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Progress of the EU MRL Review process – Article 12

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Agricultural Situation

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Report Highlights:

On June 12, 2017, the European Commission notified a first revision of its communication regarding the ongoing review of Maximum Residue Levels (MRLs) in the EU to the World Trade Organization (WTO). This communication 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. This revision provides an updated list of substances subject to the review process by the European Food Safety Authority (EFSA), including an indicative time schedule of their review.

The EFSA progress report will be updated quarterly and should therefore be consulted at a regular basis.

General Information:

Introduction

The EU first notified this communication to the WTO in June 2016, explaining how non-EU countries can contribute to the ongoing 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. According to this document, there will be a quarterly update in order to improve the communication with stakeholders and to allow them 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 level 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) and is then 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

An overview of the MRL review progress under Article 12 of Regulation (EU) No 396/2005 is available in the [EFSA progress report](#), which also refers to the change in procedures. However, the main difference is the introduction of an additional call for data under the future procedure to initiate the review process and EFSA will coordinate the activities of the RMS and Member States when collecting data.

The substances that have been reviewed up until now were subject to the current (interim) procedure and a few substances are still scheduled to be assessed under this procedure in 2017 (Annex I). The remaining substances are subject to the future process and a call for data will be sent to the Member States at the start of the process (Annex 2). This data will be reviewed and further needs will be assessed by the RMS, followed by an additional call for data. Manufacturers of authorized substances will be contacted by the RMS when an Article 12 review has been initiated and made aware that the

required data should soon be made available to the RMS. While the timelines for these substances have yet to be defined, this process should allow stakeholders time to prepare their input and be ready with their data when the review is started.

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 Commission 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.

Avoid 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

A list of all substances that are under review and have been reviewed can be found here:

[EFSA progress report](#)

Annex I: Substance still reviewed under the current (interim) process and initiated in 2017

Active Substance	RMS	Process	Expected date for start of data collection	Expected date for the adoption of the EFSA reasoned opinion
Myclobutanil	BE	Interim	07/06/2017	31/01/2018
Flurochloridone	ES	Interim	19/06/2017	12/02/2018
Clethodim	NL	Interim	08/03/2017	27/12/2017
Profoxydim	ES	Interim	19/08/2017	14/04/2018
Bispyribac	IT	Interim	19/06/2017	12/02/2018
Tefluthrin	DE	Interim	19/08/2017	14/04/2018
Mandipropamid	AT	Interim	19/08/2017	14/04/2018
Tembotrione	AT	Interim	19/08/2017	14/04/2018
Fenbutatin oxide	BE	Interim	19/06/2017	12/02/2018

Annex II: Substances under the future process

Active Substance	RMS	Process	Start of data	Adoption of the
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			collection* (expected date)	RO (expected date)
Dithianon	EL	New	to be defined	to be defined
Zoxamide	LV	New	to be defined	to be defined
Ziram	BE	New	to be defined	to be defined
Thiram	BE	New	to be defined	to be defined
Quinoxifen	UK	New	to be defined	to be defined
Propineb	IT	New	to be defined	to be defined
Phosmet	ES	New	to be defined	to be defined
Metribuzin	EE	New	to be defined	to be defined
Metiram (aka carbatene, aka zineb ethylene thiuram disulphide adduct)	IT	New	to be defined	to be defined
Methiocarb (aka mercaptodimethur)	UK	New	to be defined	to be defined
Aluminium silicate (aka	HU	New	to be defined	
MCPB	PL	New	to be defined	to be defined
MCPA	PL	New	to be defined	to be defined
Maneb	IT	New	to be defined	to be defined
Mancozeb	IT	New	to be defined	to be defined
Glyphosate (incl trimesium aka sulfosate)	DE	New	05/10/2016	27/12/2017
Fosthiazate	DE	New	to be defined	to be defined
Ethoprophos	IT	New	to be defined	to be defined
Dimethoate	IT	New	to be defined	to be defined
Cypermethrin	BE	New	to be defined	to be defined
Cyfluthrin	DE	New	to be defined	to be defined
Clopyralid	FI	New	to be defined	to be defined
beta-Cyfluthrin	DE	New	to be defined	to be defined
alpha-Cypermethrin	BE	New	to be defined	to be defined
Tricyclazole	IT	New	to be defined	to be defined
Potassium permanganate	ES	New	to be defined	to be defined
Beauveria brongniartii	DE	New	to be defined	to be defined
Chlorates (incl. Mg, Na, K chlorates)	FR	New	to be defined	to be defined
Quassia	IT	New	to be defined	to be defined
Fatty alcohols	IT	New	to be defined	to be defined
Pyriproxyfen	NL	New	to be defined	to be defined
Picloram	PL	New	to be defined	to be defined
Oxadiazon	IT	New	to be defined	to be defined
Lenacil	BE	New	to be defined	to be defined
Imazaquin	BE	New	to be defined	to be defined
Fenoxaprop-P	AT	New	to be defined	to be defined
Diflubenzuron	EL	New	to be defined	to be defined
Difenoconazole	ES	New	to be defined	to be defined

Dicamba	DK	New	to be defined	to be defined
Clofentezine	ES	New	to be defined	to be defined
Nicotine	UK	New	to be defined	to be defined
Epoxiconazole	DE	New	to be defined	to be defined
Pyrethrins	IT	New	to be defined	to be defined
Metamitron	UK	New	to be defined	to be defined
Denathonium benzoate	PT	New	15/05/2017	16/04/2018
2,5-Dichlorobenzoic acid methylester	DE	New	15/05/2017	16/04/2018
Sodium hypochlorite	NL	New	to be defined	to be defined
Sodium aluminium silicate	HU	New	to be defined	to be defined
Aluminium silicate (aka kaolin)	HU	New	to be defined	to be defined
Potassium phosphonates	FR	New	to be defined	to be defined
Halosulfuron-methyl	IT	New	to be defined	to be defined
Bixafen	UK	New	to be defined	to be defined
Penflufen	UK	New	15/11/2017	17/10/2018
Pyriofenone	UK	New	15/12/2017	16/11/2018
Disodium phosphonate	FR	New	to be defined	to be defined
Sedaxane	FR	New	15/12/2017	16/11/2018
Fluopyram	DE	New	15/11/2017	17/10/2018
Potassium thiocyanate	NL	New	to be defined	to be defined
Penthiopyrad	UK	New	to be defined	to be defined
Chlorantraniliprole	IE	New	to be defined	to be defined
Spirotetramat	AT	New	to be defined	to be defined
Pyroxsulam	UK	New	to be defined	to be defined
Benalaxyl-M	PT	New	15/10/2017	16/09/2018
Emamectin	NL	New	to be defined	to be defined
Amisulbrom	UK	New	to be defined	to be defined
1,4-Dimethylnaphthalene	NL	New	to be defined	to be defined
Thiencarbazone	UK	New	to be defined	to be defined
Valifenalate	HU	New	to be defined	to be defined
Pyridalyl	NL	New	to be defined	to be defined
Spinetoram	UK	New	to be defined	to be defined
Flubendiamide	EL	New	to be defined	to be defined
Ipconazole	UK	New	to be defined	to be defined
Acequinocyl	NL	New	to be defined	to be defined
Metaflumizone	UK	New	to be defined	to be defined
Aminopyralid	UK	New	to be defined	to be defined
Metobromuron	FR	New	to be defined	to be defined
Meptyldinocap	UK	New	to be defined	to be defined
Gamma-cyhalothrin	UK	New	to be defined	to be defined
Chromafenozide	HU	New	to be defined	to be defined
pinoxaden	UK	New	to be defined	to be defined

