PLANT PROTECTION

APPLICATION EU MRL / IMPORT TOLERANCE

Procedure with Belgium involved as Evaluating Member State (EMS)

Federal Public Service **Health, Food Chain Safety and Environment**
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DOCUMENT INFORMATION

Application EU MRL / Import tolerance:
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Version 2.0
01/02/2017

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1. Introduction

In accordance with Reg. (EC) No 1107/2009, one of the prerequisites to authorize a plant protection product (PPP) is that potential residues in food and feed resulting from the intended use of the PPP are covered by EU Maximum Residue Limits (EU MRLs) set in accordance with Reg. (EC) No 396/2005.

If this condition is not fulfilled, a new EU MRL (or modification of the existing EU MRL) shall be applied for. The overall procedure for setting MRLs has to be completed before an authorisation can be granted by a Member State.

The **procedure for the application and setting of an EU MRL (incl. import tolerance)** is clarified in *Guidance Document SANTE/2015/10595*[1] from the European Commission:
http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-setting-proc.pdf

The submission and evaluation of **confirmatory data for an EU MRL following the MRL review** follows more or less the same procedure as a standard application for modification of an EU MRL (see above). Additional guidance is available in the following working document prepared by the European Commission services:
http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_sanco-10235-2016.pdf

Besides the **applicant** for an authorisation of a plant protection product, also other stakeholders may submit an application for modification of an EU MRL (see EC guidance document).

The EU MRL application is to be submitted to an EU Member State, which will act as ***Evaluating Member State (EMS)***. In principle, this is the Member State where the authorisation of the PPP is sought (or the zonal RMS in case of a zonal evaluation). If the application however implies the assessment of new core studies[2], the MRL application should preferably be submitted to the MS appointed as Rapporteur Member State (RMS) in the framework of the (renewal of) approval of the active substance (under Dir. 91/414/EEC or Reg. (EC) No 1107/2009).[3] Also applications for import tolerances, which are per definition not associated with an application for an authorisation of a PPP in the EU, should be submitted to the RMS.

If Belgium is involved as EMS for the MRL application, the following is applicable.

[1] Guidance Document on MRL setting procedure in accordance with articles 6 to 11 of Regulation (EC) No 396/2005 and article 8 of Regulation (EC) No 1107/2009 (SANTE/2015/10595).
[2] "Core studies" refer to the studies supporting the setting of the plant and animal residue definitions (i.e. studies regarding storage stability, metabolism in plants and animals, livestock feeding studies, studies on nature of residues in processed commodities and rotational crop studies).
[3] Note: An MRL application may also be submitted together with the dossier for (renewal of) approval of the active substance.

2. Submission of the application

The assessment of a national application for authorisation of a plant protection product (by the Belgian Authorisation Committee) and the treatment of an MRL application (at EU level) are run as two separate processes. Therefore, also two separate applications need to be submitted.

Also in the case where an MRL application is submitted together with the EU dossier supporting the application for (renewal of) approval of the active substance, a separate MRL application form still needs to be submitted.

Applicants are invited to clearly mention the link between both applications in their accompanying letters and communication, as to clarify for which requested use(s) a new EU MRL is necessary and whether the corresponding MRL application is already under evaluation or not.

According to the indicative timelines stipulated in the EU Guidance Document SANTE/2015/10595, the total period between submission of the MRL application and the effective publication (and entry into force) of the EU MRL is approximately 2 years. Taking this into account, it is **recommended to submit the MRL application on beforehand, if possible, i.e. before the submission of the national application for the PPP authorisation.**

3. Dossier requirements

The requirements for a dossier supporting an MRL application are stipulated in art. 7 of Reg. (EC) No 396/2005. Some practical information regarding the submission of the dossier to the Belgian authorities is summarised here below.

Address to be sent to	To the attention of: Ms Davina Fevery Federal Public Service Public Health, Food Chain Safety and Environment DG Plants, Animals and Food Service Plant Protection Products & Fertilizers Eurostation II, 7th floor Place Victor Horta 40 box 10 1060 Brussels Belgium
Accompanying letter	This letter should clarify: ○ Context of the application, e.g. link with national application for authorisation of plant protection product ○ Invoice address

Dossier content	- MRL application form (duly filled out in English and signed) – see latest template on http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-appl-form.doc - Doc D (the relevant GAP using the international presentation of intended uses). - Doc L-CA and L-CP, sections 2 and 4 - Doc M-CA and M-CP, sections 2 and 4 (including summary of results from supervised residue trials) - Doc K-CA and K-CP (data addressing the data requirements for the setting of MRLs for pesticides including, where appropriate, toxicological data and data on routine analytical methods for use in control laboratories, as well as plant and animal metabolism data; cf. Reg. (EU) No 283/2013, section 6 and, where appropriate, sections 4 and/or 5). - An index of the documentation (reference list). - A comprehensive overview of relevant concerns raised in the available scientific literature about the plant protection product and/or its residues. In case an import tolerance is applied for, a toxicological dossier for the setting of an ADI and an ARfD could be necessary.
Dossier format	1 Electronic copy on CD-ROM: preferably CADDY XML-format (if available) or individual files (summary docs. D, M and L in Word format; docs K in pdf or Word format).

If complementary data are added during the evaluation process, a CD-ROM with the completed file (including complementary data) needs to be provided.

4. Admissibility of the application and fees

After receipt of the MRL application, Belgium will assess the admissibility of the application and will perform an administrative completeness check of the dossier.

After receipt, the applicant will receive an invoice with the request to pay the corresponding fee (cf. www.fytoweb.be – Annex 2 of the 'Guidance for the applicant of an authorisation of a PPP').

In case of admissibility of the application and completeness of the dossier, Belgium will undertake the appropriate actions to inform the European Commission, the EFSA and the other EU Member States (via EFSA) about the application.

This step normally covers 1 month (after receipt).

5. Assessment by BE as EMS

The assessment by Belgium will be launched when the applicant has paid the requested fee (see above).

According to the EC *guidance document SANTE/2015/10595* the Evaluating Member State (EMS) has to draw up an Evaluation Report (EF) within 12 months after receipt of the application. This period can be extended with max. 6 months in case additional data are required to finalise the assessment.

In practice, Belgium aims at assessing an MRL application within 3 months after payment of the fee, if no new core studies (e.g. new metabolism studies) need to be evaluated.

6. Follow-up after MRL publication

The authorisation of a plant protection product in Belgium, for which the application has been put *'on hold'* pending the setting of an appropriate EU MRL (as the only remaining unfulfilled condition for authorisation) can be granted from the moment that the new/modified EU MRL is published in the *Official Journal of the EU* (http://eur-lex.europa.eu/oj/direct-access.html).

The applicant is invited to contact the service Plant Protection Products and Fertilisers again at that moment.

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