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PLANT PROTECTION PRODUCTS

GUIDANCE DOCUMENT

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1. Introduction

This guidance document outlines the criteria required for an applicant to apply for authorizing a plant protection product. The legislative basis for PPP applications is outlined in L.N. 115 of 2004 (Plant Protection Products Regulations, 2004) of the Pesticides Control Act 2001.


2. Submission of a Plant Protection Product Application

The PPP application should be submitted to the Foodstuffs Chemicals and Cosmetics Directorate (FCCD) of the Malta Standards Authority, hereinafter referred to as MSA-FCCD, as early as possible before the product is first intended to be placed on the market in order to allow for sufficient time to examine the documentation.

3 Information requirements for a Plant Protection Product Application

The information required in this form should include a technical dossier supplying the information necessary for evaluating efficacy and the foreseeable risks, whether immediate or delayed, which the plant protection product may entail for humans, animals and the environment and containing at least the information and results of the studies referred to below. Also, information should be generated using suitable internationally or nationally validated test guidelines or guidelines accepted by the competent authority. If this is not possible, a justification is included which is acceptable to the competent authority. Above all, when required, a full description of test guidelines used (except if they are referred to or described in Annex III of Council Directive 91/414/EEC) and a full description of any deviations from them including a justification (which is acceptable to the competent authority) for these deviations should be included. A full and unbiased report of the studies conducted as well as a full description of them or a justification, which is acceptable to the competent authority should be included when particular data and information which would not be necessary owing to the nature of the product or its proposed uses are not provided or if it is not scientifically necessary or technically possible to supply information and data.


Where relevant, guidelines are to be taken in accordance with the requirements of Directive 86/609/EEC and Regulation 1907/2006.

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Tests and analyses must be conducted in accordance with the principles laid down in Directive 87/18/EEC where testing is done to obtain data on the properties and/or safety with respect to human or animal health or the environment. Tests and analyses should be conducted by official or officially recognized testing facilities or organizations which satisfy at least the following requirements:

- (a) Have at their disposal sufficient scientific and technical staff, having the necessary education, training, technical knowledge and experience for their assigned functions;
- (b) Have at their disposal suitable items of equipment required for correct performance of the tests and measurements which it claims to be competent to carry out. This equipment shall be properly maintained and calibrated where appropriate before being put into service and thereafter according to an established program;
- (c) Have at their disposal appropriate experimental fields and where necessary glasshouses, growth cabinets or storage rooms. The environment in which the tests are undertaken shall not invalid its results or adversely effect the required accuracy of measurement;
- (d) Make available to all relevant personnel operating procedures and protocols used for the trials;
- (e) Make available, where requested by the competent authority, prior to the commencement of a test, detailed information on it, containing at least its location and the plant protection products included in it;
- (f) Ensure that the quality of the work performed is appropriate to its type, range, volume and intended purpose;
- (g) Maintain records of all original observations, calculations and derived data.

Officially recognized testing facilities and organizations, official facilities and organizations should report to the national authority all detailed information necessary to demonstrate that they can satisfy the requirements provided previously. These facilities/organizations should accept at any time the inspections regularly organized by the Member State to verify the compliance with the requirements laid down previously.

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Section 1

Trade Name / Proposed Trade Name / Development code number of preparation

Indicate name of product. All former and current trade names as well as the current names and numbers must be provided. Where trade names and code numbers referred to, relate to similar but different preparations (possibly obsolete), full details of the differences, must be provided. In other words, the proposed trade name must not give rise to confusion with the trade name of already registered plant protection products.

Type of Plant Protection Product:

The information provided, including that provided for the active substance(s), must be enough to identify the use of the preparation and define them in terms of their specification and nature. One type should be identified accordingly.

Name & address of Applicant / Representative in Malta:

The name and permanent community address of the applicant must be provided as must the name, position, telephone/mobile and fax numbers of the appropriate person to contact.

Where in addition, the applicant has an office, agent or representative in Malta, the name and address of the local office agent or representative should be provided as should the name, position, telephone / mobile and fax numbers of the appropriate person to contact.


Manufacturer of the preparation and the active substance(s):

The name, address of the manufacturer of the preparation and of each active substance in the preparation must be provided, including the name and address of each manufacturing plant in which the preparation and active substance are manufactures. A contact point is included.

Note that if the active substance originates from a manufacturer from which data according to Annex II of Council Directive 91/414/EEC has not been submitted previously, a statement of purity and detailed information on the impurities in Annex II have to be provided.

EU Member States where the product is authorized:

State the product/Member State where the product is authorized within the European Community.

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Purpose of Application:

Indicate what applicant is applying for, to determine the different information which would be requested.

Section 2 Active Ingredients

Detailed quantitative and qualitative information on the composition of the preparation (in this section the active ingredients)

Active Ingredient


For the active substances, their ISO (proposed) common names and their CIPAC numbers and where available the EEC (EINECS or ELINCS) numbers must be given. Also, it must be stated which salt, ester, anion or cation is present where applicable.

It is important to note the authorized products in Malta containing the same active ingredients, for comparable reasons and functions.

The ownership of the data concerning the active ingredient should also be given for future investigations, queries and to confirm data.

The letter of authorization for access to data is important as the purpose of this letter of access is to provide the evaluator and the registration authority with one of the following:

- (a) Authorization to access the registration data submitted by the original company for the active ingredient held by the registration authority for pesticides in Malta;
- (b) Authorization to send the data provided by the original company for the active ingredient to the registration authority for their assessment of the similarity and subsequent communication with the evaluator.

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Section 3 Formulation

Detailed quantitative and qualitative information on the composition of the preparation (in this section the formulants)

Concentrations should be expressed in terms as provided for in Article 6 (2) of Directive 78/631/EEC.

Formulant details include:

- Must be identified both by their chemical name as give in Council Directive1907/2006; OR
- IUPAC & CA nomenclature;
- Structure or Structural Formula;
- EEC number & CAS number;
- Trade name when applicable;
- Function from the list given in the application form.


The type and code of preparation must be designated according to the 'Catalogue of pesticide formulation types and international coding system (GIFAP Technical Monograph No 2. 1989)'.

Reference should also be made to Directive 91/414 Annex II Section A.

Section 4 Use of Product

Information should be chosen from application to specify exactly what the use of product is. It is important also to note the nature of effect on harmful organisms, giving full descriptions in both cases. Other information which must be filled in the application form include:

1. maximum individual dose rate
2. maximum number of applications
3. maximum total dose
4. intervals between applications
5. minimum rate of use

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6. concentration of active substance in material used: the content of active substance shall be reported, as appropriate, in g/l, g/kg, mg/kg or in g/tonne

7. diluent type & volume per unit area or volume

8. methods of application & type of equipment: the method of application proposed must be described fully, indicating the type of equipment to be used, if any, as well as the type and volume of diluent to be used per unit of area or volume

9. recommended time of application

10. duration of application

11. latest time of application

12. maximum interval between applications

13. waiting period before consumption

14. limitations on choice of succeeding crops

15. possible combinations with other products


16. other specific limitations

17. proposed instructions for use / labels & leaflets information

For each method of application and each use, the rate of application per unit (ha, m², m³) treated, in terms of g or kg of both preparation and active substance must be provided.

Application rates shall normally be expressed in g or kg/ha or in kg/m³ and where appropriate in g or kg/tonne. For protected crops and home gardening rates shall be expressed in g or kg/100 m² or g or kg/m³.

The maximum number of applications to be used and their timing, must be reported. Where relevant, the growth stages of the crop or plants to be protected and the development stages of the harmful organisms must be indicated. Where possible the

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interval between applications, in days, must be stated. The duration of protection afforded both by each application and by the maximum number of applications to be used, must be indicated.

Where relevant, the minimum waiting periods between last application and sowing or planting of succeeding crops which are necessary to avoid phytotoxic effects on succeeding crops must be stated. Limitations on choice of succeeding crops, if any, must also be stated.


Sections 5, 6, 7

Physical, chemical and technical properties of the plant protection product

Accepting physical, chemical and technical properties is by complying with relevant FAO specifications as agreed by the Group of Experts on Pesticide Specifications of the FAO Panel of Experts on Pesticide Specifications, Registration Requirements and Application Standards. Divergences from FAO specifications must be described in detail and fully justified.

A summary and evaluation of data of presented below should be added in the technical dossier:

- Appearance (colour & odour)
- Explosivity & oxidizing properties
- Flammability
- Acidity / alkalinity
- Viscosity & surface tension
- Relative density & bulk density
- Storage stability & shelf-life
- Technical characteristics
- Wettability
- Persistent foaming
- Suspensibility & suspension stability
- Emulsion properties
- Flowability, pourability & dustability
- Physical & chemical properties
- * Adherence distribution to seeds

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Further information necessary on the PPP according to Directive 91/414/EEC include:

- Packaging using the 'Guidelines for the Packaging of Pesticides' of FAO
- Procedures for cleaning application equipment, investigating and reporting the effectiveness of such procedure
- Re-entry periods, necessary waiting periods or other precautions to protect man, livestock and the environment
- Specific conditions
- Recommended methods & precautions concerning handling, storage, transport or fire at both warehouse and user level according to ISO – TR 9122 and sufficient to evaluate the suitability and effectiveness under realistic conditions
- Emergency measures in case of an accident
- Procedures for destruction or decontamination of the PPP and its packaging

D Amendments to application form


Any request for a modification to the authorization shall be made by the holder of the authorization on such form and such manner and within such time as the Director may from time to time by notice in the Gazette.

The applicant must notify the Competent Authority in writing of any change in the information supplied to the Competent Authority in the application or dossier and shall provide the Competent Authority with all the evidence that may be deemed necessary to support any identified change as soon as practicable.

E Granting of an authorization to place a PPP on the market

The Director shall determine the application within a reasonable time not exceeding 90 working days from the date of receipt of an application, provided that such time shall be suspended until all the relevant information is received.

Any authorization issued by the Director shall be valid for such period not exceeding ten years, provided that this may be extended upon the submission of an application for its renewal and if the Director is satisfied that the conditions mentioned in Council Directive 91/414/EEC and L.N 115 of 2004 are still being complied with.

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F Obligations of the holder of an authorization

The duty of any person holding an authorization is to keep records for the period indicated to be preserved or maintained by the holder, draw up a report of each PPP or active substance placed on the market during the previous calendar year at least annually and inform the Director in writing of any change in any information provided for the granting of an authorization or any unexpected adverse effects and must allow the Director or his/her authorized representatives access to the land or premises at any reasonable time. The holder must always comply with any provision made by or under the Pesticides Control Act.

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