Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 21,519, 10 ta' Ottubru, 2025
Taqsima B

L.N. 230 of 2025

PRODUCT SAFETY ACT
(CAP. 427)

Biocidal Products (Implementing) Regulations, 2025

IN EXERCISE of articles 38 and 39 of the Product Safety Act, the Minister responsible for consumer affairs, on the advice of the Director General (Technical Regulations), has made the following regulations:-

Citation and scope.

1. (1) The title of these regulations is the Biocidal Products (Implementing) Regulations, 2025.

(2) The scope of these regulations is to implement the requirements of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

Interpretation.

2. In these regulations, unless the context otherwise requires:

"Act" means the Product Safety Act; Cap. 427.

"Director General" shall have the same meaning as assigned to it in the Act;

"Regulation (EU) No 528/2012" means Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

Establishment of the competent authority. Cap. 510.

3. The Technical Regulations Division within the Malta Competition and Consumer Affairs Authority as established by article 19 of the Malta Competition and Consumer Affairs Authority Act, shall be the competent authority responsible for the application of these regulations within the meaning of Article 81 of Regulation (EU) No 528/2012.

Language requirements for labelling of biocidal products.

4. With reference to Articles 27 and 53 of Regulation (EU) No 528/2012, the language used on the labels shall be that as indicated in the Schedule.

Notification of biocidal products.

5. (1) Biocidal products which contain active ingredients or active substances which are not included in the approved list specified in Article 9(2) of Regulation (EU) No 528/2012 and which are undergoing evaluation, shall be notified by means of an application to the Technical Regulations Division before being placed on the market.

(2) The application referred to in sub-regulation (1) shall at least include the following information:

(a) safety data sheets of all the hazardous ingredients of the product;

(b) original labels of the product;

(c) a copy of the authorisation certificate issued by an EU Member State;

(d) a declaration of the chemical composition of the product;

(e) a letter of access as defined in point (t) of Article 3 of Regulation (EU) No 528/2012.

(3) The applicant shall also provide documented evidence that the supplier is included in the updated version of the list referred to in Article 95 of Regulation (EU) No 528/2012 regarding the product type to which the product belongs.

(4) The Director General shall determine the application within a reasonable period which shall not exceed forty-five (45) working days from the date of receipt of an application:

Provided that such period may be suspended until all relevant information has been submitted.

Penalties.

6. Part IV of the Act shall apply to any offence carried out in breach of Regulation (EU) No 528/2012 and these regulations.

Repeal and saving. S.L. 430.09.

7. The Biocidal Products (Implementation of Regulation (EU) No 528/2012) Regulations are hereby repealed without prejudice to anything done or omitted to be done thereunder.

SCHEDULE
(regulation 4)

Labelling Requirements according to the Product Type

Product Type (PT) **(According to Annex V of Regulation (EU) No 528/2012)**	**Language Requirements**
PT 1	Maltese or English
PT 2	Maltese or English

PT 3	Both Maltese and English*
PT 4	Maltese or English
PT 5	Maltese or English
PT 6	Maltese or English
PT 7	Maltese or English
PT 8	Maltese or English
PT 9	Maltese or English
PT 10	Both Maltese and English*
PT 11	Maltese or English
PT 12	Both Maltese and English*
PT 13	Maltese or English
PT 14	Both Maltese and English*
PT 15	Both Maltese and English*
PT 16	Both Maltese and English*
PT 17	Both Maltese and English*
PT 18	Both Maltese and English*
PT 19	Both Maltese and English*
PT 20	Both Maltese and English*
PT 21	Maltese or English
PT 22	Maltese or English

*Either Maltese or English may be used provided that the product is intended for professional use only.

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