in a purification centre, after relaying. Live bivalve molluscs from these areas must not exceed the limits of a fivetube, threedilution MPNtest of 6 000 faecal coliforms per 100 g of flesh or 4 600 E. Coli per 100 g of flesh in 90 % of samples. After purification or relaying, all the requirements set out in Chapter V of this Schedule must be met;
(c) can be collected but placed on the market only after relaying over a long period (at least two months), whether or not combined with purification, or after intensive purification for a period to be fixed in accordance with the requirements of the European Community and in accordance with the procedure provided for in article 10 of the Veterinary Services Act, so as to meet the requirements under (a). Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three-dilution MPNtest of 60 000 faecal coliforms per 100 g of flesh.
2. Any change in the demarcation of production areas and the temporary or definitive closure thereof must be immediately announced by the Veterinary Services to those affected by these rules and in particular to producers and operators of purification and dispatch centres.

CHAPTER II

REQUIREMENTS FOR HARVESTING AND TRANSPORTATION OF BATCHES TO A DISPATCH OR PURIFICATION CENTRE, RELAYING AREA OR PROCESSING PLANT

1. Harvesting techniques must not cause excessive damage to the shells or tissues of live bivalve molluscs.
2. Live bivalve molluscs must be adequately protected from crushing, abrasion or vibration after harvesting and must not be exposed to extremes of hot or cold temperature.
3. Techniques for harvesting, transporting, landing and handling live bivalve molluscs must not result in additional contamination of the product, nor in a significant reduction in the quality of the product, nor in any changes significantly affecting their ability to be treated by purification, processing or relaying.
4. Live bivalve molluscs must not be reimmersed in water which could cause additional contamination between harvesting and landing.
5. The means of transport used for transporting live bivalve molluscs must be used under conditions which protect the latter from additional contamination and crushing of shells. They must permit adequate drainage and cleaning. In the event of bulk transport over long distances of live bivalve molluscs to a dispatch centre, purification centre, relaying area or processing plant, the means of transport must be equipped in such a way as to ensure the best survival conditions possible, and in particular must comply with the requirements laid down in Chapter IX, Section 2 of this Schedule.
6. A registration document for the identification of batches of live bivalve molluscs during transport from the production area to a dispatch centre, purification centre, relaying area or processing plant must be issued by the Veterinary Services upon request by the gatherer. For each batch, the gatherer must complete legibly and indelibly the relevant sections of the registration document which must contain the following information:
- the gatherer's identity and address,
- the date of harvesting,
- the location of the production area described in as precise detail as is practicable or by a code number,
- the health status of the production area as referred to in Chapter I,
- the shellfish species and quantity indicated in as precise detail as is practicable,

- the approval number and place of destination for wrapping, relaying, purification or processing.

The registration document must be dated and signed by the gatherer.

The registration documents must be numbered regularly and in sequence. The Veterinary Services must keep a register indicating numbers of registration documents together with the names of the persons collecting live bivalve molluscs to whom the documents were issued. The registration document for each batch of live bivalve molluscs must be date-stamped upon delivery of a batch to a dispatch centre, purification centre, relaying area or processing plant and must be kept by operators of such centres, areas or plants for at least twelve months. In addition, the gatherer is also obliged to keep it for the same period.

However, if gathering is carried out by the same staff operating the dispatch centre, purification centre, relaying area or processing plant of destination, the registration document may be replaced by a permanent transport authorisation granted by the Veterinary Services. A standard registration document, containing a reference to the various requirements which are to be included in it and which are mentioned in Chapters II, III and IV of this Schedule will be introduced according to the model laid down by the European Commission.

7. If a production or relaying area is closed temporarily, the Veterinary Services must refrain from issuing registration documents for that area and immediately suspend the validity of all registration documents already issued.

CHAPTER III

CONDITIONS FOR RELAYING LIVE BIVALVE MOLLUSCS

The following conditions must be met:

1. live bivalve molluscs must be gathered and transported in accordance with the requirements of Chapter II of this Schedule;

2. techniques for handling live bivalve molluscs intended for relaying must permit the resumption of filter-feeding activity after immersion in natural waters;

3. live bivalve molluscs must not be re-laid at a density which does not permit purification;

4. live bivalve molluscs must be immersed in seawater at the relaying area for an appropriate period which must exceed the time taken for levels of faecal bacteria to become reduced to the levels permitted by these rules taking account of the fact that the standards of Chapter V of this Schedule must be met;

5. the minimum water temperature for effective relaying must, where necessary, be determined and announced by the Veterinary Services for each species of live bivalve mollusc and approved relaying area;

6. areas for relaying live bivalve molluscs must be approved by the Veterinary Services. The boundaries of the sites must be clearly identified by buoys, poles or other fixed means; there must be a minimum distance of 300 metres between relaying areas, and also between relaying areas and production areas;

7. sites within a relaying area must be well separated to prevent mixing of batches; the 'all in, all out' system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed;

8. permanent records of the source of live bivalve molluscs, relaying periods, relaying areas and subsequent destination of the batch after relaying must be kept by the operators of relaying areas for inspection by the Veterinary Services;

9. after harvesting from the relaying area, batches must, during transport from the relaying area to the approved dispatch centre, purification centre or processing plant, be accompanied by a registration document, established according to a specimen drawn up by the European Commission, setting out, in addition to the information specified in point 6 of Chapter II of this Schedule, inter alia the location and approval number of the relaying area and the duration of relaying, together with any other information needed to identify and trace the product.

However, the above shall not be required where the same staff operate both in the relaying area and in the dispatch centre, purification centre or processing plant.

CHAPTER IV

CONDITIONS FOR THE APPROVAL OF DISPATCH OR PURIFICATION CENTRES

I. General conditions relating to premises and equipment

Centres must not be located in areas which are close to objectionable odours, smoke, dust and other contaminants. The location must not be subject to flooding by ordinary high tides or runoff from surrounding areas. Centres must have at least:

1. on premises where live bivalve molluscs are handled or stored:

(a) buildings or facilities of sound construction, designed and maintained adequately for the purpose of preventing contamination of live bivalve molluscs by any type of waste, dirty water, fumes, dirt or by the presence of rodents or other animals;

(b) flooring which is easy to keep clean and is laid in such a way as to facilitate drainage;

(c) adequate working space to allow for satisfactory performance of all operations;

(d) durable walls which are easy to clean;

(e) adequate natural or artificial lighting;

2. access to an appropriate number of changing rooms, wash basins and lavatories; there must be a sufficient number of wash basins close to the lavatories;

3. adequate equipment for washing tools, containers and equipment;

4. facilities for the supply and, where appropriate, storage of exclusively potable water within the meaning of European Community relating to the quality of water intended for human consumption or facilities for the supply of clean sea water. Facilities supplying non-potable water may be authorised. The water concerned may not come into direct contact with live bivalve molluscs or be used for cleaning or disinfecting containers, plant or equipment which come into contact with live bivalve molluscs. Pipes and outlets carrying non-potable water must be clearly distinguished from those carrying potable water;

5. equipment and instruments or their surfaces which are intended to come into contact with live bivalve molluscs must be made of corrosion-resistant material which is easy to wash and clean repeatedly.

II. General hygiene requirements.

A high degree of cleanliness and hygiene must be required of staff, premises, equipment and working conditions:

1. staff who treat or handle live bivalve molluscs must in particular wear clean working clothes and, where appropriate, gloves which are suitable for the work in which the person is engaged;

2. staff are obliged to refrain from personal behaviour, such as spitting, which could result in contamination of live bivalve molluscs; any person suffering from an illness which can be transmitted by live bivalve molluscs must be temporarily prohibited, until recovery, from working with or handling these products;

3. any rodents, insects or other vermin found must be destroyed and further infestation prevented. Domestic animals must not enter the facilities;

4. premises, equipment and instruments used for handling live bivalve molluscs must be kept clean and in a good state of repair; equipment and instruments must be thoroughly cleaned at the end of the day's work and at such other times as may be appropriate;

5. premises, instruments and equipment must not be used for purposes other than the handling of live bivalve molluscs without authorisation by the Veterinary Services;

6. waste products must be stored hygienically in a separate area and, where appropriate, in covered containers suitable for the purpose intended. Waste material must be removed from the vicinity of the establishment at appropriate intervals;

7. the finished products must be stored under cover and must be kept away from the areas where animals other than live bivalve molluscs, such as crustaceans, are handled.

III. Requirements for purification centres

In addition to the requirements under Sections I and II, the following conditions must be met:

1. the floors and walls of the purification tanks and any water storage containers must have a smooth, hard and impermeable surface and be easy to clean by scrubbing or use of pressurised water. The base of the purification tanks must be sufficiently sloped and be equipped with drainage sufficient for the volume of work;
2. live bivalve molluscs must be washed free of mud with pressurised clean sea water or potable water before purification. The initial washing may also be carried out in the purification tanks before purification commences, the drainage pipes being kept open during the entire initial washing and sufficient time being allowed thereafter for the system to be flushed clean before the purification process begins;
3. the purification tanks must be supplied with a sufficient flow of sea water per hour and per tonne of live bivalve molluscs treated;
4. clean sea water or sea water cleaned by treatment must be used for purifying live bivalve molluscs; the distance between the sea water intake point and the waste water outlets must be sufficient to avoid contamination; if treatment of the sea water is necessary, the process shall be authorised once its effectiveness has been verified by the Veterinary Services; potable water used to prepare sea water from its major constituent chemicals must comply with the requirements laid down by the European Community;
5. operation of the purification system must allow live bivalve molluscs to rapidly resume filter feeding activity, remove sewage contamination, not to become re-contaminated and be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market;
6. the quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre; the live bivalve molluscs must be continuously purified for a period sufficient to allow the microbiological standards laid down in Chapter V of this Schedule to be met. This period starts from the moment at which the live bivalve molluscs in the purification tanks are adequately covered by the water until the moment when they are removed.
The purification centre must take account of the data relating to the raw materials (the type of bivalve mollusc, its area of origin, microbe content, etc.) in case it is necessary to extend the purification period so as to ensure that the live bivalve molluscs meet the bacteriological requirements of Chapter V of this Schedule;
7. should a purification tank contain several batches of molluscs, they must be of the same species and come from the same production area or different areas conforming to the same health conditions. The length of the treatment must be based on the time required by the batch needing the longest period of purification;
8. containers used to hold live bivalve molluscs in purification systems must have a construction which allows sea water to flow through; the depth of layers of live bivalve molluscs should not impede the opening of shells during purification;
9. no crustaceans, fish or other marine species must be kept in a purification tank in which live bivalve molluscs are undergoing purification;
10. after completion of purification, the shells of live bivalve molluscs must be washed thoroughly by hosing with potable water or clean sea water; this may take place in the purification tank if necessary; the washing water must not be recirculated;
11. purification centres must have their own laboratories or secure the services of a laboratory equipped with the necessary facilities for checking the efficiency of purification by use of microbiological specifications. Laboratory facilities outside the centres must be recognised by the Veterinary Services;
12. purification centres must regularly keep a record of the following data:
- results of microbiological tests on purification system water entering the purification tanks;
- results of microbiological tests on unpurified live bivalve molluscs;
- results of microbiological tests on purified live bivalve molluscs;
- dates and quantities of live bivalve molluscs delivered to the purification centre and corresponding registration document numbers;
- the times of filling and emptying of purification systems (purification times) ;
- dispatch details of consignments after purification. These records must be complete and accurate, legible and recorded in a permanent ledger book which must be available for inspection by the Veterinary Services;
13. purification centres must accept only those batches of live molluscs which are accompanied by the registration document referred to in Chapter II of this Schedule;

Purification centres dispatching batches of live bivalve molluscs to dispatch centres must provide a registration document, established according to a specimen drawn up by the European Commission, setting out, in addition to the information specified in point 6 of Chapter II of this Schedule, inter alia the approval number and address of the purification plant and the duration of purification, the dates of entering and leaving the purification centre, together with any other information needed to identify and trace the product.
14. every package containing purified live bivalve molluscs must be provided with a label certifying that all molluscs have been purified.

IV. Requirements for dispatch centres

1. In addition to the requirements under Sections I and II, the following conditions must be met:
(a) conditioning must not cause any contamination of the product; conditioning facilities must be used in accordance with procedures recognised by the competent authorities, with special regard to the bacteriological and chemical quality of the sea water used in those facilities;
(b) equipment and containers in the conditioning facilities must not constitute a source of contamination;.
(c) procedures for calibration of live bivalve molluscs must not result in additional contamination of the product or in any changes affecting the ability of the product to be transported and stored after wrapping;
(d) any washing or cleaning of live bivalve molluscs must be carried out using pressurised clean sea water or potable water; cleaning water may not be recycled.
2. Dispatch centres must accept only those batches of live bivalve molluscs which are accompanied by the registration document referred to in Chapter II, section 6 of this Schedule and coming from an approved production area, relaying area or purification centre.
3. Dispatch centres must have their own laboratories or secure the services of a laboratory equipped with the necessary facilities for checking, inter alia, whether the molluscs comply with the microbiological standards of Chapter V of this Schedule. Laboratory facilities outside the centres must be recognised by the Veterinary Services. However, these requirements do not apply to dispatch centres obtaining their molluscs exclusively and directly from a purification centre where they have been examined after purification.
4. Dispatch centres must keep the following at the disposal of the Veterinary Services:
- the results of microbiological tests on live bivalve molluscs from an approved production area or relaying area or from a purification plant,
- the dates and quantities of live bivalve molluscs delivered to the dispatch centre, together with the corresponding registration documents,
- dispatch details including the names and addresses of consignees, the dates and quantities of live bivalve molluscs dispatched, together with the corresponding entry registration document number (s). These data must be classified chronologically and preserved for a period to be laid down by the Veterinary Services, but not less than twelve months.
5. Dispatch centres situated aboard vessels shall be subject to the conditions laid down in point 1 (b), (c) and (d) and in points 3 and 4. The conditions laid down in I and II shall apply mutatis mutandis to such dispatch centres although special conditions may be laid down in accordance with the requirements of the European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

CHAPTER V

REQUIREMENTS CONCERNING LIVE BIVALVE MOLLUSCS

Live bivalve molluscs intended for immediate human consumption must comply with the following requirements:
1. The possession of visual characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion, and normal amounts of intra-valvular liquid.
2. They must contain less than 300 faecal coliforms or less than 230 E. Coli per 100 g of mollusc flesh and intra-valvular liquid based on a five-tube, three-dilution MPN-test or any other bacteriological procedure shown to be of equivalent accuracy.
3. They must not contain salmonella in 25 g of mollusc flesh.

4. They must not contain toxic or objectionable compounds occurring naturally or added to the environment such as those listed in the Annex to Council Directive 2000/60/EC in such quantities that the calculated dietary intake exceeds the permissible daily intake (PDI), or that the taste of the molluscs may be impaired. The testing methods for checking the chemical criteria and the limit values applicable are those determined by the European Commission.
5. The upper limits as regards the radionuclide contents must not exceed the limits for foodstuffs as laid down by the Community.
6. The total Paralytic Shellfish Poison (PSP) content in the edible parts of molluscs (the whole body or any part edible separately) must not exceed 80 micro-grams per 100 g of mollusc flesh in accordance with the biological testing method in association if necessary with a chemical method for detection of Saxitoxin or any other method recognised by the European Community. If the results are challenged, the reference method shall be the biological method.
7. The customary biological testing methods must not give a positive result to the presence of Diarrhetic Shellfish Poison (DSP) in the edible parts of molluscs (the whole body or any part edible separately).
7a. The total Amnesic Shellfish Poison (ASP) content in the edible parts of molluscs (the entire body or any part edible separately) must not exceed 20 micrograms of domoic acid per gram using the HPLC method.
8. In the absence of routine virus testing procedures and the establishment of virological standards, health checks must be based on faecal bacteria counts.
Examinations for checking compliance with the requirements of this Chapter must be carried out in accordance with proven methods which are scientifically recognised.
For the application of these rules sampling plans as well as the methods and analytical tolerances to be applied in order to check compliance with the requirements of this Chapter are those established by the European Community.
The effectiveness of the faecal indicator bacteria and their numerical limits as well as the other parameters laid down in this Chapter must be kept under constant review and, where scientific evidence proves the need to do so, be revised following the procedure laid down in rule 12 of these rules.
When there is scientific evidence indicating the need to introduce other health checks or to amend the parameters in this Chapter for the purpose of protecting public health, the Veterinary Services shall implement the relevant measures adopted by the European Community.

CHAPTER VI

PUBLIC HEALTH CONTROL AND MONITORING OF PRODUCTION

The Veterinary Services shall set up a public health control system in order to verify whether the requirements laid down in these rules are complied with. This control system must include:
1. periodic monitoring of live bivalve mollusc relaying and production areas in order to:
(a) avoid any malpractice with regard to the origin and destination of the live bivalve molluscs;
(b) check the microbiological quality of the live bivalve molluscs in relation to the production and relaying areas;
(c) check the possible presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs;
(d) check the possible presence of chemical contaminants, the maximum authorised level of which will be this fixed by the European Community.
For the purposes of points (c) and (d), sampling plans must be established by the competent authorities for checking such possible presence at regular intervals or on a case-by-case basis in the event of irregular periods of harvesting.
2. Sampling plans as provided for in point 1, must in particular take account of:
(a) likely variations in faecal contamination at each production and relaying area;
(b) possible variations in production at relaying areas in the presence of plankton containing marine bio-toxins. The sampling must be carried out as follows:
(i) monitoring: periodic sampling organised to detect changes in the composition of the plankton containing toxins and the geographical distribution thereof. Information leading to a suspicion of accumulation of toxins in mollusc flesh must be followed by intensive sampling;

(ii) intensive sampling: monitoring plankton in the growing and fishing waters by increasing the number of sampling points and the number of samples, and toxicity tests using the molluscs from the affected area which are most susceptible to contamination. Placing on the market of molluscs from that area may not be re-authorised until new sampling has provided satisfactory toxicity test results;

(c) possible contamination of the molluscs in the production and relaying area; If the result of a sampling plan shows that placing on the market of live bivalve molluscs may constitute a hazard to human health, the Veterinary Services must close the production area, as regards molluscs concerned, until the situation has been restored.

3. Laboratory tests in order to check compliance with the requirements for the end product as laid down in Chapter V of this Schedule. A control system must be established to verify that the level of marine bio-toxins does not exceed safety limits.

4. An inspection of establishments at regular intervals. These inspections must include in particular checks:

(a) to verify whether the approval conditions are still being complied with;

(b) on the cleanliness of the premises, facilities, equipment and on staff hygiene;

(c) to verify whether the live bivalve molluscs are handled and treated correctly;

(d) on the correct application and functioning of purification or conditioning systems;

(e) on the ledger books referred to in Chapter IV section III, 12 of this Schedule;

(f) on the correct use of health marks.

These checks may include the taking of samples for laboratory tests; the results of these tests are notified to the persons responsible for the establishments.

5. Checks on the storage and transport conditions for consignments of live bivalve molluscs.

CHAPTER VII

WRAPPING

1. Live bivalve molluscs must be wrapped under satisfactory conditions of hygiene. The wrapping material or container must: not impair the organoleptic characteristics of the live bivalve molluscs, not be capable of transmitting substances harmful to human health to the live bivalve molluscs, be strong enough to give adequate protection to the live bivalve molluscs.

2. Oysters must be wrapped with the concave shell downwards.

3. All wrappings of live bivalve molluscs must be sealed and remain sealed from the dispatch centre until delivery to the consumer or retailer.

CHAPTER VIII

PRESERVATION AND STORAGE

1. In any storing rooms, live bivalve molluscs must be kept at a temperature which does not adversely affect their quality and viability; the wrapping must not come into contact with the floor of the store room, but must be placed on a clean, raised surface.

2. Re-immersion in or spraying with water of live bivalve molluscs must not take place after they have been wrapped and have left the dispatch centre except in the case of retail sale at the dispatch centre.

CHAPTER IX

TRANSPORT FROM THE DISPATCH CENTRE

1. Consignments of live bivalve molluscs intended for human consumption must be transported wrapped as sealed parcels from the dispatch centre until offered for sale to the consumer or retailer.

2. The means of transport used for consignments of live bivalve molluscs must have the following characteristics:

(a) their interior walls and any other parts which might come into contact with the live bivalve molluscs must be made of corrosion-resistant materials; the walls must be smooth and easy to clean;

(b) they must be suitably equipped to provide efficient protection of the live bivalve molluscs against extremes of hot and cold, contamination with dirt or dust, and damage to the shells from vibration and abrasion;
(c) the live bivalve molluscs must not be transported with other products which might contaminate them.
3. Live bivalve molluscs must be transported and distributed using closed vehicles or containers, which maintain the product at a temperature which does not adversely affect their quality and viability. The parcels containing live bivalve molluscs must not be transported in direct contact with the floor of the vehicle or container but must be supported on raised surfaces or by some other means which prevents contact. Where ice is used in transporting consignments of live bivalve molluscs, it must have been made from potable water or clean sea water.

CHAPTER X

MARKING OF CONSIGNMENTS

1. All parcels in a consignment of live bivalve molluscs must be provided with a health mark so that the original dispatch centre may be identified at all times during transport and distribution until retail sale. Without prejudice to Council Directive 2000/13/EC, the mark must contain the following information:
- the country of dispatch,
- the species of bivalve mollusc (common name and scientific name),
- the identification of the dispatch centre by the approval number issued by the Veterinary Services,
- the date of wrapping, comprising at least the day and the month.
- by way of derogation from Council Directive 2000/13/EC the date of durability may be replaced by the entry these animals must be alive when sold.
2. The health mark may be printed on the wrapping material or be put on a separate label which is then affixed to the wrapping material or put inside the wrapping. It may also be of a twisttie or staple design; self-adhesive health marks must not be used, unless they are not detachable. All types of health mark must be for single use only and may not be transferred.
3. The health mark must be durable and waterproof, and the information presented must be legible, indelible and in easily decipherable characters.
4. The health mark attached to consignments of live bivalve molluscs which are not wrapped in individual consumer-size parcels must be kept for at least 60 days by the retailer after splitting up the contents of the consignment.

Nru. 1220

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

IL-MINISTRU għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qiegħed b'din jippubblika l-abbozz ta' regoli li ġej skond l-artikolu 10 ta' l-Att dwar is-Servizzi Veterinarji, biex jippermetti lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunux restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar Problemi ta' Saħħa Pubblika u Saħħa ta' Annimali rigwardanti l-Qtil ta' Kaċċa Selvaġġa u t-Tqegħid fis-Suq ta' Laħam ta' Kaċċa Selvaġġa.

Id-19 ta' Novembru, 2004

No. 1220

VETERINARY SERVICES ACT (CAP. 437)

THE Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, is hereby publishing the following draft rules in accordance with article 10 of the Veterinary Services Act, to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed rules are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft:-

Public Health and Animal Health Problems relating to the Killing of Wild Game and the Placing on the Market of Wild Game Meat Rules, 2004.

19th November, 2004

VETERINARY SERVICES ACT
(CAP. 437)

IN exercise of the powers conferred by article 10 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, after consultation with the Minister of Health, the Elderly and Community Care, has made the following rules:-

Title and scope

1. (1) The title of these rules is the 'Public Health and Animal Health Problems relating to the Killing of Wild Game and the Placing on the Market of Wild Game Meat Rules, 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 92/45/EEC of the 16th June, 1992 on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat in accordance with article 10 of the Veterinary Services Act.

CHAPTER I
General provisions

Applicability of rules.

2. (1) Without prejudice to any rules relating to hunting, these rules lay down public health and animal health rules applicable to the killing of wild game and to the preparation and placing on the market of wild game meat.

(2) These rules shall not apply to:

(a) small numbers of wild game, un-skinned or un-plucked, and, in the case of small wild game, ineviscerated, supplied directly by the hunter to the consumer or to the retailer;
(b) small quantities of wild-game meat supplied directly to the final consumer;
(c) the cutting and storage of wild-game meat in retail shops or in premises adjacent to sales points, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot. The above operations shall continue to be subject to the public health checks provided for in national rules governing retailing.

(3) The provisions of these rules concerning trade or imports from third countries shall not apply to trophies or to killed wild game carried by travellers in their private vehicle provided that only a small quantity of small wild game or a single large wild game animal is involved and the circumstances indicate that there is no question of the meat of such game being intended for trade or commercial use, and provided that the game in question does not come from a country or a part of a country trade from which is prohibited pursuant to Rules 12 (2) and (3) or by decision of European Community.

(4) These rules shall not affect European Community rules adopted for the conservation of wildlife.

Definitions.

3. (1) For the purposes of these rules, the following definitions shall apply:
'wild game': wild land mammals which are hunted (including wild mammals living within an enclosed area under conditions of freedom similar to those enjoyed by wild game) and wild birds which are not covered by Article 2 of Council Directive 91/495 EEC concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat;
'large wild game': wild ungulates;
'small wild game': wild mammals of the Leporidae family and wild game birds intended for human consumption;
'wild-game meat': all parts of wild game which are fit for human consumption;
'wild game processing house': an establishment approved in accordance with Rule 8 in which wild game is processed and wild game meat is obtained and inspected in accordance with the hygiene rules laid down in these rules;
'collection centre': any place where killed wild game is kept in accordance with the hygiene rules in Schedule I, Chapter IV (2) prior to being transported to a processing house;
'placing on the market': holding or displaying for sale, offering for sale, selling, delivering or any other form of placing on the market of wild game meat for human consumption in the European Community, excluding supplies pursuant to Rule 2.(2);
'trade': trade between Member States within the meaning of the Treaty on European Community.
'the competent authority' means the Veterinary Services.

(2) For the purposes of these rules the definitions in Article 2 of Directive 89/662 EEC and Directive 90/425 EEC and the definition of fresh meat in Article 2 (b) of Council Directive 64/433 EEC shall apply as necessary.

CHAPTER II

Provisions applicable to Community production and trade

Placing of wild game on the market.

4. (1) In the territory of Malta there shall only be placed on the market wild game meat which:

(a) comes from wild game which:

(i)has been killed in a hunting area by means authorised under national legislation governing hunting

(ii) does not come from a region subject to restrictions pursuant to Council Directive 72/461/EEC of 12 December 1972 on health problems affecting intra-Community trade in fresh meat, Council Directive 91/494/EEC of 26 June 1991 on animal health conditions governing intra-Community trade in and imports from third countries of fresh poultry-meat and Council Directive 91/495/EEC or from a hunting area subject to restrictions pursuant to rules 11 and 12 of these rules,

(iii) immediately after killing has been prepared in accordance with Schedule I, Chapter III, and transported within a maximum of 12 hours to a processing house as referred to in (b) or to a collection centre where it must be chilled to the temperatures specified in Schedule I, Chapter III, and from which it must be taken to a processing house as referred to in paragraph (b) hereof within 12 hours or, in the case of remote regions where climatological conditions so permit, within a period to be fixed by the competent authority to enable the official veterinarian of the said processing house to carry out the post mortem inspection provided for in Schedule I, Chapter V, under satisfactory conditions; Veterinary Services shall implement the specific rules decided by European community applicable to collection of wild game under special climatic conditions;

(b) is obtained:

(i) either in a wild game processing house fulfilling the general conditions of Schedule I, Chapters I and II, and approved for the purposes of the present Chapter in accordance with Article 8;

(ii) in the case of large wild game, in an establishment approved in accordance with Article 10 of Directive 64/433/EEC, or, in the case of small wild game, in accordance with Article 5 of Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultry-meat provided that:

(A) such game is skinned in rooms separate from those reserved for meat covered by those Directives, or at different times,

(B) such establishments are given special approval for the purposes of these rules'

(C) such measures are taken to allow clear identification of meat obtained pursuant to the present rules and meat obtained pursuant to Directives 64/433/EEC and 71/118/EEC;

(c) comes from killed animals which have undergone visual inspection by the official veterinarian:

(i) to detect any anomalies. The official veterinarian may base his diagnosis on any information supplied by the hunter, where appropriate on the basis of a certificate laid

down by the authority responsible for hunting rules, on the behaviour of the animal before killing,
(ii) to check that death is not due to causes other than hunting;

(d) comes from wild game which:
(i) has been handled under satisfactory hygiene conditions, in accordance with Schedule I, Chapters III and IV,
(ii) has undergone, in accordance with Schedule I, Chapter V, post-mortem inspection by an official veterinarian or, by auxiliaries holding the professional qualifications specified in accordance with requirements of the European Community, acting under the supervision of the official veterinarian,
(iii) has not shown any change except for traumatic lesions which occurred during killing or localised malformations or changes, provided that it is established, if necessary by appropriate laboratory tests, that these do not render the meat unfit for human consumption or dangerous to human health,
(iv) on which, in the case of small wild game which has not immediately after killing been eviscerated in accordance with Schedule I, Chapter V (1), an official veterinary health inspection has been carried out on a representative sample of animals from the same source.
If the official veterinarian finds a disease communicable to man or defects as referred to in Schedule I, Chapter V (4), he must carry out more checks on the entire batch. In the light of the results of these further checks, he must either exclude the entire batch from human consumption or inspect each carcass individually.

(2) The official veterinarian must ensure that wild game meat is excluded from human consumption:
(i) if it is found to contain defects as referred to in Schedule Chapter V (3) (e), or if it has been seized in accordance with paragraph 4 of that Chapter;
(ii) if the checks provided for in rule 4(1)(d)(iii) have revealed the presence of a disease communicable to man;
(iii) if it comes from animals which have ingested substances which are likely to make the meat dangerous or harmful to human health and on which a decision has been taken according to Council Rule (EEC) 2377/90 of the 26th June laying down a community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.. Pending the implementation of such a decision, national rules on these substances shall remain in force, subject to the general provisions of the Treaty on European Community;
(iv) if, without prejudice to any European Community legislation applicable to ionisation, it has been treated with ionising or ultraviolet radiation or by means of substances likely to affect its organoleptic properties or using colourings other than those used for health marking.

(3) Meat of wild boar or of other species susceptible to trichinosis must undergo analysis by the digestion method in accordance with Council Directive 77/96/EEC of the 21st December, 1976 on the examination for trichinae (trichinella spiralis) upon importation from third countries of fresh meat derived from domestic swine, or a trichinoscopic examination with microscopic observation of several samples from each animal taken from the jaw and diaphragmatic muscles, from the muscles of the lower front leg, from the intercostal muscles and the tongue muscles at

least. The Veterinary Services shall implement any provisions lay down by the European Community concerning the methods for the analysis by digestion which are suitable for detecting trichinosis in wild boar or other species of wild game susceptible to trichinosis; the same procedure shall apply with regard to the trichinoscopic or microscopic examination for the detection of trichinosis.

(4) Wild game meat declared fit for human consumption must:

(i) bear a health mark in accordance with Schedule I, Chapter VIII. A decision may be taken, where appropriate, to amend or supplement the provisions of the aforementioned Chapter in accordance with requirements of European Community and in accordance with the procedure provided for in Chapter 437 Veterinary Services Act, Article10, in order to take into account notably the different forms of commercial presentation, providing they conform to the hygiene rules laid down in these rules. The provisions of point 68 of Chapter XII of Directive 71/118/EEC on the health marking of large packaging shall be applicable mutatis mutandis to meat of small wild game.

(ii) after post-mortem inspection, be stored in accordance with Schedule I, Chapter X, under satisfactory hygiene conditions in wild game processing houses approved in accordance with Article 8 of these rules, or in establishments approved in accordance with Article 10 of Directive 64/433/EEC or Article 5 of Directive 71/118/EEC, or in cold stores approved and inspected in accordance with Article 10 of Directive 64/433/EEC;

(iii) be accompanied during transportation by:

(A) an accompanying commercial document as authorised by the official veterinarian. This document must:

(i) in addition to the particulars provided for in Annex I, Chapter VII (2), including in the case of frozen meat the month and year of freezing in clear, bear a code number by which the official veterinarian can be identified,

(ii) be kept by the consignee for at least one year so that it can be produced at the request of the competent authority. Detailed rules for applying this point, and in particular those concerning the allocation of code numbers and the compilation of one or more lists identifying the official veterinarians, shall be adopted in accordance with the European Community requirements,

(B) a public animal health certificate corresponding to the specimen in Annex II, in the case of meat from a wild game processing house situated in a restricted region or area or meat to be sent to another Member State after transit through a third country in a sealed lorry;

(iv) be transported under satisfactory hygiene conditions in accordance with Schedule I, Chapter XI;

(v) in the case of parts of carcasses or boned meat of small wild game birds, also be obtained in conditions similar to those provided for in Article 3 B. of Directive 71/118/EEC, in establishments specially approved for this purpose in accordance with rule 8 of these rules;

(vi) without prejudice to Council Directive 2000/13/EC of the European Parliament and of the Council of the 20th March, 2000 on the approximation of the laws of the Member

States relating to the labelling, presentation and advertising of foodstuffs, be labelled with an indication of the animal species.

Meat to be distinguished.

5. (1) In the territory of Malta, Veterinary Services shall ensure that:

(a) meat declared unfit for human consumption can be clearly distinguished from meat declared fit for human consumption;

(b) meat declared unfit for human consumption is treated in accordance with Rule (EC) No 1774/2002 of the European Parliament and of the Council of the 3rd October, 2002 laying down health rules concerning animal by-products not intended for human consumption.

(2) Meat from an area subject to animal health restrictions shall be subject to specific rules to be determined on a case-by-case basis in accordance with requirements of European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

(3) Detailed rules for implementing this rule shall if necessary be determined in accordance with requirements of European Community and in accordance with the procedure laid down in article 10 of the Veterinary Services Act.

Meat subject to trade.

6. Only the following are the subject to trade with Member States and in the territory Malta:

(1) skinned and eviscerated wild game meeting the requirements of rules 4 and 5, or fresh wild game meat;

(2) unskinned or unplucked and uneviscerated small game, not frozen or deep-frozen which is controlled in accordance with rule 4(1)(b)(ii)(C) ,provided it is handled and stored separately from fresh meat covered by Directive 64/433/EEC, poultry meat and skinned or plucked game meat;

(3) unskinned large game which:

(a) meets the requirements of rules 4(1)(a)(i) and 4(1)(a)(ii), rule 4(1)(c), and rule 4(1)(d)(i);

(b) the viscera of which have undergone post-mortem inspection in a wild game processing house;

(c) is accompanied by a health certificate corresponding to a specimen drawn up by the European Community, signed by the official veterinarian to certify that the result of the post mortem inspection provided for in paragraph (b) was satisfactory and that the meat has been declared fit for human consumption;

(d) has been cooled to a temperature of between 1 °C and:

(i) +7 °C and kept at that temperature during transportation to a processing house within a maximum period of seven days from the post mortem inspection referred to in paragraph (b),

or,

(ii) +1 °C and kept at that temperature during transportation to a processing house within a maximum period of 15 days from the post-mortem inspection referred to in

paragraph (b). Meat from such unskinned wild game cannot bear the health mark provided for in rule 4(4)(i) unless, after skinning in the processing house of destination, it has undergone post mortem inspection in accordance with Schedule I, Chapter V, and has been declared fit for human consumption by the official veterinarian.

Wild game.

7. Veterinary Services shall ensure that:

(b) wild game processing houses which do not meet the standards laid down in Schedule I, Chapter I, and which are not covered by the derogation provided for in rule 9 cannot be approved in accordance with rule 8 and that products from such establishments do not bear the health mark provided for in Schedule I, Chapter VII and cannot be the subject of trade,

(b) wild game which does not meet the requirements of rule 4 cannot be the subject of trade or be imported from third countries,

(c) offal of wild game declared fit for human consumption cannot be the subject of trade unless it has undergone appropriate treatment in accordance with Council Directive 77/99/EEC on health problems affecting intra-Community trade in meat products.

Wild game processing houses

8. (1) To be traded in the territory of Malta, wild game meat must come from a wild game processing houses laid down on a list of approved wild game processing houses, each having a veterinary approval number. Veterinary Services may approve, for the processing of wild game in Malta, establishments approved in accordance with rules 64/433 and 71/118, provided that such establishments are equipped to process wild game meat and that they work in conditions ensuring compliance with the hygiene rules.
For Malta, Veterinary Services shall send this list to the other Member States and to the European Commission. A wild game processing house shall not be approved unless it is satisfied that it complies with these rules. Where hygiene is found to be inadequate and where the measures provided for in Schedule I, Chapter V (5), second subparagraph have proved insufficient to remedy the situation, the competent authority shall temporarily suspend approval. If the operator or manager of the wild game processing house does not make good the shortcomings noted within the period fixed by the competent authority, the latter shall withdraw approval. It shall be taken due account of the conclusions of any check carried out in accordance with rule 14. The other Member States and the European Commission shall be informed of the suspension or withdrawal of approval.

(2) The operator or manager of the wild game processing house must, in accordance with sub-rule (4) hereof, conduct regular checks on the general hygiene of conditions of production in his establishment, inter alia, by means of microbiological controls. Checks must cover utensils, fittings and machinery at all stages of production and, if necessary, products. The operator or manager of the wild game processing house must inform the official veterinarian or the European Commission's veterinary experts of the nature, frequency and results of the checks conducted to

this end, together with the name of the investigating laboratory if need be. The nature of the checks, their frequency, as well as the sampling methods and the methods for bacteriological examination shall be established in accordance with the requirements of the European Community.

(3) The operator or manager of the wild game processing house must establish a staff training program enabling workers to comply with conditions of hygienic production adapted to the production structure. The official veterinarian responsible for the wild game processing house must be involved in the planning and implementation of that program.

(4) Inspection and supervision of wild game processing houses shall be carried out under the responsibility of the official veterinarian, who may be assisted by auxiliaries in accordance with Article 9 of Directive 64/433/EEC. The official veterinarian must at all times have free access to all parts of processing houses in order to ensure that these rules are being complied with and, where there is doubt as to the origin of meat or killed wild game, to relevant documents which enable him to trace the hunting area of origin. The official veterinarian must regularly analyse the results of the checks provided for in sub-rule (2) hereof. He may, on the basis of this analysis, conduct further microbiological examinations at all stages of production or on the products. The result of these analyses shall be written up in a report, the conclusions and recommendations of which shall be notified to the operator or manager of the establishment, who shall rectify the shortcomings noted with a view to improving hygiene.

Processing houses.

9. In the territory of Malta, wild game processing houses which, on the 31st December, 2003 have not been judged to comply with the conditions for approval laid down by these rules shall stop their activity.

Post-mortem inspection.

10. Veterinary Services must be entrusted to collect and make use of the results of the post-mortem inspection carried out by the official veterinarian as regards the diagnosis of diseases communicable to man. Whereas such a disease is diagnosed, the results of the specific case shall be communicated as soon as possible to the competent veterinary authorities responsible for supervision of the hunting area where the wild game in question originated. Veterinary Services shall submit to the European Commission information on certain diseases and particularly cases where diseases communicable to man have been diagnosed. Veterinary Services shall implement provisions of European Community concerning detailed rules adopted for implementing this rule, and in particular:

(a) the frequency with which information must be submitted to the European Commission,
(b) the type of information,
(c) the disease to which the collection of information is to apply,
(d) procedures for collecting and using information.

Health survey.

11. (1) Without prejudice to the Malta rules concerning hunting, a survey of the health of wild game shall be performed by the Veterinary Services on the territory of Malta at regular intervals.

(2) To this end Veterinary Services shall be entrusted with the task of collecting and using the results of the health inspections carried out in accordance with these rules, where diseases communicable to man or to animals or the presence of residues in excess of permitted levels are diagnosed.

(3) Where a disease or condition as referred to in sub-rule (2) is diagnosed, the survey results relating to the specific case shall be communicated as soon as possible to the Veterinary Services and to the other authorities responsible in Malta for supervision of hunting.

(4) Depending on the epizootic situation, the Veterinary Services shall carry out specific tests on wild game in order to detect the presence of the diseases referred to in Schedule II of the Veterinary Services Act. The presence of these diseases shall be communicated to the European Commission and to the other Member States in accordance with the provisions of article 6 of the Veterinary Services Act.

Measures for the monitoring of residues and substances.

12. (1) Plans for measures to detect residues referred to in Chapter II of Council Directive 96/23/EC of the 29th April, 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC, shall be supplemented in the territory of Malta by the Veterinary Services in order, where necessary, to subject wild game meat to the inspections provided for in that Council Directive in order to make spot checks on the presence of contaminants in the environment.

(2) Taking into account the results of the monitoring referred to in sub-rule (1) and in rule 11(4), Veterinary Services shall ensure that wild game and wild game meat from hunting areas implicated by the monitoring is excluded from trade.

(3) The Veterinary Services shall implement detailed rules adopted by the European Community for implementing the provisions of these rules.

Spot Checks.

13. Veterinary experts from the European Commission may, in so far as is necessary for the uniform application of the Council Directive 92/45/EEC on public health and animal health problems relating to the killing of wild game and the placing on the market of wild-game meat, and in co-operation with the Veterinary Services and other relevant national authorities, make on-site checks. In particular, they may verify by checking a representative percentage of wild game processing houses whether the veterinary Services are ensuring that approved processing houses are complying with these rules. In particular, access on the same basis as officials of the competent authority shall be given to all concerned persons, information and documentation as well as access to places, establishments, installations and means of transport in order for the checks to be carried out. Veterinary Services shall give all the necessary assistance to the experts in carrying out their duties.

Veterinary Checks.

14. (1) Without prejudice to the specific provisions of these rules, the official veterinarian or the Veterinary Services shall, where it is suspected that veterinary legislation has not been complied with or there is doubt as to whether wild game meat is fit for consumption, carry out any veterinary checks he or it deems appropriate.

(2) The Director shall take administrative and/or penal measures to penalise any infringement of European Community veterinary legislation, in particular where it is found that the certificates or documents drawn up do not correspond to the actual state of the wild game meat, that identification marks do not comply with the rules, that the wild game meat was not presented for inspection or that such meat was not used for the purpose originally intended.

Checks to complete internal market.]

15. The rules laid down in Council Directive 89/662/EEC concerning veterinary checks to be carried out in intra-Community trade with a view to the completion of the internal market shall apply in particular to the organisation of and the action to be taken following the checks carried out by the Veterinary Services at destination and to the safeguard measures to be applied in relation to health problems affecting the production and distribution of wild game meat in the territory of the European Community.

CHAPTER III
Provisions applicable to imports into the Community

Applicable conditions.

16. The conditions applicable to the placing on the market of wild game meat imported from third countries shall be at least equivalent to those laid down for the production and placing on the market of wild game meat obtained in accordance with Chapter II, excluding those in Articles 7 and 9.

Requirements for the importation of wild game.

17. (1) For the purpose of application of rule 16, and in order to be imported into the Community, wild game or wild game meat must:

(a) come from third countries or parts of third countries from which imports are not prohibited on animal health grounds;.

(b) come from a third country on the list to be drawn up in accordance with sub-rule (2)(a) hereof ;

(c) be accompanied by a health certificate the model of which corresponding to the specimen drawn up by the European Community, signed by the competent authority and certifying that the products meet the requirements of Chapter II of Council Directive 92/45/EEC or any additional conditions or offer the equivalent guarantees referred to in paragraph 3 (c) of Council Directive 92/45/EEC and come from establishments offering the guarantees provided for in Annex I of Council Directive 92/45/EEC.

(2) The following shall be implemented by the Veterinary Services where established by the European Community:

(a) a provisional list of third countries or parts of third countries able to provide Member States and the European Commission with the conditions and guarantees referred to in paragraph 2 (c) of Council Directive 92/45/EEC and a list of establishments for which they are able to give these guarantees. This provisional list shall be compiled from the lists of establishments approved and inspected by the competent authorities of the Member States, once the European Commission has checked that they abide by the principles and general rules laid down in the Council Directive 92/45/EEC;

(b) updates of that list in the light of the checks provided for in sub-rule (3) hereof;

(c) the specific conditions and the equivalent guarantees relating to the requirements of the Council Directive 92/45/EEC, other than those enabling meat to be excluded from human consumption in accordance with Article 3 (2) (d) and those of Article 5 of Council Directive 92/45/EEC and those laid down in Annex I, Chapters IV and V of Council Directive 92/45/EEC, and, as regards the trichinoscopic examination by the digestion method, in accordance with Directive 77/96/EEC, on the understanding that such conditions and guarantees may not be less stringent than those laid down in Chapter II, excluding those in Articles 6 and 8 of Council Directive 92/45/EEC.

(3) Where experts from the European Commission and the Member States carry out on-the-spot inspections to verify whether:

(a) the guarantees given by the third country regarding the conditions of production and placing on the market can be considered equivalent to those applied in the Community;

(b) the conditions of rule 19 are fulfilled. Experts from Malta may be authorised by the Director and at the request of the European Commission to participate to these inspections . These inspections shall be made on behalf of the Community.

Importation of Wild Game into the Community

18. (1) Veterinary Services shall ensure that wild game or wild game meat covered by Council Directive 92/45/EEC is imported into the Community only if it:

(a) is accompanied by the certificate provided for in Article 16 (1) (c) of Council Directive 92/45/EEC, covering public and animal health requirements issued by the competent authority at the time of loading,

(b) has satisfied the checks required by Council Directive 97/78/EC.

Lists provided in Directive.

19. The lists provided for in Article 16 (2) of Council Directive 92/45/EEC may include only third countries or parts of third countries:

(a) from which imports are not prohibited as a result of the existence of one of the diseases referred to in Annex A to the OIE list, or of any other disease exotic to the Community, or pursuant to Articles 6, 7 and 14 of Directive 72/462/EEC, or Articles 9 to 12 of Directive 91/494/EEC;

(b) which, in view of their legislation and the organisation of their veterinary services and of their inspection services, the powers of such services and the supervision to which they are subject, have been recognised, in accordance with Article 3 (2) of Directive

72/462/EEC or Article 9 (2) of Directive 91/494/EEC, as capable of guaranteeing the implementation of their legislation in force;
or
(c) the veterinary services of which are able to guarantee that health requirements at least equivalent to those laid down in Chapter II are being complied with.

Principles to be adopted.

20. The principles and rules laid down in Council Directive 97/78/EC shall apply, with particular reference to the organisation of and follow-up to the inspections to be carried out by the Veterinary Services and the safeguard measures to be implemented.

Schedule I

CHAPTER I

General conditions for the approval of processing houses

Processing houses must have at least:
1. the following rooms:
- a sufficiently large refrigerated room for reception of wild game,
- a room for inspection and, if necessary, evisceration, skinning and plucking,
- a sufficiently large room for cutting and other preparation, in so far as this is done by the establishment; this room must have an adequate chilling facility as well as a temperaturemeasuring instrument,
- a room for packaging and dispatching, where these operations are carried out in the processing house and where the conditions laid down in Chapter VIII, point 5 of this Schedule are met;
if these conditions are not met there must be a separate room for dispatching,
- sufficiently large chilling or refrigeration rooms for storing wild game meat;

2. in rooms where meat is produced, worked on or stored and in areas and corridors through which meat is transported:
(a) waterproof flooring which is easy to clean and disinfect, rot-proof and laid in such a way as to facilitate the draining of water;
the water must be channelled towards drains fitted with gratings and traps to prevent odours. However:
- in the case of chilling or refrigeration rooms a device with which water may easily be removed is sufficient,
- in the case of stores and in areas and corridors through which meat is transported, waterproof and rot-proof floorig is sufficient;
(b) smooth, durable, impermeable walls, with a light-coloured, washable coating up to a height of at least two metres;
in chilling or refrigeration rooms and in stores the walls must be coated at least to storage height. Walltofloor junctions must be rounded or similarly finished except in stores. However, the use of wooden walls in stores in wild game processing houses in operation on the date of notification of these rules does not constitute grounds for withholding approval;
(c) doors in hard-wearing, non-corrodible material and, if of wood, with a smooth and impermeable covering on all surfaces;
(d) insulation materials which are rot-proof and odourless;
(e) adequate ventilation and good extraction of steam;
(f) adequate natural or artificial lighting which does not distort colours;
(g) a clean and easily cleaned ceiling; failing that, a roof covering with an interior surface which fulfils these conditions;

3. (a) as near as possible to the work stations, a sufficient number of facilities for cleaning and disinfecting hands and for cleaning tools with hot water. Taps must not be hand operable. For washing hands, these facilities must have hot and cold running water or water premixed to a suitable temperature, cleaning and disinfecting products and hygienic means of drying hands;
(b) facilities for disinfecting tools, with hot water supplied at not less than 82° C;

4. appropriate arrangements for protection against pests such as insects and rodents;

5. (a) instruments and working equipment such as cutting tables, tables with detachable cutting surfaces, containers, conveyor belts and saws, made of corrosion-resistant material not liable to taint meat and easy to clean and disinfect. Surfaces coming into, or capable of coming into, contact with meat, including welds and joins, must be maintained smooth. Use of wood is forbidden except in rooms where the only meat stored is hygienically packaged meat;
(b) corrosion-resistant fittings and equipment meeting hygiene requirements for:
- meat handling,
- storing meat containers, in such a way that neither the meat nor the containers come into direct contact with the floor or walls;
(c) facilities, including suitably laid out and equipped reception and marshalling areas, for the hygienic handling and protection of meat during loading and unloading;

(d) special watertight non-corrodible containers, with lids and fasteners to prevent unauthorised persons from removing things from them, for keeping meat not intended for human consumption, or a lockable room for such meat if the quantities are large enough to necessitate this or if the meat is not removed or destroyed at the end of each working day. Where such meat is removed through conduits, these must be so constructed and installed as to avoid any risk of contamination of the meat;
(e) facilities for the hygienic storage of materials for wrapping and packaging where such activities are carried out in the establishment;

6. refrigeration equipment to keep the internal temperature of the meat at the levels required by these rules. This equipment must include a system for draining off water of condensation without any possibility of contamination of the meat;

7. an adequate pressurised supply of potable water complying with European Community rules on potability of water in particular parameters concerning toxic substances and microbiological parameters. However, a nonpotable water supply is authorised in exceptional cases for steam production, fire fighting and the cooling of refrigeration equipment, provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no risk of contamination of meat. Nonpotable water pipes must be clearly distinguished from those used for potable water;

8. an adequate supply of hot potable water within the meaning of Directive 80/778/EEC

9. liquid and solid disposal systems which meet hygiene requirements;

10. an adequately equipped lockable room for the exclusive use of the veterinary service;
or, in the case of stores, suitable facilities;

11. facilities enabling the veterinary inspections provided for in these rules to be carried out efficiently at any time;

12. an adequate number of changing rooms with smooth, waterproof, washable walls and floors, wash basins, showers and flush lavatories so equipped as to protect the clean parts of the building from contamination. Lavatories must not open directly onto the work rooms. Showers are unnecessary in cold stores receiving and storing hygienically packaged meat only. Wash basins must have hot and cold running water or water premixed to a suitable temperature, materials for cleaning and disinfecting the hands and hygienic means of drying hands. Wash basin taps must not be hand or armoperable. There must be a sufficient number of such wash basins near the lavatories;

13. a place and adequate facilities for cleaning and disinfecting means of transport except in the case of cold stores receiving and dispatching hygienically packaged meat only. However, these places and facilities are not compulsory if provisions exist requiring that means of transport be cleaned and disinfected at officially authorised facilities;

14. a room or a secure place for the storage of detergents, disinfectants and similar substances.

CHAPTER II

Hygiene of the staff, premises and equipment in the establishments

1. Absolute cleanliness shall be required of staff, premises and equipment. Specifically:
(a) staff handling meat or working in rooms and areas in which meat is handled, packaged or transported must in particular wear clean and easily cleanable headgear and footwear, light-coloured working clothes and, where necessary, neck shields or other protective clothing. Staff engaged in working on or handling meat must wear clean working clothes at the commencement of each working day and must renew such clothing during the day as necessary and must wash and disinfect their hands several times during the working day and each time work is resumed. Persons who have been in contact with infected game or infected meat must immediately afterwards carefully wash their hands and arms with hot water and then disinfect them. Smoking is forbidden in work rooms, storerooms, loadin, reception, marshalling and loadout areas, and in other areas and corridors through which wild game meat is transported;

(b) no animal may enter the establishments. Rodents, insects and other vermin must be systematically destroyed;
(c) equipment and instruments used for working on meat shall be kept clean and in a good state of repair. They shall be carefully cleaned and disinfected several times during the working day, at the end of the day's work and before being reused when they have been soiled.

2. Premises, instruments and working equipment must not be used for purposes other than work on fresh meat, poultry meat or game meat. The cutting of wild game animals and wild game birds must be carried out at a different time and the cutting room must be completely cleaned and disinfected before being made use of again for the cutting of meat of another category. Meatcutting instruments must be used solely for cutting meat.

3. Implements must not be left in the meat;
cleansing of meat by wiping with a cloth or other materials, and inflation, are prohibited.

4. Meat and meat containers must not come into direct contact with the ground.

5. Potable water must be used for all purposes. However, nonpotable water may be used in exceptional cases for steam production provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no danger of contamination of meat. In addition, nonpotable water may be used in exceptional cases for cooling refrigeration equipment. Nonpotable water pipes must be clearly distinguished from pipes used for potable water.

6. The spreading of sawdust or any other similar substance on the floor of the workrooms and meat storage rooms is prohibited.

7. Detergents, disinfectants and similar substances must be used in such a way that instruments, working equipment and meat are not affected. Such instruments and working equipment must be rinsed thoroughly with potable water after use.

8. Persons likely to contaminate meat are prohibited from working on it and handling it. When recruited, any person working on and handling meat shall be required to prove, by a medical certificate, that there is no medical impediment to such employment. The medical supervision of such a person shall be governed by the national legislation in force in Malta.

CHAPTER III

Hygiene in respect of the preparation of wild game and the cutting and handling of wild game meat

1. Wild game must undergo the following operations immediately after killing:
- large wild game must be drawn and eviscerated,
- the thoracic viscera, even if detached from the carcass, and the liver and the spleen, must accompany the game and be identified in such a way that the official veterinarian can carry out the post-mortem inspection of the viscera in conjunction with the rest of the carcass; the other abdominal viscera must be removed and inspected on the spot. The head may be removed as a trophy,
- small wild game may, without prejudice to the case provided for in the third indent of rule 4.1.a. be totally or partially eviscerated on the spot or in a processing house where the game is transported to the said house at an ambient temperature not exceeding 4°C within 12 hours of being killed.

2. Wild game must be chilled immediately after the operations provided for in paragraph 1 so that the internal temperature is + 7°C or lower in the case of large game or + 4°C or lower in the case of small game. If the external temperature is not sufficiently low, killed game must be moved as soon as possible, and in any event not more than 12 hours after being killed, to a wild game processing house or to a collection centre on the understanding that:
- large wild game must be transported under satisfactory hygiene conditions, in particular avoiding heaping and stacking, to a wild game processing house as soon as possible after the operations provided for in paragraph 1,
- during transportation to the processing house, wild game whose viscera have already undergone veterinary inspection must be accompanied by a certificate issued by the veterinarian attesting to the favourable outcome of the inspection and stating the estimated time of killing.

3. Evisceration must be carried out without undue delay upon arrival at the wild game processing house, except in the case provided for in rule 4.1.d., if it has not been carried out on the spot. The lungs, heart, liver, kidney, spleen and mediastinum may either be detached or left attached to the carcass by their natural connections.

4. Until the inspection has been completed, it must not be possible for carcasses and offal not inspected to come into contact with carcasses and offal already inspected, and the removal, cutting or further treatment of the carcass shall be forbidden.

5. It must not be possible for meat detained or declared unfit for human consumption, stomachs, intestines and inedible by-products to come into contact with meat declared fit for human consumption, and the former must be placed as soon as possible in special rooms or containers located and laid out in such a way as to avoid any contamination of other meat.

6. The dressing, handling, further treatment and transport of meat, including offal, must be performed in compliance with all hygiene requirements. Where such meat is packaged, the conditions of Chapter VIII must be complied with. Packaged meat must be stored in a separate room from exposed meat.

7. The Veterinary Services shall lay down specific rules applicable to inspection of trophies to be kept by the hunter.

CHAPTER IV

Requirements for wild game meat intended for cutting

1. Cutting pieces smaller than carcasses, or halfcarcasses in the case of large wild game, and boning are authorised only in processing houses approved in accordance with rule 8 of these rules or in accordance with Directives 64/433/EEC and 71/118/EEC and equipped with skinning and cutting rooms.

2. The operator or manager of the establishment must facilitate operations for supervising the plant, in particular any handling which is considered necessary, and must place the necessary facilities at the disposal of the supervisory service. In particular, he must be able on request to inform the official veterinarian responsible for supervision of the source of meat brought into his establishment or the origin of killed wild game.

3. (a) Wild game meat must be brought into the work rooms as and when it is needed. As soon as it is cut, and where appropriate packaged, the meat must be transferred to an appropriate chilling or refrigeration room.
(b) Wild game meat entering a cutting room must be checked and, if necessary, trimmed. The work station for these operations must be equipped with suitable facilities and adequate lighting.
(c) During cutting, boning, wrapping and packaging the internal temperature of the wild game meat must be kept at a constant + 7 °C or lower in the case of large wild game or + 4 °C or lower in the case of small wild game. During cutting, the temperature of the cutting room must not exceed + 12 °C.
(d) Cutting must be carried out in such a way as to avoid any soiling of the wild game meat. Splinters of bone and clots of blood must be removed. Meat obtained from cutting and not intended for human consumption must be collected in the facilities, containers or rooms provided for in Chapter I, point 5 (d) as it is cut.

CHAPTER V

Post-mortem health inspection

1. All parts of wild game must be inspected, within 18 hours of admission to the processing house, to determine whether the wild game meat is fit for human consumption; in particular, the body cavity must be opened to permit visual inspection.

2. If the official veterinarian so requires, the spinal column and the head must be split lengthwise.

3. In his post-mortem inspection, the official veterinarian must carry out:
(a) a visual inspection of the wild game and the organs belonging to it. If the results of the visual inspection do not enable an assessment to be made, a more extensive inspection must be carried out in a laboratory. These more extensive inspections may be restricted to a number of samples sufficient to assess all the game killed during a hunt;

(b) investigation of anomalies of consistency, colour or odour;
(c) palpation of organs, if he considers it necessary;
(d) an analysis of residues by sampling, particularly where there are serious grounds for believing it to be justified. Where a more extensive inspection is carried out on the basis of such serious grounds, the veterinarian must wait until that inspection has been concluded before going on to assess all the game killed during a specific hunt, or parts of it which may be supposed, owing to the circumstances, to present the same anomalies;
(e) detection of characteristics indicating that the meat presents a health risk. This applies particularly in the following cases:
(i) abnormal behaviour or disturbance of the general condition of the live animal reported by the hunter;
(ii) presence of tumours or abscesses where they are numerous or affect different internal organs or muscles;
(iii) arthritis, orchitis, changes in the liver or the spleen, inflammation of the intestines or the umbilical region;
(iv) presence of foreign bodies in the body cavities, especially in the stomach and intestines or in the urine, where the pleura or the peritoneum are discoloured;
(v) formation of a significant amount of gas in the gastrointestinal tract with discolouring of the internal organs;
(vi) considerable anomalies in the colour, consistency or odour of muscle tissues or organs;
(vii) open fractures in so far as they are not directly linked to the hunt;
(viii) emaciation and/or general or localised oedema;
(ix) signs that organs have recently adhered to the pleura and the peritoneum;
(x) other obvious extensive changes, such as discolouring and putrefaction.

4. The official veterinarian must order the confiscation of any wild game meat:
- presenting lesions, apart from recent lesions stemming from the killing, and localised malformations or anomalies, in so far as these lesions, malformations or anomalies render the wild game meat unfit for human consumption or dangerous to human health,
- from animals which have not been killed in accordance with national rules on hunting,
- in respect of which the findings listed in paragraph 3 (e) were made during post mortem inspection,
- from small wild game which has been seized in accordance with the fourth indent of rule 4.1.d.,
- which has been found to be infested with trichinae.

5. In the event of doubt, the official veterinarian may perform the further cuts and inspections of the relevant parts of the animals necessary in order to reach a final decision. Where the official veterinarian finds that the hygiene rules laid down in this Chapter are clearly being breached or that adequate health inspection is being hampered, he shall be empowered to take action with regard to the use of equipment or premises and to take any measure required, up to and including an interruption of the production process.

6. The results of the post-mortem health inspections shall be recorded by the official veterinarian and, where diseases communicable to man as referred to in the third indent of rule 4.1.d. or rule 10 are diagnosed, communicated to the competent veterinary authorities responsible for supervision of the hunting area from which the wild game originated, as well as to the person responsible for the said area.

CHAPTER VI

Health control of cut wild game meat and stored wild game meat

Supervision by the official veterinarian must include the following tasks:
- supervision of the entry and exit of meat,
- health inspection of meat held in processing houses,
- health inspection of meat prior to cutting and when it leaves the processing houses referred to in the second indent,
- supervision of the cleanliness of the premises, facilities and instruments provided for in Chapter I, and of staff hygiene, including their clothing,
- any other supervision which the official veterinarian considers necessary for ensuring compliance with this These rules.

CHAPTER VII

Health marking

1. Health marking must be carried out under the responsibility of the official veterinarian, who shall keep for that purpose:
(a) instruments for meat health marking, to be handed over to the assistant staff only at the actual time of marking and for the length of time necessary for this purpose;
(b) labels and wrappers where these already bear one of the marks or of the seals referred to in paragraph 2. These labels, wrappers and seals shall be handed over in the required number by the official veterinarian to the assistant staff at the time when they are to be used.

2. (a) The health mark must be:
(i) a pentagonal mark bearing, in perfectly legible characters, the following information:
- on the upper part the full name or the initial letter or letters of the country of dispatch in capitals:
for Malta, the following letters: MT.
In the centre, the veterinary approval number of the wild game processing house or, where appropriate, the cutting premises,
- on the lower part, the following initials for Malta: **KEE**
or initials identifying the third country of origin.

The height of the letters and the figures must comply with the requirements of Annex I, Chapter XI, of Directive 64/433/EEC in the case of large wild game, and of Annex I, Chapter III, of Directive 91/495/EEC in the case of small wild game;
(ii) a pentagonal stamp sufficiently large to contain the information listed in point (a) ;
(b) The material used for marking must meet all hygiene requirements and the information referred to in point (a) must appear on it in perfectly legible form.
(c) (i) The health marking referred to in point (a) must be applied:
- to exposed carcasses by means of a seal containing the information listed in point (a),
- on or visibly beneath wrappers or other packaging of packed carcasses,
- on or visibly beneath wrappers or other packaging of parts of carcasses or offal wrapped in small quantities.
(ii) The health marking referred to in point (a) (ii) must be applied to large packaging.

CHAPTER VIII

Wrapping and packaging of wild game meat

1. (a) Packaging (for example packing cases, paperboard boxes) must fulfil all rules of hygiene, and in particular:
- must not alter the organoleptic characteristics of the meat,
- must not be capable of transmitting to the meat substances harmful to human health,
- must be strong enough to ensure effective protection of the meat during transportation and handling.
(b) Packaging must not be reused for wild game meat unless it is made of corrosion-resistant materials which are easy to clean and has been previously cleaned and disinfected.

2. Where cut wild game meat is wrapped, this operation must be carried out immediately after cutting and in accordance with hygiene requirements. Such wrapping must be transparent and colourless and must also fulfil the conditions of the first and second indents of paragraph 1 (a) ;
it may not be used again for wrapping wild game meat.

3. Wrapped wild game meat must be packaged.

4. However, when wrapping fulfils all the protective conditions of packaging it need not be transparent and colourless and placing in a second container is not necessary provided that the other conditions of paragraph 1 are fulfilled.

5. Cutting, boning, wrapping and packaging operations may take place in the same room subject to the following conditions:

(a) the room must be sufficiently large and so arranged that the hygiene of the operations is assured;
(b) the packaging and wrapping must be enclosed in a sealed protective cover immediately after manufacture; this cover must be protected from damage during transport to the establishment and stored under hygienic conditions in a separate room in the establishment;
(c) the rooms for storing packaging material must be dust and verminfree and have no air connection with rooms containing substances which might contaminate meat. Packaging must not be stored on the floor;
(d) packaging must be assembled under hygienic conditions before being brought into the room;
(e) packaging must be hygienically brought into the room and used without delay. It must not be handled by staff handling meat;
(f) immediately after packaging the meat must be placed in the storage room provided.

6. The packaging referred to in this chapter may contain only cut wild game meat from the same animal species.

CHAPTER IX

Health certificate

The original copy of the health certificate which must accompany wild game meat during transportation to the place of destination must be issued by an official veterinarian at the time of loading. The certificate must correspond in form and content to the specimen in Schedule II and be drawn up in the official language or languages of the place of destination at least. It must consist of a single sheet of paper.

CHAPTER X

Storage

After post mortem inspection, wild game meat must be chilled or frozen and kept at a temperature which must not at any time exceed + 4°C in the case of small wild game and + 7°C in the case of large wild game if chilled or + 12°C if frozen.

CHAPTER XI

Transport

1. Wild game meat must be dispatched in such a way that during transport it is protected from anything liable to contaminate it or to impair it, having regard to the duration and conditions of transport and to the means of transport employed. In particular, vehicles used for this transport must be equipped in such a way as to ensure that the temperatures laid down in Chapter X are not exceeded.

2. Wild game meat may not be transported in a vehicle or container which is not clean and has not been disinfected.

3. Carcasses, or half carcasses, excluding frozen meat packaged in accordance with hygiene requirements, must be suspended throughout transport except in the case of air transport.
Other cuts must be suspended or placed on supports if not packaged or contained in corrosion-resistant containers. Such supports, packaging or containers must meet hygiene requirements and, in particular as regards packaging, the provisions of this These rules. They may only be reused after cleaning and disinfection.

4. The official veterinarian must ensure before dispatch that transport vehicles and loading conditions meet the hygiene requirements of this Chapter.

Schedule II

SPECIMEN PUBLIC/ANIMAL HEALTH CERTIFICATE

For wild game meat ([1]) intended for consignment to a Member State after transit through a third country Exporting country: ...…….
Ministry:.....…….
Competent service:..……..
Reference ([2])
:.....……..

I. Identification of meat

Wild game meat of:.....…….
(animal species)

Nature of cuts:...
……
Nature of packaging:.....…….
Number of packages:.....
Net weight:...……

II. Origin of meat Address (es) and veterinary approval number (s) of the establishments:

.....…….

Address (es) and veterinary approval number (s) of the approved cutting premises:([4])
:.....……
……

III. Destination of wild game meat

The meat will be sent from.
.....…….....
(place of loading)

to.....……
….
(country and place of destination)

by the following means of transport ([3])
:.....……..
Name and address of consignor:.....…….
Name and address of consignee:.....……

IV. Health attestation

I, the undersigned, official veterinarian, certify that:

a) the wild game meat of the species described above was obtained in a processing house situated in a region or area subject to animal health restrictions and has been passed as fit for human consumption following a veterinary inspection carried out in accordance with Directive 92/45/EEC ([5]).

b) the transport vehicles or containers and the loading conditions of this consignment meet the hygiene requirements laid down in that Directive.

c) the wild game or wild game meat ([6]) is intended for consignment to a Member State after transit through a third country.

Done at.,..... on. .....

……..

(Signature of official veterinarian)

([1]) Wild game meat which has not been treated, other than by chilling or freezing to ensure its preservation.

([2]) Optional.

([3]) Indicate the number or registration number (railway wagons and lorries), the flight number (aircraft) or the name (ship).

([4]) Delete as appropriate.

([5]) Including the trichinoscopic examination provided for in Rule 4(3).

([6]) Delete whichever is not applicable.

Nru. 1221

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 10 ta' l-Att dwar is-Servizzi Veterinarji (Kap. 437), il-Ministru għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni mal-Ministru tas-Saħħa, l-Anzjani u Kura fil-Komunità, għamel ir-regoli li ġejjin:-

Regoli ta' l-2004 dwar Iġjene u Problemi ta' Saħħa li jolqtu l-Produzzjoni u t-Tqegħid fis-Suq ta' Prodotti tal-Bajd.

Id-19 ta' Novembru, 2004

No. 1221

VETERINARY SERVICES ACT (CAP. 437)

IN exercise of the powers conferred by article 10 of the Veterinary Services Act, 2003, the Minister for Rural Affairs and the Environment, after consultation with the Minister of Health, the Elderly and Community, has made the following rules:-

Hygiene and Health Problems affecting the Production and the Placing on the Market of Egg Products Rules, 2004

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Hygiene and Health Problems affecting the Production and the Placing on the Market of Egg Products Rules, 2004

IN exercise of the powers conferred by article 10 of the Veterinary Services Act, 2003, the Minister for Rural Affairs and the Environment, after consultation with the Minister of Health, the Elderly and Community, has made the following rules:-

Title and Scope

1. (1) The title of these rules is the Hygiene and Health Problems affecting the Production and the Placing on the Market of Egg Products Rules, 2004".

(2) The scope of these rules is to implement the rules found under European Union Council Directive 89/437/EEC on hygiene and health problems affecting the production and the placing on the market of egg products and in accordance with article 10 of the Veterinary Services Act.

Definitions

2. For the purposes of these rules, and unless the context otherwise requires –

the definition given in Article 1(2) of Regulation (EEC) No 2772/75 shall apply;

"batch" means a quantity of egg products which have been prepared under the same conditions and in particular treated in a single continuous operation;

"Competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"consignment" means a quantity of egg products for a single delivery to one destination for further processing by the food industry or intended for direct human consumption;

"country of destination" means the Member State to which egg products are dispatched from another Member State or from a third country;

"country of dispatch" means the Member State or third country from which egg products are dispatched to another Member State;

"cracked eggs" means eggs with a damaged but unbroken shell, with intact membranes;

"egg products" means products obtained from eggs, their various components or mixtures thereof, after removal of the shell and membranes, intended for human consumption; they may be partially supplemented by other foodstuffs or additives; they may be liquid, concentrated, dried, crystallized, frozen, quick-frozen or coagulated;

"establishment" means an establishment approved for the manufacture and/or treatment of egg products;

"farm of production" without prejudice to Regulation (EEC) No 2782/75 means, a farm for the production of eggs intended for human consumption;

"Member State" means a State which is a Member within the European Community;

"packing" means the placing of egg products in any form of package;

(l) "placing on the market" means the marketing of egg products, as defined in point 5 of Article 1 of Regulation (EEC) No 2772/75.

(m) "Third country" means a State which is not a Member within the European Community;

(n) "the Commission" means the European Commission;

(o) "the Community" means the European Community as established under the Treaty establishing the European Community;

Applicability

3. These rules lay down hygiene and health requirements concerning the production and the placing on the market of egg products for direct human consumption or for the manufacture of foodstuffs:

(2) These rules shall not apply to:

(a) finished foodstuffs manufactured from egg products, as defined in rule 2 and which meet with the provisions of rule 4,

(b) egg products which are obtained in small scale enterprises and which, without having undergone any treatment, are used for the manufacture of foodstuffs intended for direct sale, without any intermediary, to the consumer or consumed on the spot immediately after having been prepared.

Requirements for production or use as foodstuffs.

4. In the territory of Malta only egg products which meet the following general requirements are produced as foodstuffs or used in the manufacture of foodstuffs:

(a) they must have been obtained from the eggs of hens, ducks, geese, turkeys, guinea fowls or quails, but not a mixture of eggs of different species;

(b) they must bear an indication of the percentage of egg ingredients they contain when they are partially supplemented by other foodstuffs or, provided they fulfil the requirements of rule 10, by additives;

(c) they must have been treated and prepared in an establishment approved in accordance with Article 6 which complies with Chapters I and II of the Annex, and satisfy the requirements of this Directive;

(d) they must have been prepared under hygiene conditions complying with Chapters III and V of the Schedule, from eggs meeting the requirements laid down in Chapter IV of the Schedule;

(e) they must have undergone a treatment process authorized under the European Community requirements which enables them to meet *inter alia* the analytical specifications laid down in Chapter VI of the Schedule. However, where it is necessary for technological reasons associated with the preparation of certain foodstuffs obtained from egg products, the competent authority shall decide, on the basis of criteria to be determined by the European Commission, that certain egg products need not undergo treatment; in such a case, the egg products must be used without delay in the establishment where they are intended for the manufacture of other foodstuffs;

(f) they must comply with the analytical specifications set out in Chapter VI of the Schedule;

(g) they must have undergone a health check in accordance with Chapter VII of the Schedule;

(h) they must have been packed in accordance with Chapter VIII of the Schedule;

(i) they must be stored and transported in accordance with Chapters IX and X of the Schedule;

(j) they must bear the mark of wholesomeness provided for in Chapter XI of the Schedule and, where intended for direct human consumption, must meet

the requirements of Council Directive 2000/13/EC of the European Parliament and of the Council of the 20th March, 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.

Measures to be adopted by manufacturers of egg products

5. The competent authority shall ensure that the manufacturers of egg products adopt all measures necessary to comply with this Directive, and in particular that:

(a) samples for laboratory examination are taken in order to check that the analytical specifications set out in Chapter VI of the Schedule have been observed;
(b) egg products that may not be kept at the ambient temperature are transported or stored at the temperatures stipulated in Chapters IX and X of the Schedule;
(c) the period during which the conservation of egg products is assured is laid down;
(d) the results of the various checks and tests are recorded and kept for presentation to them for a period of two years;
(e) each batch marked in such a way that its date of treatment can be identified; this batch mark must appear on the treatment record and on the mark of wholesomeness provided for in Chapter XI.

Checks to detect residues of certain substances

6. (1) In the territory of Malta it shall be ensured that checks are effected to detect any residues of substances having a pharmacological or hormonal action, and of antibiotics, pesticides, detergents and other substances which are harmful or which might alter the organoleptic characteristics of egg products or make their consumption dangerous or harmful to human health.

(2) If the egg products examined show traces of residues in excess of the permitted levels fixed in accordance with Council Regulation (EEC) 2377/90 of the 26th June, 1990 laying down a community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, they must not be allowed to be used in food for human consumption or placed on the market, either for the manufacture of foodstuffs or for direct human consumption.

Lists of approved establishments

7. (1) The Competent Authority shall draw up lists of the approved establishments in the territory of the Republic of Malta, each of which shall have an approval number. The Competent Authority shall forward this list to the other Member States and to the Commission. The Competent Authority shall not approve

any establishment unless compliance with these rules is assured. The Competent authority shall withdraw approval if the conditions for granting it cease to be fulfilled. The other Member States and the Commission shall be informed of the withdrawal of approval.

(2) The inspection and monitoring of establishments and packaging centres shall be carried out regularly on the responsibility of the competent authority, which shall at all times have free access to all parts of the establishments, in order to ensure that these rules are being observed. If such inspections reveal that not all the requirements of these rules are being met, the competent authority shall take the appropriate action to remedy the situation.

On-the-spot checks

8. (1) Experts from the Commission may, in cooperation with the competent authority in Malta, make on-the-spot checks insofar as that is indispensable for ensuring uniform application of the Council Directive 89/437/EEC; they may in particular verify whether establishments and packing centres approved in accordance with Article 5 (3) of Council Regulation (EEC) No 1907/90 of 26 June 1990 on certain marketing standards for eggs are actually complying with these rules.

(2) The Competent authority shall give all necessary assistance to the experts in carrying out their duties. The Commission shall inform the Member State concerned of the results of the checks.

(3) The Competent authority in Malta shall take any measures required to take account of the results of the checks. Should an inspection carried out in terms of these rules bring to light serious facts against an approved establishment, the Competent authority shall immediately suspend the placing on the market of egg products from the establishment which fails to comply with this Directive.

Imports from third countries of fresh poultry meat

9. (1) Pending the application of the provisions of Council Directive 89/437/EEC, the rules applicable to imports from third countries of fresh poultry meat as laid down in Governmental Legal Notice (91/494) apply mutatis mutandis to egg products and must not be more favourable than those governing intra-Community trade.

(2) Experts from the competent authority of Malta instructed to carry out these inspections may, at the request of the European Commission and on the proposal from the Director, participate to on-the-spot inspections carried out by experts from the Member States and the European Commission.

(3) The competent authority shall use the list of the establishments drawn up by the European Commission which meet the requirements set out in the Annex of Council Directive 89/437/EEC.

(4) The health certificate accompanying the products on importation and the form and nature of the mark of wholesomeness applied to the products shall correspond to a model determined by the European Commission.

Additives to be used in foodstuffs

10. The European Parliament and Council Directive No 95/2/EC of the 20th February, 1995 on food additives other than colours and sweeteners shall be used to decide which additives may be used in foodstuffs may be used for the egg products defined in rule 4 (a) and the detailed rules on such use.

SCHEDULE

CHAPTER I

GENERAL CONDITIONS OF APPROVAL AND OPERATION

Establishments must possess at least:

1. in areas where eggs are stored and where egg products are manufactured or stored:

(a) waterproof flooring which is easy to clean and disinfect, rotproof and laid in such a way as to facilitate the draining of water; the water must be channelled towards drains fitted with gratings and traps to prevent odours;

(b) smooth, durable, impermeable walls, with a light-coloured, washable coating up to a height of at least two metres and up to at least storage height in chilling or refrigeration rooms and in stores. Wall to floor junctions must be rounded or similarly finished in such a way as to facilitate cleaning;

(c) doors in material that does not deteriorate and, if of wood, with a smooth and impermeable covering on both sides;

(d) ceilings which are easy to clean and which have been built and finished in such a way as to prevent the accumulation of dirt and the formation of mould, the possible peeling of paint-work and the condensation of water vapour;

(e) adequate ventilation and, if necessary, good steam extraction;

(f) adequate natural or artificial lighting;

(g) as near as possible to the work stations:

(i) an adequate number of facilities for the cleaning and disinfecting of hands and the cleaning of equipment with hot water. Taps must not be operable by hand or the arms. For the cleaning of hands, these facilities must be provided with hot and cold running water or water premixed to a suitable temperature, cleaning and disinfecting products and hand towels which can be used once only,

(ii) facilities for the disinfecting of tools;

2. an appropriate number of changing rooms, with smooth, impermeable and washable walls and floors, wash basins and flush lavatories. The latter must not give directly on to the work area. Wash basins must have hot and cold running water or water premixed to a suitable temperature, materials for cleaning and disinfecting the hands, and hand towels which can be used once only. Wash basin taps must not be hand-operable. There must be a sufficient number of wash basin close to the lavatories;

3. a separate area and adequate facilities for cleaning and disinfecting fixed and mobile containers and tanks. However, this area and these facilities shall not be required if there are provisions for the cleaning and disinfecting of containers and tanks at other centres;

4. facilities for the supply of exclusively potable water within the meaning of European Community Legislation relating to the quality of water intended for human consumption;

However, facilities supplying non-potable water are authorized for steam-production, fire-fighting and the cooling of refrigeration equipment, provided that the pipes installed for this purpose preclude the use of such water for other purposes and present no risk of contamination to the egg products. The steam and water concerned may not come into contact with the egg products or be used for cleaning or disinfecting containers, plant or equipment which come into contact with the egg products. Pipes carrying nonpotable water must be clearly distinguished from those carrying potable water;

5. appropriate equipment for protection against pests such as insects and rodents;

6. equipment, couplings and instruments or their surfaces which are intended to come into contact with egg products must be made of smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the egg products in such quantities as to endanger human health, cause deterioration in the composition of the egg products or adversely affect their organoleptic characteristics.

CHAPTER II

SPECIAL CONDITIONS FOR THE APPROVAL OF ESTABLISHMENTS

In addition to the general conditions laid down in Chapter I, establishments must have at least:

1. suitable rooms large enough for the separate storage of the eggs and the finished egg products, where necessary, with refrigeration equipment to keep the egg products at the appropriate temperatures; cold stores must be equipped with a thermometer or a remote recording thermometer;

2. where dirty eggs are used, facilities for washing and disinfecting the eggs; a list of products authorized for performing this disinfection shall be drawn up in accordance with the European community requirements;

3. (a) a special room with appropriate facilities for breaking eggs and collecting their contents and removing the parts of shell and membrane;

(b) a separate room for operations other than those referred to in (a).

Where egg products are pasteurized, pasteurization may be carried out in the room referred to in (a), when the establishment has a closed pasteurization system; in other cases pasteurization must be carried out in the room referred to in (b). In the latter case, every step must be taken to prevent the contamination of egg products after their pasteurization;

4. suitable facilities for in-plant conveying of egg contents;

5. in the cases provided for in these rules, equipment approved by the competent authority for the treatment of egg products, fitted at least with:

(a) in the case of pasteurization:

(i) automatic temperature control,

(ii) a recording thermometer,

(iii) an automatic safety device preventing insufficient heating;

(b) in the case of a continuous pasteurization system, the equipment must also be fitted with:

(i) an adequate safety system preventing the mixture of pasteurized egg products with incompletely pasteurized egg products, and

(ii) an automatic safety recording device preventing the aforementioned mixture;

6. a room for the storage of other foodstuffs and additives;

7. where the products are packed in disposable containers, an appropriate and, if necessary, separate area for the storage of such containers and the raw materials intended for their manufacture;

8. facilities for the immediate removal and separate storage of empty shells, and of eggs and egg products which are unfit for human consumption;

9. suitable equipment for the hygienic packaging of egg products;

10. to carry out analyses and examinations in accordance with the requirements of these rules on raw materials and egg products, an establishment must have an appropriate laboratory. If it does not, it must secure the services of a laboratory that fulfils those requirements. In the latter case it shall inform the competent authority accordingly;

11. where required, suitable equipment for the thawing of frozen egg products which must undergo treatment and further handling in an approved establishment;

12. a separate room for the storage of cleaning and disinfection products.

CHAPTER III

HYGIENE REQUIREMENTS RELATING TO THE PREMISES, EQUIPMENT AND STAFF OF ESTABLISHMENTS

The highest degree of cleanliness must be required of staff, premises and equipment:

1. staff who treat or handle eggs and egg products must, in particular, wear clean working clothes and headgear. They must wash and disinfect their hands several times in the course of each working day and on each resumption of work.

It must be forbidden to smoke, eat, spit or chew in areas where eggs and egg products are handled and stored;

2. no animals may enter the establishments. Any rodents, insects or other vermin found must be systematically destroyed;

3. premises, equipment and instruments used for working on egg products must be kept clean and in a good state of repair. Equipment and instruments must be carefully cleaned and disinfected several times if necessary during the working day, at the end of the day's work and before being re-used where they have been soiled. Closed pipe-line systems for conveying egg products must be provided with an appropriate cleaning system which ensures their cleaning and disinfection in all parts. After having been cleaned and disinfected, pipes must be rinsed out with potable water;

4. premises, instruments and equipment must not be used for purposes other than the processing of egg products except the processing of other foodstuffs either simultaneously or at different times after the authorization of the competent authority has been obtained, provided that all appropriate measures are taken to prevent contamination of or adverse changes in the products covered by these rules;

5. potable water must be used for all purposes: however, non-potable water may be used in exceptional cases for steam production provided that the pipes installed for this purpose preclude the use of this water for other purposes and present no danger of contamination of eggs or egg products. In addition, the use of non-potable water may be authorized in exceptional cases for the cooling of refrigeration equipment. Non-potable water pipes must be clearly distinguished from pipes used for potable water;

6. detergents, disinfectants and similar substances must be used and stored in such a way that instruments, equipment and egg products are not adversely affected. Their use must be followed by thorough rinsing of such instruments and equipment with potable water;

7. persons who are possible sources of contamination must be prohibited from working with or handling eggs or egg products;

8. any person employed to work with or handle eggs or egg products must be required to produce a medical certificate to show that there is no reason why he or she should not engage in such work. The medical certificate must be renewed yearly unless another staff medical check-up scheme offering similar guarantees is recognized by the European Community.

CHAPTER IV

REQUIREMENTS CONCERNING EGGS INTENDED FOR THE MANUFACTURE OF EGG PRODUCTS

1. Eggs used for the manufacture of egg products must be put up in packaging which complies with Commission Regulation (EEC) No 1274/91 of the 15th May, 1991 introducing detailed rules for implementing Regulation (EEC) No 1907/90 on certain marketing standards for eggs.

2. (a) For the manufacture of egg products, only non-incubated eggs which are fit for human consumption may be used; their shells must be fully developed or contain no breaks;
(b) by way of derogation from (a), cracked eggs may be used for the manufacture of egg products provided they are delivered directly from the packing centres and the farm of production to an approved establishment, where they shall be broken as quickly as possible.

3. Eggs and egg products which are unfit for human consumption must be removed and denatured in such a way that they cannot be re-used for human consumption. They must immediately be placed in the room provided for in point 8 of Chapter II.

CHAPTER V

SPECIAL HYGIENE REQUIREMENTS FOR THE MANUFACTURE OF EGG PRODUCTS

All operations must be carried out in such a way as to avoid all contamination during the production, handling and storage of egg products, and in particular:

1. eggs and egg products presented for subsequent treatment at an approved establishment must be stored immediately on arrival in the rooms provided for in Chapter II point 1 until they are processed. The temperature of these rooms must be such as to ensure that they are not contaminated. Trays of shell eggs must not be placed directly on the floor;

2. eggs must be unpacked, and, if necessary, washed and disinfected, in a room which is separate from the breaking room; packaging material must not be taken into the breaking room;

3. eggs must be broken in the room provided for in Chapter II, point 3 (a); cracked eggs as mentioned in Chapter IV, point 2 (b) must be processed without delay;

4. dirty eggs must be cleaned before being broken; this must be carried out in a room which is separate from the breaking room or from any room where exposed egg contents are handled. Cleaning procedures must be such as to prevent contamination or adulteration of the egg contents. Shells must be sufficiently dry at the time of breaking to prevent adulteration of the egg contents by the remains of the cleaning water;

5. eggs other than hen eggs or those of turkeys or guinea fowl must be handled and processed separately. All equipment must be cleaned and disinfected when processing of hen eggs and those of turkeys and guinea fowl is resumed;

6. breaking, whatever procedure is used, must be carried out in such a way as to avoid as far as possible contamination of the egg contents. To that end, the contents of eggs may not be obtained by the centrifugation or crushing of eggs, nor may centrifugation be used to obtain the remains of egg whites from empty shells. The remains of shells or membranes must be kept out of the egg product as far as possible and must not exceed the quantity specified in point 2 (c) of Chapter VI;

7. after breaking, each particle of egg product must undergo treatment as quickly as possible; heat treatment consists of treating the egg product at an appropriate temperature for an appropriate period in order to eliminate any pathogenic organisms present. During heat treatment, temperatures must be registered continuously. The records of each batch having undergone treatment must be kept at the disposal of the competent authority for two years. A batch which has been insufficiently treated may immediately undergo treatment again in the same establishment provided that the new treatment renders it fit for human consumption; should it be found to be unfit for human consumption, it must be denatured in accordance with point 3 of Chapter IV;

8. if treatment is not carried out immediately after breaking, the egg contents must be stored under satisfactory hygiene conditions, either frozen or at a temperature of not more than 4 ºC. The storage period at 4 ºC must not exceed 48 hours, except in the case of ingredients to be desugared;

9. where certain production practices so require, the existence of special cases shall be determined pursuant to European Community requirements according to which egg products coming from an approved establishment may be treated in another approved establishment, on the understanding that the following general conditions are complied with:

(a) as soon as the egg products have been obtained, they must be either deep frozen or chilled to a temperature of not more than 4 ºC in the latter case, they must be treated at their place of destination during the 48 hours following the day of the breaking of the eggs from which they were obtained, except in the case of ingredients to be desugared;

(b) they must be packaged, checked, transported and handled in accordance with regulatory requirements;

(c) they must be labelled in accordance with the requirements laid down in Chapter XI. The nature of the goods must be indicated as follows: 'nonpasteurized egg products — to be treated at place of destination — date and time of breaking —';

10. further processing operations after treatment must ensure that there is no recontamination of the egg product; liquid products or concentrated products which have not been stabilized so as to keep at room temperature must be either dried or cooled to a temperature not exceeding 4 ºC immediately, or after undergoing a fermentation process; products for freezing must be frozen immediately after treatment;

11. egg products must be kept at the temperatures required by these rules until they are used for the manufacture of other foodstuffs;

12. in approved establishments, the preparation of egg products from raw materials which are not suitable for the manufacture of foodstuffs is prohibited, even for non-food purposes.

CHAPTER VI

ANALYTICAL SPECIFICATIONS

1. Microbiological criteria

All batches of egg products must, after treatment, undergo microbiological checks by sampling in treatment establishments in order to guarantee that they meet the following criteria:

(a) salmonellae: absence in 25 g or ml of egg product;
(b) other criteria:
- (i) mesophilic aerobic bacteria: M = 105 in 1 g or 1 ml,
- (ii) enterobacteriaceae: M = 102 in 1 g or 1 ml,
- (iii) staphylococcus aureus: absence in 1g of egg product,

M = maximum value for the number of bacteria; the result is considered unsatisfactory if the number of bacteria in one or more sample units is M or more.

2. Other criteria

All batches of egg products must undergo checks by sampling in treatment establishments in order to guarantee that they meet the following criteria:

(a) the concentration of 3 OH-butyric acid must not exceed 10 mg/kg in the dry matter of the unmodified egg product;

(b) in order to ensure the hygienic handling of eggs and egg products before treatment, the following standards shall apply:

(i) the lactic acid content must not exceed 1 000 mg/kg of egg product dry matter (applicable only to the untreated product),

(ii) the succinic acid content must not exceed 25 mg/kg of egg product dry matter.

In the case of fermented products, however, these values are those recorded before the fermentation process;

(c) the quantity of eggshell remains, egg membrane and any other particles in the egg product must not exceed 100 mg/kg of egg product;

(d) the residual quantities of the substances mentioned in Article 5 (1) may not exceed the permitted levels fixed in accordance with Council Regulation (EEC) 2377/90 of the 26th June, 1990 laying down a community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

CHAPTER VII

HEALTH CONTROL AND SUPERVISION OF PRODUCTION

1. Establishments will be subject to supervision by the competent authority.

Supervision by the competent authority will include any supervision measures considered necessary to ensure that manufacturers of egg products meet the requirements of these rules, and in particular:

(a) checks on the origin of eggs and the destination of egg products and of the records referred to in rule 5(d),

(b) inspection of eggs intended for the manufacture of egg products,

(c) inspection of egg products on dispatch from the establishment,

(d) verification of the cleanliness of the premises, facilities and instruments and of staff hygiene,

(e) taking of any samples required for laboratory tests to ensure that eggs and egg products comply with the requirements of these rules; the results of such tests must be entered in a register and notified to the egg products manufacturer.

2. At the request of the competent authority, manufacturers of egg products must increase the frequency of the laboratory tests referred to in rule 5(a) where this is considered necessary to ensure hygienic production of the egg products.

CHAPTER VIII

PACKAGING OF EGG PRODUCTS

1. Egg products must be packaged in satisfactory hygiene conditions so as to ensure that they are not contaminated.

Containers must comply with all rules of hygiene, including the following:

(a) they must not be such as to impair the organoleptic characteristics of the egg products,

(b) they must not be capable of transmitting to the egg products substances harmful to human health,

(c) they must be strong enough to protect the egg products adequately.

2. The room in which containers are stored must be dust and vermin free; materials for making disposable containers must not be stored on the floor.

3. Containers used for egg products must be clean prior to being filled; reusable containers must be cleaned, disinfected and rinsed before being filled.

4. Containers must be brought into the work room in a hygienic manner and must be used without undue delay.

5. Immediately after packaging, the containers must be closed and placed in the storage rooms referred to in Chapter II, point 1.

6. Containers intended for egg products may be used for other foodstuffs if required, provided they are cleaned and disinfected so as not to contaminate the egg products.

7. Containers which are to be used for the transport of egg products in bulk must comply with all the rules of hygiene, and in particular the following:

(a) their inside surfaces and any other part which may come into contact with the egg product must be made of a smooth material which is easy to wash, clean and disinfect, resists corrosion and does not transfer substances to the egg product in such quantities as to endanger human health, cause deterioration in the composition of the egg product or adversely affect its organoleptic characteristics,

(b) they must be designed so that the egg product can be removed completely; if they are fitted with taps, these must be easy to remove, dismantle, wash, clean and disinfect,

(c) they must be washed, cleaned, disinfected and rinsed immediately after each use and, if necessary, before re-use,

(d) they must be appropriately sealed after being filled and remain sealed during transportation until they are used,

(e) they must be reserved for the transport of egg products.

However, without prejudice to the provisions of this Chapter, the Competent authority, according to the requirements of the European Community and to the extent that the egg products and the other foodstuffs concerned suffer no adverse effects as a result, shall fix, if necessary, the specific conditions with which such containers must comply in order to be used to transport other foodstuffs, in particular, conditions relating to:

(i) the washing, cleaning and disinfection of containers before they are reused,
(ii) transport conditions,
(iii) the length of time during which the may be used.

When Malta makes provision for such an authorization, it may neither restrict nor prohibit the entry into its territory of transport from other Member States which provide for the same authorization;

Member States which forbid the transport on their territory of other foodstuffs in containers designed for the transport of egg products may make the transport of egg products coming from Malta subject to the same requirements.

CHAPTER IX

STORAGE

1. Egg products must be stored in the storage rooms referred to in point 1 of Chapter II.

2. Egg products for which certain storage temperatures are required must be maintained at those temperatures. The storage temperatures must be recorded continuously, the cooling rate must be such that the product reaches the required temperatures as quickly as possible and the containers must be stored in such a way that air can freely circulate round them.

3. The temperature in storage must not exceed the following values:
(a) deep frozen products: −18º C,
(b) frozen products: −12º C,
(c) chilled products: + 4º C.

CHAPTER X

TRANSPORT

1. Vehicles and containers for the transport of egg products must be designed and equipped in such a way that the temperatures required by these rules can be maintained continuously throughout the period of transport.

2. Egg products must be dispatched in such a way that they are adequately protected during transportation from anything which may be detrimental to them.

3. The temperatures prescribed in point 3 of Chapter IX, must be maintained during transport.

CHAPTER XI

MARKING OF EGG PRODUCTS

1. Without prejudice to the provisions of Council Directive 2000/13/EC, relating to the labeling, presentation and advertising of foodstuffs, presentation and advertising of foodstuffs for sale to the ultimate consumer, every consignment of egg products that leaves an establishment must have a label bearing the following particulars:

(i) either:
— on the upper part, the initial letters MT of Malta in capitals, followed by the approval number of the establishment,
— on the lower part, one of the following sets of initials: KEE;
—
(ii) or:
— on the upper part, the name of Malta in capitals,
— in the centre, the approval number of the establishment,
— on the lower part, one of the following sets of initials: KEE;

(iii) the temperature at which the egg products must be maintained and the period during which their conservation may thus be assured.

The label must be legible, indelible and in easily decipherable characters.

2. The transport documents must in particular include:

(a) the nature of the products with an indication of the species of origin;
(b) the batch numbers;
(c) the place of destination and the name and address of the first addressee.

3. This information, and that contained in the mark of wholesomeness, must be given in the official language or languages of the Member State of destination.

Nru. 1222

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 23(b) ta' l-Att dwar is-Servizzi Veterinarji il-Ministru għall-Affarijiet Rurali u ta' l-Ambjent, wara konsultazzjoni ma' l-Awtorità Kompetenti, qegħdin b'din jippubblikaw l-abbozz ta' regolamenti li ġej biex jippermettu lil kull persuna perijodu ta' erba' ġimgħat biex tagħmel rappreżentazzjonijiet lid-Direttur Ġenerali tad-Diviżjoni ta' l-Ikel u Regolamenti Veterinarji, fejn tiddikjara kif fil-fehma tagħha r-regolamenti proposti jkunu restrittivi ż-żejjed bla bżonn jew jikkawżawlha diffikultà jew telf ekonomiku u titlob għal reviżjoni ta' dak l-abbozz:-

Regoli ta' l-2004 dwar il-Kundizzjonijiet u Arranġamenti biex Japprovaw u Jirreġistraw Ċerti Stabbilimenti u Intermedjarji li Joperaw fis-Settur ta' l-Għalf ta' l-Annimali.

Id-19 ta' Novembru, 2004

No. 1222

VETERINARY SERVICES ACT (CAP. 437)

BY virtue of the powers conferred by article 23(b) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, after consultation with the Competent Authority, are hereby publishing the following draft regulations in accordance with article 23(b) of the Veterinary Services Act to allow any person a period of four weeks to make representations to the Director General of the Food and Veterinary Regulation Division, stating how in his opinion the proposed regulations are too unnecessarily restrictive or cause him hardship or economic loss and asking for a revision of such draft.

Conditions and Arrangements for Approving and Registering Certain Establishments and Intermediaries Operating in the Animal Feed Sector Rules, 2004

19th November, 2004

VETERINARY SERVICES ACT (CAP. 437)

Conditions and Arrangements for Approving and Registering Certain Establishments and Intermediaries Operating in the Animal Feed Sector Rules, 2004

IN exercise of the powers conferred by article 23(b) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, after consultation with the Competent Authority has made the following Rules:-

Title and Scope

1. (1) The title of these rules is the Conditions and Arrangements for Approving and Registering Certain Establishments and Intermediaries Operating in the Animal Feed Sector Rules, 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 95/69/EEC laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector to allow them to exercise the activities described in rules 3 and 8 and rules 4 and 9 respectively, and in accordance with article 23(b) of the Veterinary Services Act.

(3) These rules shall apply without prejudice to the legislative provisions concerning the organization of official checks on animal feed.

Definitions

2. (1) For the purposes of these rules:

"establishment" means any unit producing or manufacturing additives, pre-mixtures prepared from additives, compound feeding stuffs or products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Schedule to these rules;

"intermediary" means any person other than the manufacturer or the person producing for the exclusive requirements of his holding, compound feeding stuffs, who holds additives, pre-mixtures prepared from additives, or one of the products covered by Directive 82/471/ EEC and referred to in Chapter I.1 (a) of the Schedule to these rules at an intermediate stage between production and use.

"putting into circulation" means holding products for the purposes of sale, including offering for sale, or for the purposes of any other form of transfer, whether or not free of charge, to third parties, and the sale and other forms of transfer themselves;

"trading partner" shall have the same meaning as provided under article 2 of the Veterinary Services Act and shall include Trading Partners of the European Union.

(2) The definitions laid down in legislation on animal feed shall apply where necessary.

CHAPTER I

APPROVAL OF ESTABLISHMENTS AND INTERMEDIARIES

Approval of establishments

3. (1) An establishment wishing to exercise one or more of the activities referred to in sub-rule (2) must receive approval for each of its activities. It may be decided not to approve establishments referred to in sub-rule (2)(f).

(2) To be approved by the competent authorities an establishment:

(a) manufacturing additives or products covered by Directive 82/471/EEC and referred to in Chapter I.1 (a) of the Schedule to these rules with a view to putting them into circulation, must meet

the minimum conditions laid down in Chapter I.1 (b) of the said Schedule 1;

(b) manufacturing pre-mixtures prepared from additives referred to in Chapter I.2 (a) of the Schedule, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.2 (b) of the said Schedule;

(c) manufacturing compound feeding stuffs containing pre-mixtures prepared from additives referred to in Chapter I.3 (a) of the Schedule, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter I.3 (b) of the Schedule;

(d) manufacturing compound feeding stuffs, with a view to putting them into circulation, from raw materials referred to in Article 5 of Directive 1999/29/EEC which contain high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter I.4 of the Schedule to these rules;

(e) producing, for the exclusive requirements of its holding, compound feeding stuffs containing pre-mixtures which include additives referred to in Chapter I.3 (a) of the Schedule must meet the minimum conditions laid down in Chapter I.3 (b) of the Schedule, with the exception of the requirements set out in point 7 thereof;

(f) producing, for the exclusive requirements of its holding, compound feeding stuffs which contain raw materials referred to in Article 5 of Directive 1999/29/EEC containing high levels of undesirable substances or products, must meet the minimum conditions laid down in Chapter 1.4 of the Schedule to these rules, with the exception of the requirements set out in point 7 thereof.

(3) Approval shall be:

(i) withdrawn if an establishment ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time,

(ii) amended if the establishment has demonstrated its ability to engage in activities which are additional to those for which it was first approved or which replace them.

Approval of intermediaries

4. (1) Where additives, products covered by Directive 82/471/EEC or pre-mixtures of additives referred to in Chapters I.1 (a) and I.2 (a) of the Schedule respectively are put into circulation, intermediaries must be approved. The

provisions laid down in point 7 of Chapter I.1 8 (b) or Chapter I.2(b) of the Schedule shall apply, as appropriate, to intermediaries which wrap, package, store or put into circulation additives, pre-mixtures of additives or products covered by Directive 82/471/EEC.

(2) Approval shall be:

(a) withdrawn if an intermediary ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time;

(b) amended if the intermediary has demonstrated its ability to engage in activities which are additional to those for which it was first approved or which replace them.

Approval procedure for establishments and intermediaries

5. (1) To obtain approval, establishments referred to in rule 3 and intermediaries referred to in rule 4 which intend to exercise for the first time one or more of the activities referred to in rules 3 and 4 shall submit an application to the competent authority of the territory of Malta in which their facilities are located.

(2) The competent authority shall ensure that a decision is taken on applications for approval mentioned in the first subparagraph within six months of their submission.

Register of approved establishments and intermediaries

6. (1) (a) For each activity, the competent authority shall enter the establishments and intermediaries it has approved in accordance with rules 3 and 4 in a register under an individual approval number which identifies them, once it has established by means of on-the-spot verification that they satisfy the conditions laid down by these rules.

(b) In respect of intermediaries who act solely as dealers without ever holding the product in their facilities, it is not needed to carry out on-the-sport verification of compliance with the conditions under point 7 of Chapters I.1 (b) or I.2 (b) of the Schedule, providing that those intermediaries lodge with the competent authority a declaration to the effect that they meet the requirements laid down under point 6.2 in the Schedule for the exercise of their activity.

(2) The competent authority shall update the entries of establishments and intermediaries in the register in accordance with the decisions referred to in sub-rule 3 (3) and sub-rule 4 (2) to withdraw or amend approval.

Publication and communication of the list of approved establishments and intermediaries

7. (1) A list of the establishments and intermediaries approved in accordance with rules 3 and 4 shall be published, and then each year, by the 30th November at the latest, the list of amendments made during the year; every five years, a consolidated list shall be published.

(2) Before the 31st December of each year, the competent authority shall send to the Commission the list referred to in sub-rule (1). Before the 31st December each year, the competent authority shall send the Trading Partners a list of the establishments referred to in sub-rule 3(2)(a) and (b) and of the intermediaries approved in accordance with sub-rule 4(1) and a list of corresponding establishments and intermediaries referred to in sub-rule 5(2) which have submitted applications for approval on which the competent authority has not yet taken a decision. On request, the competent authority shall send the Trading Partners all, or part of the list of establishments referred to in sub-rule 3(2)(c) to (f) and all or part of the list of corresponding establishments referred to in sub-rule 5(2) which have submitted applications for approval on which the competent authority has not yet taken a decision.

CHAPTER II

REGISTRATION OF ESTABLISHMENTS AND INTERMEDIARIES

Registration of establishments

8. (1) An establishment wishing to exercise one or more of the activities referred to in sub-rule (2) must be registered by the competent authority for each activity in accordance with these rules.

(2) In order to be registered by the competent authorities an establishment:

(a) manufacturing additives for which a prescribed maximum level is set and which are not included in Chapter I.1 (a) of the Schedule, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter II (c) of the Schedule;

(b) manufacturing pre-mixtures containing additives referred to in Chapter II (a) of the Schedule, with a view to putting them into circulation, must meet the minimum conditions laid down in Chapter II(c) of the Schedule;

(c) manufacturing compound feeding stuffs containing pre-mixtures of additives referred to in Chapter II (b) of the Schedule or additives referred to in Chapter II (a) of the Schedule with a view to putting

them into circulation, must met the minimum conditions laid down in Chapter II (c) of the Schedule;

(d) manufacturing, for the exclusive requirements of its holding, compound feeding stuffs containing pre-mixtures of additives referred to in Chapter II (b) of the Schedule or containing additives referred to in Chapter II (a) of the Schedule, must met the minimum conditions laid down in Chapter II (c) of the Schedule.

(3) Approved establishments exercising the corresponding activities referred to in sub-rule 3 (2) (a), (b), (c) and (e) shall be regarded as satisfying *de facto* the conditions laid down in sub-rule (2)(a), (b), (c) and (d).

(4) Registration shall be:

(a) withdrawn if an establishment ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time,

(b) amended if the establishment declares that it is engaged in activities which are additional to those for which it was first registered or which replace them.

Registration of intermediaries

9. (1) Where additives for which a prescribed maximum level is set other than those referred to in Chapter I.1 (a) of the Schedule or pre-mixtures of additives referred to in Chapter II (a) of the Schedule are put into circulation, intermediaries must be registered. The provisions laid down in point 7 of Chapter II (c) of the Schedule shall apply, as appropriate, to intermediaries which wrap, package, store or put into circulation additives or pre-mixtures of additives.

(2) Intermediaries approved in accordance with rule 4 shall be regarded as meeting *de facto* the conditions laid down in sub-rule (1) hereof.

(3) Registration shall be:

(a) withdrawn if an intermediary ceases its activities or if it is shown that it no longer fulfils an essential condition applicable to its activities and does not comply with that requirement within a reasonable time,

(b) amended if the intermediary has declared that it is engaged in activities which are additional to those for which it was first registered or which replace them.

Registration procedure for establishments and intermediaries

10. In order to be registered, the establishments referred to in sub-rule 8 (2) and the intermediaries referred to in sub-rule 9 (1) shall submit a declaration to the competent authority of the Trading Partner in which they intend to exercise their activities.

List of registered establishments and intermediaries

11. (1) For each activity, the competent authority shall enter the establishments and intermediaries which it has registered in accordance with rules 8 and 9 on a list under an individual registration number which identifies them.

(2) The entries of establishments and intermediaries on the list shall be updated in accordance with the decisions referred to in sub-rules 8 (4) and 9 (3) to withdraw or amend registration.

Communication of the list of registered establishments and intermediaries

12. (1) Before the 31st December of each year, the list of establishments and intermediaries registered during the year in accordance with rules 8 and 9 shall be sent to the Commission and, every five years, a consolidated list thereof shall be sent.

(2) Upon request, the competent authority of the territory of Malta shall send to the Trading Partners all or part of the lists referred to in sub-rule (1) hereof.

CHAPTER III

COMMON PROVISIONS

Simplified procedure

13. Where an establishment manufacturing an additive is already authorized to manufacture the same active substance as a veterinary medicinal product within the meaning of article 29 of the Veterinary Services Act, the competent authority shall not be obliged to verify that the conditions laid down in Article 3 (2) (a) and contained in Chapter I.1 (b) of the Schedule to these rules have been fulfilled, with the exception of the requirements set out in points 4, 5, 6.2 and 7.

Checks

14. The competent authority shall ensure, by means of appropriate checks carried out in establishments and at the premises of intermediaries which they have approved or registered, that the requirements imposed by these rules are met.

Fees

15. According to the procedure laid down in article 28(b) of the Veterinary Services Act, the rules for calculating the level of the fee to be charged for the approval of establishments and their intermediaries shall be adopted.

Detailed arrangements, amendment of the Annex and imports from non-member countries

16. The following shall be adopted in accordance with the procedure laid down in Article 16 of Directive 95/69/EEC:

(a) practical arrangements for the approval pursuant to rule 3 and registration pursuant to rule 8 of establishments located in a third country and putting additives, pre-mixtures, products covered by Directive 82/471/EEC as referred to in Chapter 1.1 (a) of the Schedule to these rules or feeding stuffs into circulation within the territory of Malta or a Trading Partner, so that safeguards are provided equivalent to those supplied by establishments located in the territory of Malta or a Trading Partner.

These arrangements shall comprise:

(i) publication of the list established and updated by the Commission, of third countries able to provide safeguards equivalent to those offered by the territory of Malta or a Trading Partner in respect of their own establishments and able to perform the checks referred to in rule 14,

(ii) publication of the list established and updated by the Commission of establishments which have been found by the third countries on the list referred to in (i) above to fulfil the conditions laid down in these rules,

(iii) the possibility that experts from the Commission, the territory of Malta and the Trading Partners may carry out on-the-spot checks if necessary;

(b) measures for implementing this Schedule;

(c) the amendments to be made to the Schedule.

SCHEDULE

CHAPTER 1

Minimum conditions which must be fulfilled by establishments and intermediaries referred to in rules 3 and 4 (subject to approval)

CHAPTER I.1. (a)

Additives and products covered by Directive 82/471/EEC ('products') and referred to in sub-rule 3 (2) (a) and sub-rule 4 (1) of these rules

Additives

— Antibiotics:	all additives in the group
— Coccidiostats and other medicinal substances:	all additives in the group
— Growthpromoters:	all additives in the group
— Vitamins, provitamins and chemically well-defined substances having a similar effect:	all additives in the group
— Trace elements:	all additives in the group
— Enzymes:	all additives in the group
— Micro-organisms:	all additives in the group
— Carotenoids and xanthophylls:	all additives in the group
— Substances with antioxidant effects:	only those with a fixed maximum content

Products covered by Directive 82/471/EEC

— Proteins obtained from microorganisms belonging to the group of bacteria, yeasts, algae, lower fungi:	all products in the group (except for sub-group 1.2.1)
— Co-products of the manufacture of amino acids by fermentation:	all products in the group
— Amino acids and their salts:	all products in the group
— Hydroxy analogues of amino acids:	all products in the group

CHAPTER I.1. (b)

Minimum conditions which must be fulfilled by establishments referred to in Article 3 (2) (a) and intermediaries referred to in Article 4 (1) ('products' referred to in Chapter I.1(a))

1. ***Facilities and equipment***

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of the 'products' concerned. The lay-out, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products must undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer for production of the products.

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the 'products' concerned. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the 'products' concerned.

3. ***Production***

A qualified person responsible for production must be designated. The manufacturer must ensure that the different stages of production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process.

Technical or organizational measures must be taken to avoid cross-contamination and errors. There must be sufficient and appropriate means of carrying out checks in the course of manufacture.

4. ***Quality control***

A qualified person responsible for quality control must be designated.

The manufacturer must have access to a quality control laboratory having adequate staff and equipment to guarantee and check, before the release of the 'products' concerned with a view to putting them into circulation, that they comply with the

specifications defined by the manufacturer and are in conformity with the provisions laid down in Directive 70/524/EEC or Directive 82/741/EEC. The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and the destination in the event of non-compliance — of raw materials, active substances, carrier substances and 'products'.

Samples of the active substance and of each batch of 'product' put into circulation or of each specific portion of production in the case of continuous production must be taken in sufficient quantity by a procedure pre-established by the manufacturer and be retained in order to ensure traceability. The samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities at least until the guarantee date of the finished product.

5. ***Storage***

Raw materials, active substances, carrier substances, 'products' which meet the specifications — and those which do not — must be stored in suitable containers in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

They must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances. Additives must be packaged and labelled in particular in compliance with the provisions laid down in Directive 70/524/EEC. Products covered by Directive 82/471/EEC must be labelled in compliance with the provisions of those rules.

6. ***Documentation***

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure mastery of the critical points in the manufacturing process and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. This set of documents must be kept so that it is possible to trace the manufacturing history of each batch of 'product' put into circulation and to establish responsibility if complaints arise.

6.2. Register

The manufacturer must record the following information in order to ensure traceability:

(a) *register of additives:*

— the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture, and the names and addresses of the intermediaries or manufacturers to whom the additives have been delivered,
— indication of the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture;

(b) *register of products covered by Directive 82/471/EEC:*

— the nature of the products and the quantity produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,
— the names and addresses of the intermediaries or users (manufacturers or stock breeders) to whom these products have been delivered, together with an indication of the nature and quantity of the products delivered and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture.

7. ***Intermediaries referred to in Article 4 (1)***

Where the manufacturer delivers additives to a person other than a manufacturer or products referred to in Directive 82/471/EEC to a person other than a user (manufacturer or stock breeder), that person and any subsequent intermediary by whom they are wrapped, packaged, stored or put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5, 6.2 and 8 and, in the case of wrapping, by those referred to in point 3.

8. ***Complaints and product recall***

The manufacturer or any intermediary putting a product into circulation under his own name must implement a system for registering and processing complaints. Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER I.2. (a)
Additives referred to in sub-rule 3 (2) (b) and sub-rule 4 (1)

— Antibiotics:	all additives in the group
— Coccidiostats and other medicinal substances:	all additives in the group

— Growth promoters:	all additives in the group
— Vitamins, provitamins and chemically well-defined substances having a similar effect:	A and D
— Trace elements:	Cu and Se

CHAPTER I.2. (b)

Minimum conditions which must be fulfilled by establishments referred to in sub-rule 3 (2) (b) and intermediaries referred to in sub-rule 4 (1) (pre-mixtures of additives referred to in Chapter I.2 (a))

1. ***Facilities and equipment***

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of the pre-mixtures concerned. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for operations which are essential for the quality of the products must undergo appropriate and regular checks in accordance with the written procedures pre-established by the manufacturer.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the pre-mixtures concerned. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the pre-mixtures concerned.

3. ***Production***

A qualified person responsible for production must be designated.

The manufacturer must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process, such as in

corporation of the additive in the pre-mixture, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the pre-mixtures concerned in accordance with the provisions of Directive 70/524/EEC.

Technical or organizational measures must be taken to avoid cross-contamination and errors.

4. ***Quality control***

A qualified person responsible for quality control must be designated.

The manufacturer must have access to a quality control laboratory having adequate staff and equipment to guarantee and check that the pre-mixtures concerned comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content, homogeneity and stability of the additives in the pre-mixture, and as low a level of cross-contamination as possible. The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and destination in the event of non-compliance — for carrier substances, additives and pre- mixtures ('products').

Samples of each batch of pre-mixture put into circulation must be taken in sufficient quantity by a procedure pre-established by the manufacturer and be retained in order to ensure traceability. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities at least until the guarantee date of the pre-mixture.

5. ***Storage***

'Products' which meet the specifications — and those which do not — must be stored in suitable containers or in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary. The 'products' must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products and with medicinal substances. Pre-mixtures must be wrapped and labelled in accordance with the provisions of Directive 70/524/EEC.

6. ***Documentation***

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. This set of documents must be kept in such a way as to make it possible to trace the manufacturing history of each pre-mixture batch put into circulation and to establish responsibility if complaints arise.

6.2. Register of pre-mixtures

The manufacturer must record the following information in order to ensure traceability:

— the names and addresses of manufacturers of additives or of intermediaries, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,

— the date of manufacture of the pre-mixture, the batch number where appropriate,

— the names and addresses of the intermediaries or manufacturers of compound feeding stuffs to whom the pre-mixture is delivered, the delivery date, the nature and quantity of the pre-mixture is delivered, and the batch number where appropriate.

7. ***Intermediaries referred to in sub-rule 4 (1)***
Where the manufacturer delivers pre-mixtures to a person other than a manufacturer of compound feeding stuffs, that person and any subsequent intermediary by whom they are wrapped, packaged, stored our put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5, 6.2 and 8 and, in the case of wrapping, by those referred to in point 3.

8. ***Complaints and product recall***

The manufacturer or any intermediary putting a product into circulation under his own name must implement a system for registering and processing complaints. Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER I.3. (a)

Additives referred to in sub-rules 3 (2) (c) and (e)

— Antibiotics:	all additives in the group
— Coccidiostats and other medicinal substances:	all additives in the group
— Growthpromoters:	all additives in the group

CHAPTER I.3. (b)

Minimum conditions which must be fulfilled by establishments referred to in sub-rule 3 (2) (c) and (e) (compound feeding stuffs containing pre-mixtures of additives referred to in Chapter I.3 (a))

1. ***Facilities and equipment***

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of compound feeding stuffs containing pre-mixtures. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid, as far as possible, contamination, cross-contamination and any adverse effects generally on the quality of the products.

Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products must undergo appropriate and regular checks, in accordance with the written procedures pre-established by the manufacturer, or possibly, in the case of manufacture solely for the manufacturer's own needs, pre-established by a qualified outside person acting at the request and under the responsibility of the manufacturer. Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of compound feeding stuffs containing pre-mixtures. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must be drawn up — if appropriate in the case of manufacture solely for the manufacturer's own needs — and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of the compound feeding stuffs containing pre-mixtures.

3. ***Production***

A qualified person responsible for production must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process, such as incorporation of the pre-mixture in the feeding stuff, chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the compound feeding stuffs in accordance with the provisions of Directive 79/373/EEC.

Technical or organizational measures shall be taken to avoid cross-contamination and errors as far as possible.

4. ***Quality control***

A qualified person responsible for quality control must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must have at his disposal a quality control laboratory having adequate staff and equipment to guarantee and check that the compound feeding stuffs containing pre-mixtures comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content and homogeneity of the additives concerned in the compound feeding stuffs, and as low a level as possible of cross-contamination, as well as, in the case of feeding stuffs to be put into circulation, the contents as regards analytical constituents (Directive 79/373/EEC). The use of an outside laboratory is permitted.

A quality control plan must be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and destination in the event of non-compliance — for raw materials, pre-mixtures and compound feeding-stuffs 'products'.

Samples must be taken in sufficient quantity by a procedure pre-established by the manufacturer on the basis of each batch of compound feeding stuffs or each specific portion of production in the case of continuous manufacture, and be retained in order to ensure traceability where it is put into circulation, or on a regular basis in the case of manufacture solely for the manufacturer's own needs. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities for an appropriate period.

5. ***Storage***

'Products' which meet the specifications — and those which do not — must be stored in suitable containers in places designed, adapted and maintained in order to ensure good storage conditions, to which only persons authorized by the manufacturer have access.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

The 'products' must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products and with medicinal substances or medicinal feeding stuffs, or with raw materials containing high levels of undesirable substances and products, or with additives. Compound feeding stuffs intended to be put into circulation must comply with the provisions of Directive 79/373/EEC.

6. ***Documentation***

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must keep the results of the relevant controls. This set of documents must be kept in such a way as to make it possible to trace the manufacturing history of each batch produced and, where it is put into circulation, to establish responsibility if complaints arise.

6.2. Register of compound feeding stuffs

The manufacturer must record the following information in order to ensure traceability:

— the names and addresses of pre-mixture manufacturers or intermediaries, with the batch number if appropriate, the nature and quantity of the pre-mixture used,

— the nature and quantity of feeding stuffs manufactured, together with the date of manufacture.

7. ***Complaints and product recall***

The manufacturer must implement a system for registering and processing complaints.

Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled

products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER I.4

Minimum conditions which must be fulfilled by establishments referred to in sub-rule 3 (2) (d) and (e) (compound feeding stuffs from raw materials which contain high levels of undesirable substances and products ('raw materials concerned'))

1. ***Facilities and equipment***

Facilities and manufacturing equipment must be located, designed, constructed and maintained to suit the manufacture of compound feeding stuffs from the 'raw materials concerned'. The layout, design and operation of the facilities and equipment must be such as to minimize the risk of error and permit effective cleaning and maintenance in order to avoid contamination, as far as possible, contamination, cross-contamination and any adverse effects generally on the quality of the products. Facilities and equipment to be used for manufacturing operations which are essential for the quality of the products must undergo appropriate and regular checks, in accordance with written procedures pre-established by the manufacturer, or possibly, in the case of manufacture solely for the manufacturer's own needs, pre-established by a qualified outside person acting at the request and under the responsibility of the manufacturer.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of compound feeding stuffs from the 'raw materials concerned'. An organizational chart setting out the qualifications (diplomas, professional experience) and responsibilities of the supervisory staff must — if appropriate in the case of manufacture solely for the manufacturer's own needs — be drawn up and made available to the competent authorities responsible for inspection. All the staff must be informed clearly in writing of their duties, responsibilities and powers, especially when any change is made, in such a way as to obtain the desired quality of compound feeding stuffs from the 'raw materials concerned'.

3. ***Production***

A qualified person responsible for production must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacture must ensure that the different stages in production are carried out according to pre-established written procedures and instructions aimed at defining, checking and mastering the critical points in the manufacturing process, such as incorporation in the feeding stuff of the 'raw material concerned', chronological order of production, meters and weighing apparatus, mixer and returns, in such a way as to obtain the desired quality of the compound feeding stuffs in accordance with the provisions of Directive 79/373/EEC.

Technical or organizational measures shall be taken to avoid cross-contamination and errors as far as possible.

4. ***Quality control***

A qualified person responsible for quality control must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must have at his disposal a quality control laboratory having adequate staff and equipment to guarantee and check that the compound feeding stuffs concerned comply with the specifications defined by the manufacturer and which will guarantee and check, in particular, the nature, content and homogeneity of the undesirable substances and products concerned in the compound feeding stuff, and as low a level as possible of cross-contamination as well as compliance with the maximum levels of undesirable substances and products as laid down in Directive 1999/29/EEC and, in the case of feeding stuffs to be put into circulation, contents as regards analytical constituents (Directive 79/373/EEC). The use of an outside laboratory is permitted.

A quality control plan shall be drawn up in writing and implemented, to include, in particular, checks on the critical points in the manufacturing process, sampling procedures and frequencies, methods of analysis and their frequency, compliance with the specifications — and destination in the event of non-compliance — for raw materials, including those with high levels of undesirable substances and products, and compound feeding stuffs.

Samples must be taken sufficient quantity by a procedure pre-established by the manufacturer on the basis of each of compound feeding stuffs or each specific portion of production in the case of continuous manufacture, and be retained in order to ensure traceability where it is put into circulation, or on a regular basis in the case of manufacture solely for the manufacturer's own needs. These samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any abnormal adulteration. They must be kept at the disposal of the competent authorities for a period appropriate to the use to which the feeding stuffs are put.

5. ***Storage***

Raw materials, notably those containing high levels of undesirable substances and products and compound feeding stuffs which meet the specifications — and those which do not — must be stored in suitable containers or in places designed, adapted and maintained in order to ensure good storage conditions.

Preventive measures must be taken to avoid, as far as possible, the presence of harmful organisms, with the introduction of a control plan if necessary.

The products must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances or medicinal feeding stuffs, or with additives or pre-mixtures of additives. Compound feeding stuffs intended to be put into circulation must comply with the provisions of Directive 79/373/EEC.

6. ***Documentation***

6.1. Documentation relating to the manufacturing process and controls

The manufacturer must have a system of documentation designed to define and ensure the mastery of the critical points in the manufacturing process, and to establish and implement a quality control plan. The manufacturer must in particular keep the results of the relevant controls. This set of documents must be kept in such a way as to make it possible to trace the manufacturing history of each batch produced and, where it is put into circulation, to establish responsibility if complaints arise.

6.2. Register of compound feeding stuffs

The manufacturer must record the following information in order to ensure traceability:

— the names and addresses of suppliers of raw materials containing high level of undesirable substances and products, and

— the nature and level of undesirable substances and products, the delivery date and the nature and quantity of the products manufactured, plus the date of manufacture.

7. ***Complaints and product recall***

The manufacturer must implement a system for registering and processing complaints.

Likewise, he must be in a position to introduce, where this proves necessary, a system for prompt recall of products in the distribution network. The manufacturer must define by means of written procedures the destination of any recalled

products, and before such products are put back into circulation they must undergo a quality-control reassessment.

CHAPTER II

Minimum conditions which must be fulfilled by establishments and intermediaries referred to in rules 8 and 9 (subject to registration)

CHAPTER II (a)
Additives referred to in sub-rule 8 (2) (b), (c) and (d) and in sub-rule 9 (1)

— Vitamins, provitamins and chemically well-defined substances having a similar action:	all additives in the group except for vitamins A and D
— Trace elements:	all additives in the group except for Cu and Se
— Carotenoids and xanthophylls:	all additives in the group
— Enzymes:	all additives in the group
— Micro-organisms:	all additives in the group
— Substances with antioxidant effects:	only those with a fixed maximum content

CHAPTER II (b)

Additives referred to in sub-rule 8 (2) (c) and (d)

— Vitamins, provitamins and chemically well-defined substances having a similar action:	all additives in the group
— Trace elements:	all additives in the group
— Carotenoids and xanthophylls:	all additives in the group
— Enzymes:	all additives in the group
— Micro-organisms:	all additives in the group
— Substances withantioxidant effect:	only those with a fixed maximum content

CHAPTER II (c)

Minimum conditions which must be fulfilled by establishments and intermediaries referred to in sub-rule 8 (2) (a) and (b) and sub-rule 9 (1), (additives for which a prescribed maximum level is set and which are not referred to in Chapter I.1 (a), pre-mixtures of additives referred to in Chapter II (a)) and establishments referred to in sub-rule 8 (2) (c) and (d), (compound feeding stuffs containing pre-mixtures of additives referred to in Chapter II (b) or additives referred to in Chapter II (a)).

1. ***Facilities and equipment***

Facilities and technical equipment must be located, designed, constructed and maintained to suit the manufacture of the additives, pre-mixtures of additives and compound feeding stuffs containing additives or pre-mixtures of additives concerned ('products concerned').

2. ***Personnel***

The manufacturer must have sufficient staff possessing the skills and qualifications necessary for the manufacture of the 'products concerned'.

3. ***Production***

A qualified person responsible for production must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must ensure that the different stages of production are carried out in such a way as to obtain the desired quality of the 'products concerned' in accordance with the provisions of Directive 70/524/EEC or Directive 79/373/EEC.

4. ***Quality control***

A qualified person responsible for quality control must be designated who, in the case of manufacture solely for the manufacturer's own needs, may if necessary be from outside, but shall act at the request and under the responsibility of the manufacturer.

The manufacturer must draw up and implement a quality control plan to guarantee and check that the 'products in question' comply with the specifications defined by the manufacturer and that they comply, as appropriate, with the provisions of Directive 70/524/EEC or Directive 79/373/EEC.

In order to ensure traceability, samples must be taken and kept, where appropriate, from each batch of the product or from each specific portion of production in the

case of continuous or regular manufacture. They must be kept at the disposal of the competent authorities for a period appropriate to the use to which the feeding stuffs are put.

5. ***Storage***

Raw materials, active substances, carrier substances, pre-mixtures and compound feeding stuffs must be stored in places designed, adapted and maintained in order to ensure good storage conditions.

The products must be stored in such a way as to be easily identifiable and to avoid any confusion or cross-contamination between the different products mentioned above and with medicinal substances or medicinal feeding stuffs. Products to be put into circulation must be wrapped, where appropriate, and labelled in accordance with the provisions of Directive 70/524/EEC or Directive 79/373/EEC, as appropriate.

6. ***Register***

The manufacturer must record the following information in order to ensure traceability:

(a) *for additives:*

— the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,

— the names and addresses of the intermediaries or users (manufacturers or stock breeders) to whom the additives have been delivered, with an indication of the nature and quantity of the additives delivered and, where appropriate, the number of the batch or
of the specific portion of production in the case of continuous manufacture.

(b) *for pre-mixtures:*

— the names and addresses of the additive manufacturers or intermediaries, the nature and quantity of the additives used and, where appropriate, the number of the batch or of the specific portion of production in the case of continuous manufacture,

— the date of manufacture of the pre-mixture, the number of the batch where appropriate,

— the names and addresses of the intermediaries or manufacturers to whom the pre-mixtures have been delivered and the nature and quantity of the pre-mixture delivered, and the number of the batch, where appropriate;

(c) *for compound feeding stuffs containing pre-mixtures or additives:*

— the names and addresses of the pre-mixture manufacturers or intermediaries, with the batch number where appropriate, the nature and quantity of the pre-mixture used,

— the names and addresses of the additive manufacturers or intermediaries, the nature and quantity of the additive used and the number of the batch or of the specific portion of production in the event of continuous manufacture,

— the nature and quantity of the feeding stuffs manufactured, with the date of manufacture.

7. ***Intermediaries referred to in sub-rule 8 (1)***

Where the manufacturer delivers additives to a person other than a manufacturer or stock breeder, or pre-mixtures to a person other than a manufacturer, that person and any subsequent intermediary by whom they are wrapped, packaged, stored or put into circulation shall be equally bound, as appropriate, by the obligations laid down in points 4, 5 and 6.2 and, in the case of wrapping, by those laid down in point 3.

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