No. 1476

MALTA COMPETITION AND CONSUMER AFFAIRS AUTHORITY

Explanatory Notes[1]

1. Introduction

Title of Regulations	Various Laws relating to Internal Market Emergency Procedures for Market Surveillance and Conformity Assessment (Amendment) Regulations, 2026, hereinafter referred to as the "proposed regulations".
Activity to be regulated	To implement emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance of various products carried out by national authorities due to an internal market emergency.
Responsible entity	The Technical Regulations Division (TRD) within the Malta Competition and Consumer Affairs Authority (MCCAA)

2. Summary and background

2.1 Aims & Objectives of the legislation

The aim and objectives of the proposed regulations is to transpose:

- Directive (EU) 2024/2749 of the European Parliament and of the Council of 9 October 2024 amending Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU as regards emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency; and

- Directive (EU) 2024/2839 of the European Parliament and of the Council of 23 October 2024 amending Directives 1999/2/EC, 2000/14/EC, 2011/24/EU and 2014/53/EU as regards certain reporting requirements in the fields of food and food ingredients, outdoor noise, patients' rights, and radio equipment.

2.2 Overview of the amending Directives and Regulations

The amending Directives may be accessed through the following links:
Directive (EU) 2024/2749:
• regarding emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency.
Directive (EU) 2024/2839:
• regarding certain reporting requirements in the fields of food and food ingredients, outdoor noise, patients' rights, and radio equipment.

Directive (EU) 2024/2749

Directive (EU) 2024/2749 amends Directives 2000/14/EC, 2006/42/EC, 2010/35/EU, 2014/29/EU, 2014/30/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU and 2014/68/EU to introduce emergency procedures for conformity assessment, the adoption of common specifications, and market surveillance. These procedures apply during an internal market emergency and enable the EU to respond to crises that affect products designated as crisis-relevant goods.

The amended Directives are transposed into national law through the following legislation:

1. Simple Pressure Vessels Regulations - S.L. 427.01
2. Noise Emission in the Environment by Equipment for Use Outdoors Regulations - S.L. 427.19.
3. Pressure Equipment Regulations - S.L. 427.29.

[1]These Explanatory Notes are in accordance with and for the purpose of article 3(2)(c) and Schedule III of Chapter 512 of the Laws of Malta.

4. Transportable Pressure Equipment Regulations – S.L. 427.30.
5. Low Voltage Electrical Equipment Regulations - S.L. 427.34.
6. Electromagnetic Compatibility Regulations S.L. 427. 35.
7. Machinery Equipment Regulations - S.L. 427.36.
8. Lifts Regulations - S.L. 427.37.
9. Equipment and Protective Systems intended for Use in Potentially Explosive Atmospheres Regulations - S.L. 427.39.
10. Radio Equipment Regulations - S.L. 427.41.

As regards the Radio Equipment Regulations, the amendments required to transpose Directive (EU) 2024/2749 has already been enacted through Legal Notice 202 of 2025.

The proposed Legal Notice amends the aforementioned legislation to align national law with the requirements of Directive (EU) 2024/2749, thereby allowing national competent authorities to derogate from the conformity assessment procedures to mitigate the potential impact of internal market disruptions during a crisis and ensure that, when the internal market emergency mode is activated, harmonised crisis-relevant goods can be placed on the market without delay.

Directive (EU) 2024/2839

Directive (EU) 2024/2839 introduces amendments to Directives 1999/2/EC, 2000/14/EC, 2011/24/EU and 2014/53/EU concerning various reporting requirements in the areas of food and food ingredients, outdoor noise, patients' rights, and radio equipment.

For the purpose of the proposed legal notice only the amendments to Directives 2000/14/EC and 2014/53/EU are of relevance since only these relate to products which are regulated by means of legislation falling under the Product Safety Act. These amendments concern noise emissions from equipment intended for outdoor use and radio equipment, which are transposed into national law through the following legislation:

1. The Noise Emission in the Environment by Equipment for Use Outdoors Regulations (S.L. 427.19); and
2. The Radio Equipment Regulations (S.L. 427.41).

As regards the Radio Equipment Regulations, the amendments required to transpose Directive (EU) 2024/2839 have already been enacted through Legal Notice 202 of 2025.

With respect to equipment for use outdoors, the proposed legal notice removes the obligation on manufacturers, or their authorised representatives, to submit to the competent authority a copy of the EC Declaration of Conformity for each type of equipment they intend to place or put into service on the EU internal market. This amendment reduces administrative burdens on both businesses and competent authorities and reflects the fact that consumers can obtain the necessary information on noise emissions directly from the equipment itself.

Thus, the above-mentioned subsidiary legislation falling under the Product Safety Act (Cap. 427 of the Laws of Malta) shall be amended accordingly on a national level by means of these proposed regulations.

3. Overview of the structure of the instrument

The proposed regulations consist of 42 regulations.

• Regulation 1 – Citation, scope and commencement
• Regulation 2 – Amendments to the Simple Pressure Vessels Regulations
• Regulation 3 – Amends regulation 4 of the principal regulations
• Regulation 4 – Adds new regulations to the principal regulations
• Regulation 5 – Amendments to the Noise Emission in the Environment by Equipment for Use Outdoors Regulations
• Regulation 6 – Amends regulation 1.2 of the principal regulations
• Regulation 7 – Substitutes regulation 3.1 of the principal regulations
• Regulation 8 – Substitutes regulation 5.2 of the principal regulations
• Regulation 9 – Amends regulation 10.1 of the principal regulations
• Regulation 10 – Amends regulation 10.3 of the principal regulations

• Regulation 11 – Amends regulation 10.4 of the principal regulations
• Regulation 12 – Amends regulation 10.5 of the principal regulations
• Regulation 13 – Deletes regulations 10.7 and 10.8 of the principal regulations
• Regulation 14 – Adds new regulations to the principal regulations
• Regulation 15 – Amends Schedule II to the principal regulations
• Regulation 16 – Amendments to the Pressure Equipment Regulations
• Regulation 17 – Amends regulation 4 of the principal regulations
• Regulation 18 – Adds new regulations to the principal regulations
• Regulation 19 – Amendments to the Transportable Pressure Equipment Regulations
• Regulation 20 – Amends regulation 3 of the principal regulations
• Regulation 21 – Adds new regulations to the principal regulations
• Regulation 22 – Amendments to the Low Voltage Electrical Equipment Regulations
• Regulation 23 – Amends regulation 3 of the principal regulations
• Regulation 24 – Adds new regulations to the principal regulations
• Regulation 25 – Amendments to the Electromagnetic Compatibility Regulations
• Regulation 26 – Amends regulation 2 of the principal regulations
• Regulation 27 – Adds new regulations to the principal regulations
• Regulation 28 – Amendments to the Machinery Regulations
• Regulation 29 – Amends regulation 3 of the principal regulations
• Regulation 30 – Amends regulation 9 of the principal regulations
• Regulation 31 – Amends regulation 10 of the principal regulations
• Regulation 32 – Amends regulation 13 of the principal regulations
• Regulation 33 – Amends regulation 16 of the principal regulations
• Regulation 34 – Deletes regulation 17 of the principal regulations
• Regulation 35 – Adds new regulations to the principal regulations
• Regulation 36 – Amends Schedule 11 of the principal regulations
• Regulation 37 – Amendments to the Lifts Regulations
• Regulation 38 – Amends regulation 2 of the principal regulations
• Regulation 39 – Addition of new regulations to the principal regulations
• Regulation 40 – Amendments to the Equipment and Protective Systems intended for Use in Potentially Explosive Atmospheres Regulations
• Regulation 41 – Amends regulation 4 of the principal regulations
• Regulation 42 – Addition of new regulations to the principal regulations

4. Commentary

Regulation 3, 7, 17, 20, 23, 26, 29, 38 and 41:

These provisions introduce or update definitions across the various principal regulations, including key terms such as "crisis-relevant goods", "common specifications", "implementing act" and "internal market emergency mode". These definitions establish the legal framework necessary for the application of emergency procedures and ensure consistency with EU legislation.

Regulations 4, 14, 18, 21, 24, 27, 35, 39 and 42:

These provisions add new regulations to the respective principal regulations. They introduce a harmonised framework governing internal market emergency procedures, including:
• the application of emergency measures
• the prioritisation of conformity assessment procedures
• derogations from standard conformity assessment requirements
• presumption of conformity based on harmonised standards or common specifications

Application of emergency procedures (new provisions across all sectors):

These provisions establish that emergency procedures may only apply where an internal market emergency mode has been activated at EU level. They also limit the application of such measures to goods designated as "crisis-relevant goods", ensuring that the framework is targeted and proportionate.

Prioritisation of conformity assessment:

Notified bodies are required to prioritise conformity assessment procedures for crisis-relevant goods. This ensures that essential products can be made available on the market without delay, while maintaining compliance with safety requirements.

Derogations from conformity assessment procedures:

The Technical Regulations Division (TRD) is empowered to authorise, on a duly justified request, the placing on the market of certain products without full completion of conformity assessment procedures involving notified bodies. Such derogations are subject to strict conditions, including:

• demonstration of compliance with essential safety requirements
• clear identification and labelling of the products
• time-limited validity linked to the duration of the emergency
• traceability and post-market obligations

Presumption of conformity:

The new provisions clarify that products complying with harmonised standards or common specifications benefit from a presumption of conformity with applicable requirements. However, this presumption may cease following the expiry or deactivation of the internal market emergency mode.

Regulations 6, 9, 10, 11, 12, 30, 31, 32 and 33:

These provisions update references to the competent authority, replacing previous bodies (such as the Director of Consumer Affairs or other directorates) with the Technical Regulations Division (TRD), thereby streamlining enforcement and administrative responsibilities.

Regulations 8 and 22:

These provisions clarify obligations of economic operators, particularly in situations where manufacturers are not established within the European Union, ensuring that responsibility for compliance is clearly assigned.

Regulations 13 and 34:

These provisions delete obsolete or redundant regulations, simplifying the legal framework.

Regulations 15 and 36:

These provisions amend schedules to update terminology and references, aligning them with current EU law and institutional structures.

Overall, the regulations establish a consistent, cross-sectoral framework enabling Malta to respond effectively to internal market emergencies while safeguarding product safety, ensuring regulatory coherence, and minimising unnecessary burdens on economic operators.

5. Concluding Section

These regulations shall come into force on 30th May 2026, provided that regulation 10 shall be deemed to have come into force from 29th November 2025.

Should more information be required kindly contact the Regulatory Affairs Directorate within the Malta Competition and Consumer Affairs Authority on +356 23952000.

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 Explanatory Notes do not purport to be an authoritative ruling on the interpretation of the legislation.

2nd October, 2026