PLANT PROTECTION

APPLICATION EU MRL / IMPORT TOLERANCE

Procedure with Belgium involved as Evaluating Member State (EMS)

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When	***What***
2020-11-18	Update of section 3 (dossier requirements)
2022-03-28	Overall update, particularly regarding administrative requirements and dossier format, in line with the new EU procedures that have been introduced to implement the Transparency Regulation (EU) 2019/1381.

1. Introduction

In accordance with Reg. (EC) No 1107/2009, one of the prerequisites to authorise 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.

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 *Working Document SANTE/E4/VW 10235/2016*[2] prepared by the European Commission services.

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 addressed 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[3], 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).[4] 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 addressed by default to the RMS, unless agreed otherwise at EU level.

[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). Latest version available on the European Commission's website.
[2] Commission Staff Working Document – Evaluation of data submitted to confirm MRLs following the review of existing MRLs. (SANTE/10235/2016). Latest version available on the European Commission's website.
[3] "Core studies" refer to the studies supporting the setting of the plant and/or animal residue definitions (e.g. metabolism in plants and animals) and studies not exclusively related to the intended use under consideration (e.g. studies regarding storage stability, livestock feeding studies, studies on nature of residues in processed commodities and rotational crop studies).
[4] Note: An MRL application may also be submitted together with the dossier for (renewal of) approval of the active substance.

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 still needs to be submitted.

Here below, a brief summary is given of the main steps in the procedure and the administrative requirements, as well as some practicalities in case Belgium is involved as EMS for the MRL application.

2. Administrative requirements

Pre-submission

Before submitting an MRL application, the potential applicant should register in EFSA's portal (**Connect EFSA**). Through this portal, the applicant should do the mandatory notification of studies (NoS) commissioned or carried out in view of the MRL application. Via this online platform, the applicant may also, optionally, request general pre-submission advice (GPSA) from EFSA. Those pre-submission activities and contacts with EFSA will be linked to a unique pre-application identification number (PA-ID) allocated by EFSA.

However, a potential applicant should in any case inform the Belgian authority about his intention to address an MRL application to Belgium for evaluation. Preferably, the potential applicant should **CONTACT** the Belgian authority 6 months before the envisaged submission date of the application.

Submission

The MRL application itself and the supporting dossier have to be prepared by the applicant using the IUCLID (International Uniform ChemicaL Information Database) software. Once prepared, the dossier must be uploaded through a central EU submission system (**ECHA Cloud Services**) and the Evaluating Member State (EMS) as agreed (see above) should be indicated. EFSA, the European Commission and the competent authorities of the EU Member States have access to this secure online platform, which makes a separate submission to these stakeholders redundant.

A summary of the tools that applicants are expected to use in the preparation of the application and subsequent phases (e.g. EFSA's portal supporting pre-submission activities, database of study notifications, IUCLID software) is available in the **toolkit** on the EFSA website[5], together with a brief description of each tool, how to access it and dedicated user manuals/guides where available. In particular, reference is made to EFSA's **MRL Applications manual**, which gives clarification on the requirements specific to the different cases in which an MRL application is needed and which also provides very detailed guidance on how to report the data supporting the MRL application in the IUCLID format (e.g. endpoint summaries, endpoint study records[6]). When planning a dossier submission, it is recommended to check the EFSA toolkit for the latest resources to support dossier preparation (e.g. most up-to-date version of the MRL manual).

Further guidance to applicants submitting an MRL application is also available in **EFSA's administrative guidance** [7] (EFSA, 2021), particularly chapters 3.13 and 4. This administrative guidance (particularly chapter 4.5) also describes the procedure with regard to **transparency and confidentiality requirements** (e.g. submission and handling of requests for removal of confidential information before publication).

Once a valid submission is received, EFSA, the European Commission (EC), the EMS and all other EU MSs are informed via an automatic e-mail[8]. Confirmation of IUCLID submissions via e-mail or letter is therefore not necessary, as the automatic e-mail notification is sufficient as submission proof. Any cover letters should be added in the respective IUCLID sections. Dossier submissions via any route other than the EU Submission Portal should be avoided.

For a more comprehensive description of the applicable procedures implementing the provisions of the Transparency Regulation (EU) 2019/1381, reference is made to the **EFSA practical arrangements** on 'Pre-submission phase and public consultations' and 'Transparency and confidentiality', as well as to the **Questions and Answers** on those EFSA Practical Arrangements.

3. Dossier requirements

The requirements for a dossier supporting an MRL application are stipulated in art. 7 of Reg. (EC) No 396/2005. For further details and guidance, the applicants are referred to Guidance Document SANTE/2015/10595[9] and the applicable EU data requirements[10].

[5] https://www.efsa.europa.eu/en/applications/toolkit
[6] In addition, full study reports and related files should be uploaded as attachments in the Literature reference entity of the Data Source.
[7] EFSA, 2021. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6464)
[8] from noreply@echa.europa.eu
[9] 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). Latest version available on the European Commission's website.
[10] The data requirements applicable for the assessment of the MRL application are those that were applicable for the approval of the active substance or its renewal/amendment (cf. SANTE/11509/2013

4. Fees – Admissibility check – Publication

Fees

After receipt, the applicant will receive an invoice from the Belgian authority, with the request to pay the corresponding **fees** (cf. www.fytoweb.be – Annex 2 of the 'Guidance for the applicant of an authorisation of a PPP'), to cover the costs associated with the assessment by BE. If needed, the EMS BE will contact the applicant to get confirmation on the invoice address.

Admissibility of application

After receipt of the MRL application, Belgium will assess the **admissibility** of the application in line with the procedure described in EFSA's administrative guidance (EFSA, 2021)[11], particularly chapter 4.4. Besides a completeness check against the data requirements, this includes a verification of compliance with the legal obligations of notification of new studies (prior to submission of the MRL application). Non-compliance with those obligations may result in non-admissibility of the MRL application or in delays in the EMS's evaluation or EFSA's assessment.

Publication of dossier

Once the application is found admissible, Belgium will notify the applicant, the other EU MSs, the EC and also EFSA[12], who will subsequently publish the non-confidential version of the dossier (and where applicable, a summary of the GPSA provided to the applicant by EFSA) on its website (**OpenEFSA** portal). Subsequently, a public consultation (for 3 weeks) will be launched and comments received from third parties will also be made public by EFSA.

rev. 5.2 – Guidance document on the interpretation of the transitional measures for the data requirements).

[11] EFSA, 2021. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6464)

[12] fdp@efsa.europa.eu; CC: pesticides.mrl@efsa.europa.eu

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 EMS has to draw up an **Evaluation Report (ER)** 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 an annex to the ER, the EMS will report how the comments received during the public consultation of the dossier have been taken into account in the assessment.

In practice, Belgium aims at assessing an MRL application within 3 to 6 months after payment of the fee, if no new core studies (e.g. new metabolism studies) need to be evaluated.

Belgium will provide the ER to EFSA (via EFSA DMS) for further review and will inform EFSA and EC accordingly[13].

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**.

The applicant is invited to **CONTACT** the Department of Plant Protection and Fertilising Products again at that moment.

[13] fdp@efsa.europa.eu; SANTE-MRLs-applications@ec.europa.eu; CC: pesticides.mrl@efsa.europa.eu