No. 1327

MINISTRY FOR AGRICULTURE, FISHERIES AND ANIMAL RIGHTS

Explanatory Notes
(for the purposes of article 3(2)(c) of Chapter 512 of the Laws of Malta)

1. Introduction

Title of the Legal Notice	Manufacture, Placing on the Market and Use of Medicated Feed Rules, 2024 hereinafter referred to as "the rules".
Activity to be regulated	Strengthening the regulation and control of the manufacture, distribution and use of medicated feed.
Responsible entity	Ministry for Agriculture, Fisheries and Animal Rights

2. Summary and Background

2.1 Aims and Objectives of the legislation

The aim of these rules is to implement the requirements of Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.

These rules also contain a number of national provisions that are essential to manage the regulatory environment that has changed since the original transposition of Council Directive 90/167/EEC in 2004.

2.2 Importance of Rules

The improved control on the manufacture, distribution, use and disposal of medicated feed shall decrease the abuse, misuse or overuse of these products. Currently, all medicated feeds used in Malta contains antimicrobial product.

2.3 Public Consultation

No public consultation was carried out. However, consultation took place with selected stakeholders.

3. Overview of the structure of the instrument

The rules are made up of the following eleven (11) rules:

1. Citation, scope and commencement.

2. Interpretation.

3. Request for information.

4. System of disposal of unused or expired medicated feed.

5. Veterinary prescription for medicated feed.

6. Application with the Director.

7. List of medicated feed.

8. Right to appeal.

9. Offences, punishments and administrative penalties.

10. Repeal and saving.

11. Consequential amendment

4. Commentary on operative parts.

Rule 3 provides for an obligation on the part of operators and animal keepers to provide data on importation, export, intra-trade, sale, use, administration and disposal of any type of medicated feed or its intermediate products.

Rule 4 provides for the safe disposal of expired or unused medicated feed and its intermediate products.

Rule 5 specifies that the veterinary prescription for medicated feed shall be provided by the Director in conformity with Article 16 of Regulation (EU) 2019/4. The prescribed quantities shall be divided into medicated feed prescribed for production and quantity of medicated feed supplied for use. This rule also provides for the electronic veterinary prescription.

Rule 6 provides that before starting to operate, the applicants shall submit an application for approval from the Director.

Rule 7 specifies that approved operators shall provide a list of the medicated feed they manufacture and, or distribute on an annual basis. Any changes in the information shall be notified to the Director.

Rule 8 provides that decisions of the Director in terms of these regulations shall be subject to a right of appeal before the Administrative Review Tribunal established by article 5(1) of the Administrative Justice Act. An appeal in terms of this regulation shall be filed within twenty (20) days from the notification of the Director's decision; provided that the Director's decision shall become immediately applicable and enforceable and shall remain applicable throughout the term of appeal until final judgment by the Administrative Review Tribunal and shall remain applicable unless it is overturned by the Tribunal or withdrawn by the Director.

Rule 9 provides that any person who breaches the provisions of the rules and Regulation (EU) 2019/4 shall be liable to a fine (multa) of not less than one thousand euro (€1,000) and not more than five thousand euro (€5,000), or to imprisonment for a term not exceeding two (2) months. The Director is not precluded from proceeding in accordance with article 61 of the Act.

Rule 10 repeals SL 437.37 which outlines the conditions governing the Preparation, Placing on the Market and Use of Medicated Feeding stuffs Rules.

Rule 11 amends the Second Schedule to the Administrative Justice Act (CAP 490), by adding a new item linked to these rules: Manufacture, Placing on the Market and Use of Medicated Feed Rules.

5. Concluding Section

The rules shall come into force within two (2) months from their publication in the Gazette.

N.B. These Explanatory Notes are not intended to be an exhaustive description of the instrument nor a substitute thereof or a legislative supplement to it. These Notes does not purport to be an authoritative ruling on the interpretation of the legislation.

8th October, 2024

User Guidelines

1. Introduction

Title of the Legal Notice	Manufacture, Placing on the Market and Use of Medicated Feed Rules, 2024 hereinafter referred to as "the rules".
Activity to be regulated	Strengthening the regulation and control of the manufacture, distribution and use of medicated feed.
Responsible entity	Ministry for Agriculture, Fisheries and Animal Rights

2. Objectives and Purpose of the Legislation

The objective of these rules is to implement the requirements of Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.

Apart from implementing the requirements of the EU Regulation, these rules contain a number of national provisions that are essential to manage the regulatory environment that has changed since the original transposition of the EU Directive in 2004. The need for better control of medicated feed, in particular regarding the rising threats of antimicrobial resistance, and the dangers of putting ineffective medicated feed paved the way for these rules. In addition, the standards of animal care and expectations from the public have both risen significantly in recent years. Therefore, the legislation shall also live up to these expectations. To achieve these aims the rules have been drafted with the intention to include the following legal provisions:

A provision related with provision of data on sales and use of medicated feed.

A provision related with the safe disposal of expired or unused medicated feed.

A provision related to the prescription for medicated feed.

A provision related with the application of operators to be granted the approval of the manufacture, storage, transport or placing on the market of medicated feed or its intermediate products.

A provision related with information about medicated feed that shall be given to the Director.

A provision about applicable punishments and administrative penalties for these rules and Regulation (EU) 2019/4.

Primarily, these rules shall regulate activities that are already taking place but may be regulated in a better way.

3. Commentary on parts and articles

The Legal Notice is made up of eleven (11) rules that consist of the following:

1. Citation, scope and commencement.

2.Interpretation.

3. Request for information.

4. System of disposal of unused or expired medicated feed.

5. Veterinary Prescription for medicated feed.

6. Application with the Director.

7. List of medicated feed.

8. Right to appeal.

9. Offences, punishments and administrative penalties.

10. Repeal and saving.

11. Consequential amendment

4. Commentary on the rules

Rule number	Explanation
3	Provides for an obligation on the part of operators and animal keepers to provide data on importation, export, intra-trade, sale, use, administration and disposal of any type of medicated feed or its intermediate products.
4	Provides for the safe disposal of expired or unused medicated feed and its intermediate products.
5	Specifies that the veterinary prescription for medicated feed shall be provided by the Director in conformity with Article 16 of Regulation (EU) 2019/4. The prescribed quantities shall be divided into medicated feed prescribed for production and quantity of medicated feed supplied for use. This rule also provides for the electronic veterinary prescription.
6	Provides that before starting to operate, the applicants shall submit an application for approval from the Director.
7	Specifies that approved operators shall provide a list of the medicated feed they manufacture and, or distribute on an annual basis. Any changes in the information shall be notified to the Director.
8	Provides that decisions of the Director in terms of these regulations shall be subject to a right of appeal before the Administrative Review Tribunal established by article 5(1) of the Administrative Justice Act. An appeal in terms of this regulation shall be filed within twenty (20) days from the notification of the Director's decision; provided that the Director's decision shall become immediately applicable and enforceable and shall remain applicable throughout the term of appeal until final judgment by the Administrative Review Tribunal and shall remain applicable unless it is overturned by the Tribunal or withdrawn by the Director.
9	Provides that any person who breaches the provisions of the rules and Regulation (EU) 2019/4 shall be liable to a fine (multa) of not less than one thousand euro (€1,000) and not more than five thousand euro (€5,000), or to imprisonment for a term not exceeding two (2) months. The Director is not precluded from proceeding in accordance with article 61 of the Act.
10	This rule repeals SL 437.37 which outlines the conditions governing the Preparation, Placing on the Market and Use of Medicated Feeding stuffs Rules.
11	Rule 11 amends the Second Schedule to the Administrative Justice Act (CAP 490), by adding a new item linked to these rules: Manufacture, Placing on the Market and Use of Medicated Feed Rules.

Disclaimer: The information contained within this document is intended only as guidelines and is not intended, nor should be construed, as legislation. Please refer to the related legal notice for a more comprehensive understanding.

For any other information kindly contact the Feeding Stuffs and Animal Nutrition Section of the Veterinary Services within the Animal Health and Welfare Department using the following contact details:

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