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# GUIDANCE DOCUMENT

# AUTHORISATIONS OF PLANT PROTECTION PRODUCTS IN MALTA

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# List of Abbreviations

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|---|---|
| CC | Completeness Check |
| CLP | Classification Labelling and Packaging |
| CMR | Carcinogenic, Mutagenic and Reproductive Toxicity |
| cMS | Concerned Member State |
| dRR | Draft Registration Report |
| LoA | Letter of Access |
| LoS | Letter of Supply |
| MT | Malta |
| PPP | Plant Protection Product |
| RR | Registration Report |
| SDS | Safety Data Sheet |
| zRMS | Zonal Rapporteur Member State |

**Background**

There are two main types of authorisation of Plant Protection Products (PPPs) in line with Regulation (EC) No 1107/2009:

a) Zonal authorisations (in line with Articles 33 – 39)
b) Mutual recognition of authorisations (in line with Articles 40 – 42)

Different timelines for these types of authorisations are applicable in line with the Regulation (EC) No 1107/2009. Different requirements and documentation requests are applicable for each type of authorisation. These requirements are indicated in the respective application forms and are further explained hereunder. Reference can be made to the EU Guidance Document SANCO/13169/2010 for further details on the specific timeline and procedures on these authorisations.

The underneath processes and procedures for the authorisation of PPPs will come into effect for applications submitted as from 1st April 2020.

# 1. Zonal authorisations

Zonal authorisation in line with the Regulation (EC) No 1107/2009, is the standard procedure to be followed for PPP authorisation or amendment to an authorisation. This procedure applies to all applications submitted from 14th June 2011, which are not covered by the transitional arrangements in line with Article 80 of Regulation (EC) No 1107/2009.

## 1.1 The procedure of evaluation of applications in line with Articles 33 – 39

1. The applicant submits a pre-notification form to the zonal Rapporteur Member State (zRMS) and to all the concerned Member State (cMS) where the plant protection product is intended to be placed on the market. The pre-notification form should also include all intended uses for the zone.

2. The applicant submits the relevant application forms together with all the documentation requested in the same application form, including a pre-filled in completeness check form.
3. MT carries out an administrative completeness check of the documentation submitted and informs admissibility of application to applicant accordingly. If the administrative completeness check is unsuccessful, the application will be refused.
4. MT carries out completeness check to identify the data submitted in the draft Registration Report (dRR).
5. Following technical review and evaluation of the dRR, MT drafts a table of technical 'data gaps and clarifications' necessary for the completion of the evaluation. Additional data requested shall be submitted by the applicant by not later than four weeks from the date of request made to the applicant.
6. If MT is the zRMS, a 45-day commenting period is launched for review of the dRR to the other member states and to applicant simultaneously. During the commenting period, only factual issues are requested, and any new data is not accepted. Following the 45-day commenting period, the comments received are evaluated, and the dRR is reviewed and finalised accordingly. The final Registration Report (RR), the commenting table and a decision document which includes the approved label, when applicable, are provided to the applicant and made available to the other member states on CIRCABC.

## 1.2 Requirements for the submission of zonal application in line with Articles 33 – 39 with Malta as a zRMS

- Registration Report shall be:
  - Presented in the following format.
  - A 'stand-alone' document, where all information is included in the document.
- All information in Parts A, B and C of the dRR should be consistent.

- The letter of access (LoA) and letter of supply (LoS) (if applicable) must be dated, originally signed and addressed to MCCAA. The original documents have to be sent by post.
- For applications received after the 1st April 2020, RAC opinion is noted when substance is classified as Carcinogenic, Mutagenic and Reprotoxic (CMR) category 1, even if the classification is not yet published and included in Annex VI of CLP Regulation (EC) No 1272/2008.
- All study reports supporting the uses indicated in the GAP shall be finalised, dated and signed.
- Post-authorisation data requirements will not be accepted if human or environmental health risks cannot be excluded.
- Where a decision is taken without prejudice to post-authorisation requirements data, the decision is considered as 'provisional authorisation'. When all post-authorisation data requirements are provided by applicant and reviewed by Malta, the authorisation is considered as granted, without prejudice to any change in the decision taken before the provision of the data provided.
- Safety Data Sheets (SDS) should be in line with CLP Regulation (EC) No 1272/2008, and not older than two years prior to the date of submission of the application. In case no changes have been made since the date indicated on the SDS, a statement must be provided by applicant or supplier, confirming that no changes have been carried out and that SDS is still valid.
- For co-formulants composed of a mixture, the chemical composition of the mixture should be provided by the supplier.
- Products whose classification is category 1, with special reference to classifications concerning human health, may not be authorised in MT. In such case, a decision will be taken following consultation with the Pesticides Control Board, established under Article 10 of the Pesticides Control Act (Cap. 430).
- The use of herbicides is restricted in public areas and such uses cannot be authorised in line with Legal Notice 163 of 2019.
- The sale and use of products containing the active substance 'Metaldehyde' are restricted to certified distributors and professional users only.

- Data protection in line with CION notice (2019/C 229/01) is applicable. For applications in line with Article 34 of Regulation (EC) No 1107/2009, the data protection of the reference product must be expired in Malta. Data protection will expire after ten years of authorisation.
- The list of studies for which data protection is claimed in line with Article 59 of Regulation (EC) No 1107/2009, should be presented in the following format. Claims should be in line with CION notice (2019/C 229/01).
- For technical material of active substances approved in line with Article 38 of Regulation (EC) No 1107/2009, the reference specifications shall be in line with those approved at the time of renewal of the active substance.

## 1.3 Timelines for zonal application in line with Articles 33 – 39 with Malta as a zRMS

- When MT is the zRMS, evaluation is finalised within 12 months from the date of submission. In the case that the stop-of-the-clock mechanism is applied, the timeline can be extended further to a maximum of 6 months.
- When MT is the zRMS, a fast-track evaluation can be adopted and it will be finalised within 6 months. When choosing fast-track option, the dRR must be complete without any data gaps. The stop-of-the-clock mechanism cannot be applied for this type of evaluation.
- When MT is the cMS, evaluation shall be finalised within 120 days.

## 1.4 Validity of the authorisation of product in line with Articles 33 – 39 with Malta as a zRMS

- The decision document for product authorised when MT is a zRMS or cMS, is valid for 1 year after the expiry of the active substance. If applicant intends to extend the authorisation of the PPP in Malta, an application in line with Article 43 should be submitted within 3 months from the entry into force of the renewal of the approval of the active substance regulation.

# 2. Mutual recognition of authorisations

The procedure for authorisation through mutual recognition is described in Articles 40 - 42 of Regulation (EC) No 1107/2009. The holder of an authorisation granted in accordance with Article 29, for the same plant protection product, the same use and under the comparable agriculture practices in another Member State in the same zone, can apply for authorisation of PPPs under the mutual recognition process. As of 14th June 2011, mutual recognition in line with Article 40, applies to all authorisations in MS, which were either granted under Directive 91/414/EEC in compliance with Annexes II, III and VI of that Directive or under Regulation (EC) No 1107/2009.

## 2.1 The procedure of evaluation of applications in line with Articles 40 – 42

1. The applicant submits the relevant application form together with all the documentation requested in the same application form.
2. MT carries out an administrative completeness check of the documentation submitted and informs applicant of the admissibility of the application accordingly.
3. MT evaluates the documents submitted and may request submission of further documentation or clarifications. The requested documentation/information shall be submitted by not later than the deadline provided to the applicant.
4. A decision is taken on the authorisation of the application and a decision document including the approved labels when applicable, is issued. When the authorisation is not granted, the applicant is informed on the basis of such a decision.

## 2.2 Requirements for the submission of a mutual recognition application in line with Articles 40 – 42

- Applicant should be the same holder of an authorisation granted in line with Article 29 of Regulation (EC) No 1107/2009.

- Parts A, B and C of the RR shall be provided. Where the RR is not available, an Annex III dossier should be forwarded together with a signed declaration stating that the RR will be provided as soon as it is available.
- The RR or Annex III dossier should contain the necessary data to support the request for authorisation through mutual recognition.
- The LoA and LoS must be dated, originally signed, addressed to MCCAA and sent by post.
- Any declarations should be dated and originally signed.
- Where documentation provided (such as authorisation document by reference member state or original label) is not in any one of the officially recognised languages in Malta (Maltese and English), a sworn translation which needs to be signed and stamped by the translator, in any one of these languages should be provided.
- Labels in the Maltese language should be presented in the Maltese font.
- RAC opinion is noted when CMR category 1 classification is decided, even if this is not yet published and included in Annex VI of CLP Regulation (EC) No 1272/2008. This is valid even if it was not considered at the time of the finalisation of the RR.
- SDS should be in line with CLP Regulation (EC) No 1272/2008, and not older than two years prior to the submission of the application. In case no changes have been made since the date of the SDSs, a declaration must be provided by applicant or supplier confirming that no changes have been carried out and that SDS is still valid.
- Products whose classification is category 1, with special reference to classifications concerning human health, may not be authorised in MT. In such case a decision will be taken following consultation with the Pesticides Control Board established under Article 10 of the Pesticides Control Act (Cap.430).
- The use of herbicides is restricted in public areas and such uses cannot be authorised in line with Legal Notice 163 of 2019.
- The sale and use of products containing the active substance 'Metaldehyde', are restricted to certified distributors and professional users only.
- The list of studies for which data protection is claimed in line with Article 59 of Regulation (EC) No 1107/2009, should be presented in the following format. Claims should be in line with CION notice (2019/C 229/01).

## 2.3 Timelines for mutual recognition application in line with Articles 40 – 42

- Applications for mutual recognition of authorisation, will be evaluated in 120 days in line with Regulation (EC) No 1107/2009.

## 2.4 Validity of the authorisation of product in line with Articles 40 – 42

1. The authorisation document for product authorised by mutual recognition, is valid for 4 years. If the applicant intends to extend the authorisation of the PPP in Malta, an application for renewal must be submitted within 3 months of the expiry date.