SUBSIDIARY LEGISLATION 430.09

BIOCIDAL PRODUCTS (IMPLEMENTATION OF REGULATION (EU) No. 528/2012) REGULATIONS

1st September, 2013*

LEGAL NOTICE 348 of 2013, as amended by Legal Notice 325 of 2015.

Citation and scope. *Amended by: L.N. 325 of 2015.*

1. (1) The title of these regulations is the Biocidal Products (Implementation of Regulation (EU) No 528/2012) Regulations.

(2) (*a*) These regulations implement the provisions 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, hereinafter referred to as "Regulation (EU) No 528/2012".

(*b*) These regulations implement the provisions of Article 95 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, hereinafter referred to as "Regulation (EU) No 528/2012".

Interpretation. *Amended by: L.N. 325 of 2015.*

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

"dealer" means anyone involved in any activity in the manufacture, import, export, transport, storage, distribution, presenting for sale or sale of any biocidal product;

"DG" means the Director General of the Technical Regulations Division within the Malta Competition and Consumer Affairs Authority;

"supplier of the active substance or product" refers to the submitter of the dossier.

Establishment of the competent authority. Cap. 510.

3. The Technical Regulations Division as established by the Malta Competition and Consumer Affairs Authority Act, within the Malta Competition and Consumer Affairs Authority, is responsible for the application for 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 as indicated in the Schedule.

Notification of biocidal products. *Amended by: L.N. 325 of 2015.*

5. (1) Biocidal products that contain active ingredients or active substances that are not included in the approved list specified in Article 9.2 of Regulation (EU) No 528/2012, and are undergoing evaluation, shall be notified to the Technical

*see regulation 1(3) of these Regulations, as originally promulgated.

Regulations Division before being placed on the market.

(2) The application shall, as a minimum, contain the following requirements:

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

(*b*) original product labels;

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

(*d*) declaration of chemical composition;

(*e*) letter of access;

(*f*) filled-in and signed application form;

The applicant must moreover provide documented evidence that the supplier of the active substance or product is included in the latest version of the list referred to in Article 95 of Regulation (EU) No 528/2012, for the product type to which the product belongs.

(3) The DG shall determine the application within a reasonable period of time, not exceeding forty-five working days from the date of receipt of an application:

Provided that this time limit may be suspended until all relevant information is submitted.

Dealing in biocidal products.

6. (1) No person shall deal in any:

(*a*) active substance unless this is authorized in accordance with these regulations;

(*b*) biocidal product unless this is authorized for placing on the market in Malta in accordance with these regulations;

(*c*) biocidal products containing active ingredients that are under evaluation, unless there is notification of these products.

(2) No person shall deal in any active substance or biocidal product unless he is in possession of an authorisation to deal in active substances or biocidal products granted to him in accordance with regulation 7.

Application for an authorisation to deal.

7. (1) Any application for the granting of an authorisation to deal in biocidal products or active substances shall be made in writing to the DG and shall contain such information, and be accompanied by such documents, samples and other material as the DG may require.

(2) Any application shall, as a minimum, contain the following requirements:

(*a*) the nature of any activity related to the dealing of active substances and biocidal products which the applicant wishes to undertake;

(*b*) the place where such activity is to take place, and suitable information, documentation and evidence as

may be required in order to show that such place is suitable and sufficient for that purpose;

(*c*) evidence to show that the place where such activity is to take place has the necessary equipment and control facilities as may be required by the DG;

(*d*) evidence to show that the health and safety of staff shall be protected and ensured at all times;

(*e*) the name and postal address and any other contact details of the applicant;

(*f*) the name of the person who will be effectively responsible for carrying out the activity, in the case of an application for the manufacture of a biocidal product, the name of the biocidal product and any formulation which is to be, or intended to be manufactured, assembled or in any way modified including details of the type and concentration of any active substance to be found within the formulation.

(3) The DG shall determine the application within a reasonable period of time, not exceeding forty-five working days from the date of receipt of an application:

Provided that this time limit can be suspended until all relevant information is submitted.

(4) Where an application has been made to the DG for the granting of an authorisation to deal in accordance with this regulation, the DG may, before determining the application, request the applicant to submit such further information relating to the application as he may consider requisite and where any such request has been made, the provisions of sub-regulation (5) shall be suspended until the additional information has been submitted.

(5) Any authorisation issued in accordance with this regulation shall be made in writing and be subject to any such condition the DG may deem necessary so that the business of dealing shall be carried out in accordance with the provisions of the Act or made under the Act.

8. The penalties applicable for infringement of the provisions of Article 87 of Regulation (EU) No 528/2012 shall be according to article 9 of the Pesticides Control Act. Penalties. Cap. 430.

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 if the product is intended for professional use only.