



2 July 2021

(21-5296)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**ON-GOING REVIEW OF MAXIMUM RESIDUE LEVELS FOR PESTICIDES
IN THE EUROPEAN UNION
UNDER ARTICLE 12 OF REGULATION (EC) NO. 396/2005**

COMMUNICATION FROM THE EUROPEAN UNION

Revision

The following communication, received on 1 July 2021, is being circulated at the request of the Delegation of the European Union.

Purpose of the note

This note is addressed to countries outside the European Union (EU). It explains the on-going process in the European Union to review the current maximum residue levels (MRLs) for pesticides under Article 12 of Regulation (EC) No. 396/2005 (the MRL Regulation). It describes how non-EU countries can actively contribute to the reviewing process.

Non-EU countries may submit additional data to the EU risk assessors, should they wish to support specific uses of pesticides that are no longer approved in the European Union. This note highlights the specific stages in the review process when non-EU countries may send such additional data.

This note has been updated following the withdrawal of the United Kingdom from the European Union. In addition, some links were no longer valid. The revised note also includes some additional information as regards notifications by the European Food Safety Authority (EFSA) on the launch of the review procedure for specific substances.

1 THE REVIEW PROCESS OF THE EXISTING EU PESTICIDE MRLS

1.1. Article 12 of [Regulation \(EC\) 396/2005](#)¹ provides for a mechanism to review the existing maximum residue levels (MRLs) of all approved and certain non-approved pesticides. This review process has been on-going since 2008.

1.2. For each active substance, one member State of the European Union is designated as 'Rapporteur member State' (RMS). The RMS carries out the first evaluation of the existing EU pesticide MRL and prepares an evaluation report recommending its amendment if necessary.

1.3. Subsequently, the scientific risk assessment body of the European Union, the European Food Safety Authority (EFSA), is charged with delivering a reasoned opinion on each substance, based on the evaluation report prepared by the RMS.

1.4. In the reasoned opinion, if available, Codex Maximum Residue Limits (CXLs) are considered.

¹ Regulation (EC) No. 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, OJ L 70, 16 March 2005, p. 1.

1.5. According to the EU legislation, where CXLs exist, they must be taken into consideration when setting or modifying EU MRLs, except where:

- a) they would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of EU food law;
- b) there is a scientific justification;
- c) they would result in a different level of protection from the one determined as appropriate in the European Union.

1.6. The European Union is aligned with more than 70% of the CXLs established in the period of 2008-2018. This level is comparable with the level of alignment of other major economies.

1.7. The opinions are published on the EFSA webpage: <http://www.efsa.europa.eu/en/publications/efsajournal>. Using the search function and the name of the substance, the relevant opinion can be easily retrieved.

1.8. The European Commission (Commission) considers the opinion of EFSA and initiates a discussion with the EU member States about the appropriate risk management measures to be taken, i.e. possible modification of certain MRLs. The Commission also consults the network of the European Union reference laboratories on analytical aspects and takes into account other scientific information available on the specific substance.

1.9. On this basis, the Commission prepares a draft Regulation in which amendments to the existing pesticide MRLs are proposed. The draft Regulation is discussed with delegates of the EU member States in a regulatory Committee (Standing Committee on Plants, Animals, Food and Feed, shortly "PAFF Committee"). The PAFF Committee meets several times a year, is chaired by the Commission and comprised of the representatives of the 27 EU member States.

1.10. The draft Regulation is also notified to WTO Members through the WTO/SPS Secretariat. WTO Members have 60 calendar days to comment on the draft Regulation.

1.11. The PAFF Committee takes into consideration all comments received and votes on the draft Regulation. Once endorsed by the PAFF Committee, the draft Regulation is scrutinized by the Council of the European Union and by the European Parliament during a two-month period. If the two institutions do not object in that timeframe, the draft Regulation is finally adopted by the Commission as a Commission Regulation.

1.12. It is then translated into the official languages of the European Union and published in the Official Journal of the European Union².

2 WHEN AND HOW CAN NON-EU COUNTRIES INTERVENE IN THE REVIEW PROCESS?

2.1. Authorities of non-EU countries may intervene in the review process described above at two different stages: at an early stage (box 1) and at a later stage (box 2).

1) At an early stage, via the Rapporteur member State (RMS):

Non-EU countries which wish to submit additional supporting information or data on a specific active substance in which they may have a special interest, can submit such information at an early stage of the process, before the risk assessment is carried out by EFSA.

Non-EU countries should first contact the manufacturer of the active substance concerned. They then need to submit the additional data through the manufacturer to the EU member State, which has been appointed as "Rapporteur member State" for that active substance. The RMSs for each active substance are listed in the detailed document available in the dedicated webpage of the European Food Safety Authority (see paragraph 4 of this note).

² <https://eur-lex.europa.eu/homepage.html>.

2) During the WTO/SPS consultation procedure:

Before being submitted for a vote in the PAFF Committee, draft proposals amending existing pesticide MRLs are notified under the WTO SPS Agreement.

WTO Members have 60 calendar days to send their comments to the SPS contact point of the European Union. Received comments are considered by the Commission before the vote takes place at the PAFF Committee.

2.2. Non-EU countries which have a special interest in a particular active substance may intervene at one or both stages explained above. It is however strongly advised and in the interest of the country to intervene at the early stage of the procedure.

2.3. Non-EU countries are therefore invited to consult the lists of active substances for which the review process is already planned (see paragraph 4) and to provide as soon as possible the additional data to the RMS in charge.

3 WHAT HAPPENS IF NON-EU COUNTRIES DO NOT INTERVENE AT ANY STAGE?

3.1. The review process of the existing EU pesticide MRLs proceeds as described in point 1. For the protection of consumers, the European Union sets MRLs as low as reasonably achievable and supporting data are needed to support the MRL. If such data are lacking or insufficient, the MRL is lowered to the limit of quantification (LOQ). This may in some cases have a negative impact on exports of the relevant commodity from non-EU countries into the European Union.

3.2. If deemed necessary for ensuring the continuity of international trade, after the publication of new MRLs, non-EU countries may submit a specific "import tolerance" request. The request must be addressed to the RMS for the active substance. Import tolerance requests normally concern MRLs of active substance approved in the European Union, but they may also be introduced for active substances that are not approved in the European Union, provided that all the required data on the active substance are submitted. More details on the procedure for "import tolerances" are given in Article 6(4) of Regulation (EC) No 396/2005 and in the most recent version of the [Technical Guidelines on the MRL Setting Procedure](#) (SANTE/2015/10595).

3.3. In case of a favourable evaluation by EFSA, the European Union may launch a procedure to amend the respective MRL. To be noted that it takes on average around two years from the submission of the request until the entering into force of the amended MRL.

4 WHEN AND FOR WHICH ACTIVE SUBSTANCES IS THE REVIEW PROCESS PLANNED?

4.1. An overview of the MRLs review progress under Article 12 of Regulation (EU) No 396/2005 is available in the dedicated page of EFSA website:
<https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf>.

4.2. It is updated by EFSA on a quarterly basis. It is therefore recommended to consult this webpage on a regular basis to have the most updated information available.

4.3. The overview contains information on the indicative schedule for the MRLs review. Most important information for non-EU countries is the list of substances for which the review is planned, the start date of data collection and the Rapporteur member State (RMS) for each substance.

4.4. In addition, it is possible to subscribe to a notification system managed by EFSA, which informs about the launch of the review procedure for a specific substance. Requests for inclusion in the distribution list for such notifications can be made to the following e-mail address:
pesticides.mrl@efsa.europa.eu.

4.5. Non-EU countries that wish to submit additional information for the Article 12 MRL review process must have their data ready for submission to the respective RMS by the start date of the data collection.

5 BACKGROUND: THE EU LEGISLATION ON PESTICIDES

5.1. The principles of the EU legislation on pesticides are laid down in three main legislative acts:

- [Regulation \(EC\) No 1107/2009](#)³, providing rules on the placing of plant protection products on the market;
- Regulation (EC) No 396/2005, already mentioned, providing details on the maximum residue levels of pesticides (MRLs) in or on food and feed of plant and animal origin; and
- [Directive 2009/128/EC](#)⁴, setting rules for the sustainable use of pesticides to reduce the risks and impacts of their use on people's health and the environment.

5.2. EU legislation envisages that each active substance intended to be used in the European Union as a plant protection product (commonly called 'pesticide') first needs to be approved. The approval of active substances is granted at the EU level. Further details can be found at:

https://ec.europa.eu/food/plants/pesticides/approval-active-substances_en.

5.3. Along with the first approval of the active substance, specific maximum residue levels (MRLs) considered as safe for the consumers need to be established. This procedure is further described at:

https://ec.europa.eu/food/plants/pesticides/maximum-residue-levels_en.

5.4. The plant protection products containing EU approved active substances can only be placed on the EU market following prior authorisation. The authorisation of plant protection products is granted by the EU member States. Further details can be found at:

https://ec.europa.eu/food/plants/pesticides/authorisation-plant-protection-products_en.

6 FURTHER INFORMATION

6.1. For any further information, interested parties may consult the section of the European Commission website specifically dedicated to pesticides:

https://ec.europa.eu/food/plants/pesticides_en.

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market, OJ L 309, 24 November 2009, p. 1.

⁴ Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009, establishing a framework for Community action to achieve the sustainable use of pesticides, OJ L 309, 24 November 2009, p. 71.