PESTICIDES UNIT

Management of MRL applications submitted for active substances under Article 8 of Regulation (EC) No 1107/2009 and under Article 10 of Regulation (EC) No 396/2005

September 2015

European Food Safety Authority • Via Carlo Magno 1A • 43126 Parma • ITALY
Tel. +39 0521 036 111 • Fax +39 0521 036 0110 • www.efsa.europa.eu

Background

The Regulation (EC) No 1107/2009 in Article 8.1.g states that the summary dossier of an application for the approval of an active substance shall include "*where relevant, a copy of an application for a maximum residue level as referred to in Article 7 of Regulation (EC) No 396/2005..."*

In addition, Article 11.2 mentions that the Assessment Report prepared by the RMS "*shall also include where relevant, a proposal to set maximum residue levels*". A representative use is therefore considered as an MRL application.

Consequently, MRLs will be implemented under Regulation (EC) No 396/2005, for the representative uses and the intended uses included in the MRL application, on the basis of the proposals reported in the EFSA Conclusion for the approval of the active substance. The drafting of a separate Reasoned Opinion for the setting of MRLs is therefore no longer required.

In addition and according to Article 5 of Regulation (EU) No 283/2013, the data requirements and guidance documents listed in the EU notice 2013/C 95/01 (new data requirements), are applicable to the new active substances whose dossier has been submitted from 1st January 2014. These new data requirements are indeed applicable to the renewal of the AIR-3 active substances and to the MRL application related to an AIR-3 active substance that will be submitted after the date of approval of the renewal of the active substance. In the residue section, the main changes introduced by the regulation (EU) No 283/2013, are that OECD guidance and guideline documents are now applicable to the assessment of the active substance.

For the active substance whose dossier was submitted from 1st January 2014, the template to be used for the drafting of the Assessment Report is reported in the guidance document SANCO/12592-rev.0 of November 2012. However, since this template does not foresee specific chapters for the assessment of the MRL application, the structure of the Assessment Report has been reconsidered accordingly taking into account the new data requirements.

In order to consider all changes introduced by the regulations and guidelines mentioned here above, and in order to harmonise the evaluations conducted on active substances by the different Rapporteur Member States (RMS), a template for the drafting of MRL applications is proposed by EFSA, considering the following different cases:

1) The MRL application is included in the dossier for the approval of a new active substance according to Art. 8.1.g to Reg. (EC) No 1107/2009. The dossier was submitted as from 1st January 2014 and therefore, the new data requirements apply.
2) The MRL application is submitted under Art. 10 to Reg. (EC) 396/2005, the dossier for the approval of the active substance was submitted as from 1st January 2014 and the new data requirements apply.
3) The MRL application is submitted under Art. 10 to Reg. (EC) 396/2005 and the active substance has been approved under the old data requirement (EU guidelines) and therefore, the old data requirements apply.

In any circumstances, **an application form[1] where the intended uses and GAPs are clearly detailed in Annex I, should be submitted along with the dossier to the Commission and EFSA**. Annex I will be taken as the reference for the assessment of the MRL application.

The different template proposals are based on the following approach:

- The duplication of evaluations already conducted under different procedures (peer review, Article 10, Article 12…) should be avoided. In such a case, reference should be made to the previous assessment (e.g. EFSA, 20XX), the available studies should be summarised (e.g. copy of the relevant LoEP Table), the conclusion of the evaluation reported (e.g. residue definitions agreed in the framework of the peer review) and the applicability of the conclusions made in the previous evaluation are applicable to the crops under consideration in the MRL application should be discussed (e.g. are

[1] Application form available on the Commission website at the following address: http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm

the uses in the MRL application covered by the plan metabolism studies and proposed residue definitions).

- If new studies, not considered in a previous assessment, are submitted in support to an Article 10 application, a detailed assessment should be presented in Appendix C to the Evaluation Report (according to the standard template requested for the drafting of the Assessment Report) and an overall summary is reported in the core text of the Evaluation Report.

1 - MRL application included in the dossier for the approval of an active substance (New data requirements)

When the MRL application is submitted together with the dossier for approval of the active substance, two options are proposed for the drafting of the Assessment report (AR):

- **Option 1:** The evaluation of the MRL application is inserted in the AR, and the data related to the representative uses and MRL application are reported under distinct subsections (see Table 1-1).

- **Option 2:** The assessment is presented under two separate documents as follows (see table 1-2):

  1) The Assessment report, considering the representative uses. However and as agreed during the PSC of October 2011, all core studies[2] are reported and evaluated under Vol. 3, Annex B and Vol. 1, Level 2 of the AR, even if they are only relevant for the uses considered in the MRL application.

  2) An Addendum to the AR, considering the evaluation of the residue trials, processing studies, MRL proposals related to the uses supported in the MRL application.

Under both options, the overall assessment is summarised in the List of End Points (See template for LoEP, new data requirements), considering the representative uses and MRL application uses. If an MRL application is made in the context of an active substance approval procedure and all representative and intended uses are covered, a review of the existing MRLs under Article 12 will, in most cases, not be needed. Therefore, the existing CXLs should be included in the exposure assessment. In specific cases an Art. 12 review may still be necessary (e.g. if as a consequence of specific use restrictions agreed at EU level, the originally proposed MRLs for the intended uses do no longer reflect the current authorisations).

These two options were discussed with the Member States (MS) during the Pesticide Steering Committee of June 2014 and most of them were in favour of option 1 but it was agreed that option 2 could indeed be a more suitable approach, when the MRL application is related to a huge number of uses (more than 50 in some cases), since it is finally more convenient to handle two separate documents, rather than a single voluminous AR.

In some cases, the MRL application may also include a request for the **setting of Import tolerances**. An approach dealing with this situation has been discussed with the MSs in the PSC of June 2014 and is summarised in Figure 1 hereafter.

To avoid inadequate or unnecessary evaluations as carried out previously for several active substances (fluopyram, sulfoxaflor, flupyradifurone...), the assessment of the import tolerances should not be conducted if evidence of the authorisation of the respective uses of a plant protection product in the exporting country has not been provided. In such a case, the assessment is limited to the EU uses only. The evaluation of the import tolerances will be reconsidered further, in a separate Evaluation Report (see section 2), once all the requested information has been provided.

A template, giving more details for the drafting of the Addendum to the AR is available in the document "*ER Addendum to AR New DR 2015a.doc*"

[2] Core studies" refer to the studies supporting the setting of the plant and animal residue definitions (studies reported in the Assessment Report under the sections B.7.1 Storage stability, B.7.2 Metabolism in plants and animals, B.7.4 Feeding studies, B.7.5.1 Nature of the residues in processed commodities and B.7.6 Rotational crop).

Table 1-1: Assessment of the MRL application inserted in the AR **(Option 1)**

Assessment Report (AR) (SANCO/12592/2012 rev.0)	
Volume 1; Level 2 (Exposure and risk assessment)	**Volume 3; Annex B** (active substance) (hazard evaluation)
2.7 Residues 2.7.1 Summary of storage stability of residues 2.7.2 Summary of metabolism in plants, animals 2.7.3 **Definition of the residue** 2.7.4 **Summary of residue trials in plants and identification of critical GAPs** 2.7.4.1 Representative uses 2.7.4.1 MRL Application 2.7.5 Summary of feeding studies 2.7.6 Summary of effects of processing 2.7. Summary of residues in rotational crops 2.7.8 Summary of other studies 2.7.9 **Estimation exposure through diet and other sources** 2.7.10.1 Representative uses 2.7.10.2 Representative uses + MRL Application **Assessment of existing CXLs where appropriate** 2.7.10 **Proposed MRLs** and compliance with existing MRLs taking into account existing CXLs where apropriate 2.7.10.1 Representative uses 2.7.10.2 MRL Application (EU GAP) 2.7.11 **Proposed import tolerances** and compliance with existing MRLs	**B.7 Residue data** B.7.1 Storage stability B.7.2 Metabolism, distribution , expression of residues B.7.2.1 Plants B.7.2.2 Poultry B.7.2.3 Lactating ruminants B.7.2.4 Pigs B.7.2.5 Fish B.7.3 Magnitude of residue trials in plants B.7.3.1 Representative uses B.7.3.2 MRL Application B.7.4 Feeding studies B.7.4.1 Poultry B.7.4.2 Ruminants B.7.4.3 Pigs B.7.4.4 Fish B.7.5 Effects of processing B.7.5.1 Nature of the residue B.7.5.2 Distribution pulp and peel B.7.5.3 Magnitude of residues B.7.5.3.1 Representative uses B.7.5.3.2 MRL Application B.7.6 Rotational crops B.7.6.1 Metabolism in rotational crops B.7.6.2 Magnitude of residues in rotational crops B.7.7 Other studies B.7.7.1 Residue level in pollen and bee products B.7.8 References relied on
Overall assessment summarised in the **List of End Points** (LoEP; new data requirements), including the representative uses and the uses related to the MRL application.	

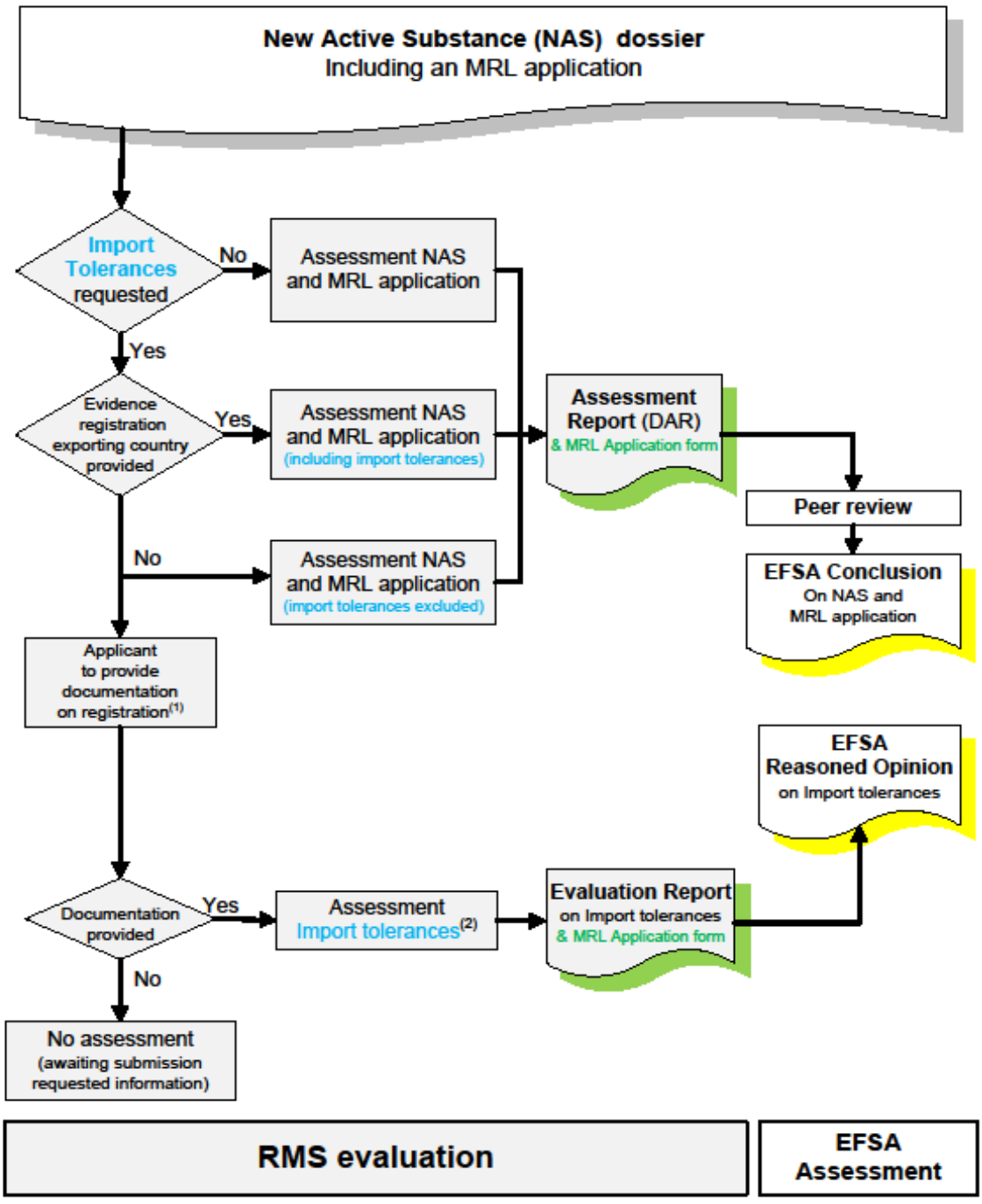
Table 1-2: MRL application reported separately in an Addendum to the AR **(Option 2)**

Assessment Report (AR) (SANCO/12592/2012 rev.0)	
Volume 1; Level 2 (Exposure and risk assessment)	**Volume 3; Annex B** (active substance) (hazard evaluation)
2.7 Residues 2.7.1 Summary of storage stability of residues 2.7.2 Summary of metabolism in plants, animals 2.7.3 **Definition of the residue** 2.7.4 **Summary of residue trials in plants and identification of critical GAPs** 2.7.5 Summary of feeding studies 2.7.6 Summary of effects of processing 2.7. Summary of residues in rotational crops 2.7.8 Summary of other studies 2.7.9 **Estimation exposure through diet and other sources** **Assessment of existing CXLs where appropriate** 2.7.10 **Proposed MRLs** and compliance with existing MRLs taking into account existing CXLs where appropriate 2.7.11 **Proposed import tolerances** and compliance with existing import tolerances	**B.7 Residue data** B.7.1 Storage stability B.7.2 Metabolism, distribution, expression of residues B.7.2.1 Plants B.7.2.2 Poultry B.7.2.3 Lactating ruminants B.7.2.4 Pigs B.7.2.5 Fish B.7.3 Magnitude of residue trials in plants B.7.3.1 Representative uses B.7.4 Feeding studies B.7.4.1 Poultry B.7.4.2 Ruminants B.7.4.3 Pigs B.7.4.4 Fish B.7.5 Effects of processing B.7.5.1 Nature of the residue B.7.5.2 Distribution pulp and peel B.7.5.3 Magnitude in processed commodities B.7.6 Rotational crops B.7.6.1 Metabolism in rotational crops B.7.6.2 Magnitude of residues in rotational crops B.7.7 Other studies B.7.7.1 Residue level in pollen and bee products B.7.8 References relied on
Addendum [X] to the Assessment Report	
Assessment of the residue trials, processing studies… and EU MRL proposals for the uses and import tolerances under consideration in MRL application. The consumer risk assessment should include all representative and MRL application uses as well as existing CXLs where appropriate. **Note:** All core studies(1) are reported in the relevant sections of the **Assessment Report**	
Overall assessment summarised in the **List of End Point** (LoEP; new data requirements) including the representative uses and the uses related to the MRL application.	

(1): "core studies" refer to the studies supporting the setting of the plant and animal residue definitions (studies reported in the Assessment Report under the sections B.7.1 Storage stability, B.7.2 Metabolism, B.7.4 Feeding studies, B.7.5.1 Nature of the residue in processed commodities and B.7.6 Rotational crop).

(e.g. The representative uses do not trigger the submission of animal metabolism and feeding studies. These latter are requested under the MRL application only. Nevertheless metabolism and feeding studies are reported and evaluated under the section B.7.2 and B.7.4 of the AR and not in the Addendum to the AR).

Figure 1: Management of an MRL application on **Import Tolerances**, included in the dossier for the approval of a new active substance under Regulation (EC) No 1107/2009



(1): **Documentation on registration in the exporting country:**
- Reference and copy of current national legislation in the exporting country related to MRL(s) under consideration.
- Evidence of the authorisation of the respective use of the plant protection product in the exporting country.

If available, links to the national websites where such information is provided. Further information may be required from the applicant as set out in chapter 2 of this document.

(2): **Import tolerances assessment**

Import tolerance requests should be consistent with the MRL values published in the exporting country.

2 - MRL application under Art. 10 to Reg. (EC) 396/2005 (New data requirements)

A template for the drafting of the **Evaluation Report** (ER) considering the new data requirements is available in the document "*ER New Data Requirements 2015a.doc*". This template applies to the active substances whose dossier for the approval under Reg. (EC) No 1107/2009 was submitted as from 1st January 2014.

As mentioned in the background section, the template proposals are based on the following approach:

- The duplication of evaluations already conducted under different procedures should be avoided. Reference to previous assessments has to be made (e.g. EFSA, 20XX), the available studies briefly listed (e.g. copy of the relevant LoEP Table) and it should be discussed whether the conclusions of the previous evaluations are applicable to the crops under consideration in the MRL application.
- If new studies, not considered in previous assessments, are submitted, a detailed assessment is conducted in Appendix C whilst a summary and an overall conclusion are reported in the relevant sections of the ER. The overall conclusion should be made considering the previous evaluation(s). For instance, if a new plant metabolism study has been provided in the framework of the MRL application, it should be concluded whether the residue definitions agreed in previous evaluation(s) are still applicable or if these have to be reconsidered accordingly.
- The template takes into account the OECD guidance and guideline documents listed under the EU notice 2013/C 95/01.

Import tolerance requests should be handled in a similar way as described in section 1. They should not be evaluated if evidence of the authorisation of the respective use of the plant protection product in the exporting country has not been provided. (see figure 2). The application should be consistent with the MRL in force in the exporting country taking into account the residue definition. If that is not the case, the application needs to be re-formulated accordingly. Further information may be required from the applicant in specific cases, e.g. when the residue data set provided leads to a lower value than the MRL in force in the exporting country. The RMS should then confirm at an early stage whether the proposed value is sufficient to cover the GAP in the exporting country. If the difference is substantial, the applicant should provide an explanation.

The Evaluation Report will be made publicly available as a background document, along with the publication of the EFSA Reasoned opinion (RO). This procedure will allow the drafting of streamline RO, avoiding redundant information that is already available in the ER.

3 - MRL application under Art. 10 to Reg. (EC) 396/2005 (Old data requirements)

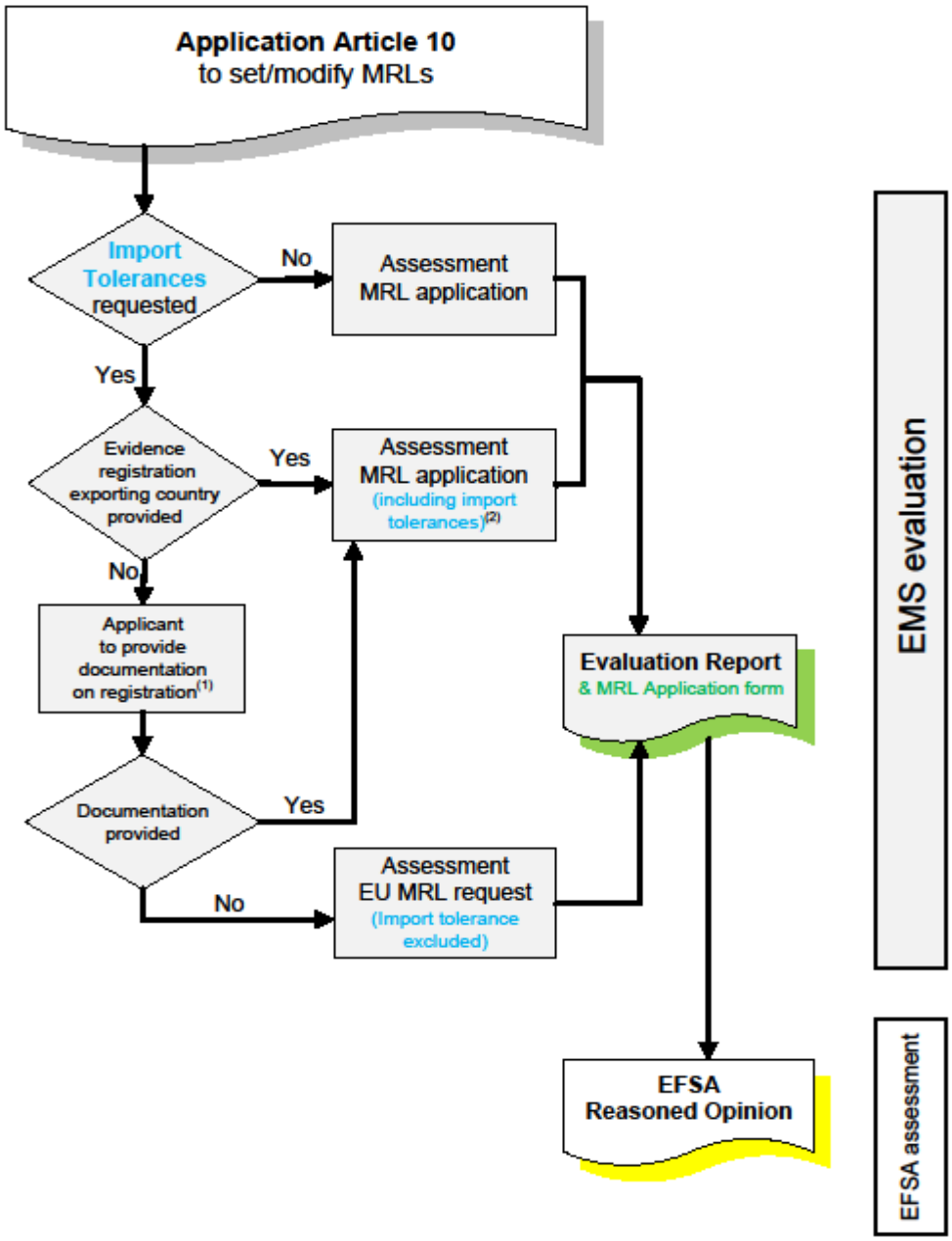
A template for the drafting of the **Evaluation Report** (ER) under the old data requirements (EU guidelines) is available in the document "*ER Old Data Requirements 2015a.doc*". MS should refer to the EU Guidance document SANCO/11509/2013-rev.3 on the transitional measures for the data requirements, to have confirmation whether the "old" or "new" data requirements apply. In short, the old data requirements apply to the active substances whose approvals have been done under the old data requirements.

A similar approach, as that described under sections 1 and 2, has been taken to propose the ER template under the old data requirements, but considering the EU guidelines and the LoEP applicable to the old data requirements.

When the setting of import tolerances is requested in the framework of the MRL application, the approach summarised in Figure 2 applies.

The Evaluation Report will be made publicly available as a background document, along with the publication of the EFSA Reasoned opinion (RO).

Figure 2: Management of an MRL application on Import Tolerances under Article 10 of Regulation (EC) No 396/2005



(1): Documentation on registration in the exporting country:
- Reference and copy of current national legislation in the exporting country related to MRL(s) under consideration.
- Evidence of the authorisation of the respective use of the plant protection product in the exporting country.

If available, links to the national websites where such information is provided. Further information may be required from the applicant as set out in chapter 2 of this document.

(2): Import tolerances assessment

Import tolerance requests should be consistent with the MRL values published in the exporting country.