



Committee on Sanitary and Phytosanitary Measures

**ON-GOING REVIEW OF MAXIMUM RESIDUE LEVELS
OF PESTICIDES IN THE EUROPEAN UNION**

COMMUNICATION FROM THE EUROPEAN UNION

Revision

The following communication, received on 12 June 2017, is being circulated at the request of the Delegation of the European Union.

This note is addressed to countries outside the European Union (EU). It explains the on-going process in the EU to review the current maximum residue levels (MRLs) for pesticides. 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 EU. This note highlights the specific stages in the review process when non-EU countries may send such additional data.

Revision 1 of this note has been updated with the reference to a dedicated page of the EFSA website, where the list of the active substances subject to the review process and an indicative time schedule of their review are provided.

This EFSA website page is updated quarterly. Regular consultation of the webpage is therefore necessary to obtain the most updated information.

1 THE REVIEW PROCESS OF THE EXISTING EU PESTICIDE MRLS

1.1. Article 12 of Regulation (EC) 396/2005¹ 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 EU, 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. 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.

1.4. 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 in case of certain substances, 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 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 and amending Council Directive 91/414/EEC.

1.5. On this basis the Commission prepares a draft proposal in which amendments to the existing pesticide MRLs are proposed. The draft proposal 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 28 EU member States.

1.6. The draft proposal is also notified to WTO members through the WTO/SPS Secretariat. WTO Members have 60 calendar days to comment on the Commission proposal.

1.7. The PAFF Committee takes into consideration all comments received and votes on the Commission proposal. Once endorsed by the PAFF Committee, the proposal 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 proposal is finally adopted by the Commission as a legislative act.

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

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) During the WTO/SPS consultation procedure:

Before being submitted for a vote in the PAFF Committee, draft proposals of the Commission amending existing pesticide MRLs are notified under the SPS Agreement of the World Trade Organisation.

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. Therefore, in the absence of any additional information from non-EU countries, MRLs may in some cases be lowered to a level that has 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.

3.3. Import tolerance requests normally concern MRLs of active substances approved in the European Union, but they may be introduced also for active substances that are not anymore approved in the European Union, provided that all the required data on the active substance are submitted. More details on the procedure of the "import tolerance" are given in Article 6.4 of Regulation (EC) No 396/2005.

3.4. In case of a positive evaluation of the data submitted by the non-EU country, the European Union may launch a procedure to amend the MRL. It must be considered that it may take one to 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 on the dedicated page of EFSA's website:

<https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf>

4.2. It has been updated on 2 May 2017 and it will be further 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. Non-EU countries that wish to submit additional information 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 1107/2009², provides rules on the placing of plant protection products on the market;
- Regulation (EC) No 396/2005, already mentioned, provides details on the maximum residue levels of pesticides (MRLs) in or on food and feed of plant and animal origin;
- Directive 2009/128/EC³, sets 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 foresees 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 EU level. Further details can be found at:

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/index_en.htm

² 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 and repealing Council Directives 79/117/EEC and 91/414/EEC.

³ 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.

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: http://ec.europa.eu/food/plant/pesticides/max_residue_levels/index_en.htm

5.4. The plant protection products containing EU approved active substances can only be placed on the EU market after prior authorisation. The authorisation of plant protection products is granted by the EU member States. Further details can be found at: http://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/index_en.htm

6 FURTHER INFORMATION

6.1. For any further information, interested parties may consult the section of the European Commission website specifically dedicated to pesticides: http://ec.europa.eu/food/plant/pesticides/index_en.htm
