EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

COMMISSION GUIDANCE DOCUMENT[1]

SANTE/12278/2020
3 December 2020

Guidance of EFSA on risk assessments for active substances of plant protection products that have stereoisomers as components or impurities and for transformation products of active substances that may have stereoisomers

[1] Does not necessarily represent the views of the Commission.

Introduction

European Food Safety Authority (EFSA), following its standard procedures for development of guidance documents, including consultation of stakeholders and general public, has published the following guidance document:

EFSA (European Food Safety Authority), Bura L, Friel A, Magrans JO, Parra-Morte JM and Szentes C, 2019. Guidance of EFSA on risk assessments for active substances of plant protection products that have stereoisomers as components or impurities and for transformation products of active substances that may have stereoisomers. EFSA Journal 2019;17(8):5804, 33 pp. https://doi.org/10.2903/j.efsa.2019.5804

The guidance document on isomers does not introduce new data requirements, but provides specific options for the applicants how to address the isomers which can be treated as a special type of metabolites. In fact, the guidance document offers some possibilities to avoid the generation of new data by using assumptions which would allow to waive new studies.

The guidance document has been presented and discussed at the Standing Committee on Plants, Animals, Food and Feed (Sections Phytopharmaceuticals and Residues) between October 2019 and December 2020. This implementation document has been adopted in the Standing Committee on Plants, Animals, Food and Feed on 3 December 2020.

Implementation schedule

The Standing Committee on Plants, Animals, Food and Feed agreed that the EFSA GD will be **applicable as from 1 August 2021 (date of dossier submission)** to dossiers submitted under Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005, as detailed below.

Approval and renewal of approval of active substances under Regulation (EC) No 1107/2009:

For the on-going peer reviews of active substances, EFSA had and will continue identifying data gaps related to isomers following current practice.

Dossiers for first approval (new active substances) or renewal of approval submitted on and after 1 August 2021 will be assessed following the principles outlined in the GD and data gaps identified will be considered in the decision making process.

MRL procedures under Regulation (EC) No 396/2005:

Specific workflows on Article 6 applications and Article 12 of Regulation (EC) No 396/2005 apply, following a suggestion as regards the implementation by EFSA. As a general rule the MRL setting procedures always follows the approval/ renewal of approval processes.

- **MRL reviews according to Art. 12 of Regulation (EC) No 396/2005 or Article 43 reviews** generally follow the procedure on the approval /renewal of approval using the applicable guidelines used in those procedures.

- **MRL setting procedures under Article 6-10 of Regulation (EC) No 396/2005** (except certain import tolerance requests (see below) also follow the procedure on the approval /renewal of approval using the applicable guidelines used in those procedures.

Three main scenarios for MRL procedures:

1. Substances that were not assessed during the approval/renewal of approval procedure according to the principles of the GD [2](active substance dossier submission before 1 August 2021):

- In subsequent MRL applications under Article 6 of Regulation (EC) No 396/2005 data gaps do not lead to clock-stops due to missing data.
- In subsequent Art. 12 reviews data gaps do not lead to confirmatory data requirements necessitating footnotes in Regulation (EC) No 396/2005.

- EFSA will however highlight the data gaps and the related uncertainties, but without referencing the new GD; in Art. 12 reviews the data gaps related to isomers will be summarised in a different chapter than other data gaps.

2. Substances that were assessed during the approval/renewal of approval procedure according to the principles of the GD (active substance dossier submission on and after 1 August 2021):

- In subsequent **MRL applications under Article 6** of Regulation (EC) No 396/2005 data gaps can lead to clock-stops due to missing data, if confirmatory information was required in the approval /renewal of approval processes.

- In subsequent **Art. 12 reviews** data gaps can lead to confirmatory data requirements necessitating footnotes in Regulation (EC) No 396/2005, if confirmatory information was required in the approval /renewal of approval processes.

- In this scenario**, a specific case can arise** where the GD was applied in the approval/renewal of approval procedure and no data gaps were identified in relation to the representative uses, but where data gaps were identified in the subsequent Article 12 review for the authorised uses. In such cases, confirmatory data requirements can be set in the Article 12 process. The Article 12 review will be the basis for any subsequent MRL applications (clock stops can be set).

3. For **import tolerance requests** under Article 6(4) of Regulation (EC) No 396/2005 of **substances that were never assessed in the EU or that are no longer approved**: the application will be assessed according to the principles of the GD, if the application was submitted as from 1 August 2021 (date of receipt of application in the EMS).

[2] This refers mainly to data on the preferential degradation of isomers and/or the toxicity of isomers.