

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

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Update of the Article 12 EU MRL Review Process

Report Categories:

Agricultural Situation

SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports

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Report Highlights:

On October 22, 2018, the European Food Safety Authority (EFSA) published its quarterly update of the MRL review progress under Article 12 of Regulation 396/2005 on its website, which includes the list of substances subject to the review process and the indicative time schedule of their review. This EFSA progress report is part of a Commission communication that explains the “Article 12” review of existing MRLs of all approved and certain non-approved pesticides and focuses on how non-EU countries can actively contribute to the review process.

General Information:

Background

The EU first notified a communication to the WTO in June 2016, explaining how non-EU countries can contribute to the ongoing Maximum Residue Level (MRL) review process. On June 12, 2017, the first revision of this [communication](#) was notified to the WTO (G/SPS/GEN/1494/Rev.1), referring to an EFSA progress report, including a list of substances subject to the review process and their indicative time schedule. This document refers to the quarterly update of this progress report that is published on the EFSA website to allow stakeholders to better prepare and support the MRL review. It is recommended for stakeholders to consult this list on a regular basis in order to be able to anticipate the need for additional data at an early stage and maintain the MRL levels for substances of interest.

What is the Article 12 MRL review process?

[Regulation 396/2005](#) on maximum residue levels of pesticides in or on food and feed of plant and animal origin, entered into force on September 2, 2008, harmonizing all MRLs throughout the EU. Article 12 (1) of this regulation requires EFSA to provide a reasoned opinion on the review of the existing MRLs for all active substances that are approved or not approved after this date.

The assigned "Rapporteur Member State" (RMS) for each active substance has to carry out the first evaluation of the existing EU pesticide MRL. EFSA must deliver a reasoned opinion based on the RMS evaluation report, which is then published on the [EFSA webpage](#). The European Commission considers the EFSA opinion and prepares a draft proposal in which amendments to the existing pesticide MRLs are proposed. In the absence of additional data, or when the existing data is insufficient, MRLs will be set to the limit of detection (0.01 mg/kg). The draft proposal is discussed with delegates of the EU member States in the regulatory Standing Committee on Plants, Animals, Food and Feed (PAFF). The draft Commission proposal is notified to WTO members, who have 60 calendar days to comment. The PAFF committee votes on the draft proposal after all comments are reviewed. If the vote is favorable, the proposal moves to the Council and the European Parliament for a two month scrutiny period and, if no objections are raised, it is adopted by the Commission as a legislative act. After translation into the official languages of the EU, it is published in the Official Journal (OJ).

Status of the Article 12 review

There have been updates of the MRL review progress under Article 12 of Regulation (EU) No 396/2005 in March and July of this year, and the latest version of the [EFSA progress report](#) has been published on October 22, 2018. Substances are subject to the "new" process, which means that a call for data is sent to the Member States at the start of the process. The RMS will review the data and identify further requirements, followed by an additional call for data. The RMS will also contact manufactures of authorized substances when an Article 12 review has been initiated and that they should make the data available. While the timelines for some of these substances still have to be defined, this process should allow stakeholders time to prepare their input and be ready with their data when the review starts.

Third Country Intervention

According to the Commission, there are two different stages at which third countries may intervene in the review process:

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

Third countries that want to submit additional supporting information or data on a specific active substance of concern can do this at an early stage of the process and before the risk assessment is carried out by EFSA. Third countries should first contact the manufacturer of the active substance concerned. They then need to submit the additional data through the manufacturer to the RMS.

2) During the WTO/SPS consultation procedure:

When draft proposals of the EC amending existing pesticide MRLs are notified under the SPS Agreement of the World Trade Organization (WTO), WTO members have 60 days to send their comments to the SPS contact point of the European Union. Received comments should be considered by the Commission before the vote takes place at the PAFF Committee.

Third countries should submit their comments at the earliest time possible to ensure the Commission has the necessary time to fully consider all of the feedback, since the PAFF Committee is usually scheduled shortly after the closing date of the WTO comment period.

Application for an Import Tolerance

If a MRL is established at a level which disrupts trade, the only possible solution is for an import tolerance request to be submitted. The request must be addressed to the RMS for the active substance and it is highly recommended to work in close collaboration. The process requires a complete data set and the whole procedure may take one to two years from the submission of the request until the implementation of the requested MRL or import tolerance. The application form for an import tolerance can be found [here](#). The [applicant guide](#) is also a useful tool for this process.

Avoiding Future Trade Barriers

In order to ensure that the ongoing MRL reviews do not disrupt trade, it is highly recommended that U.S. industry groups review the published EFSA progress report on a regular basis in order to identify substances that are scheduled for the Article 12 review and are of importance to U.S. agricultural production. Stakeholders are encouraged to reach out to the respective RMS early in the process to ensure that the necessary data is already available for the review or if trials for data collection are in progress or need to be initiated, especially if the substance is not used or authorized in the EU. If not, the only way forward is to apply for an import tolerance once a new MRL is adopted, which will have an impact on trade for at least a few years until the MRL is amended.

The list of the national contact points in each MS can be found at:

http://ec.europa.eu/food/plant/pesticides/legislation/docs/national-authorities_en.pdf

For more guidance on MRLs in the EU:

https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en

Please find attached to this GAIN report the [EFSA progress report](#), including a list of all substances that are under review and that have already been reviewed.

