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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

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Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the MRL application procedure

Does not necessarily represent the views of the Commission.

Introduction

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

European Food Safety Authority, 2021. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure, EFSA supporting publication 2021: EN-6464. 77 pp. doi:10.2903/sp.efsa.2021. EN-6464

The Transparency Regulation¹ amended the General Food Law² by introducing new requirements in the pre-submission phase and submission application procedure, such as:

- possibility to request for general pre-submission advice;
- obligation to notify information related to studies commissioned or carried out to support an application;
- submission of the application dossier using IUCLID format, including non-confidential version of the dossier;
- public disclosure of non-confidential version of all information submitted in support of the application and related confidentiality decision-making process;
- public consultation on submitted application dossiers.

The EFSA guidance describes the procedures and the associated timelines for handling applications related to pesticide active substances and for the setting of maximum residue levels, in particular concerning the provisions introduced by the Transparency Regulation amending the General Food Law and their implementation in the procedure for such applications, according to the Practical Arrangements³ laid down by EFSA.

The guidance document has been presented and discussed at the Standing Committee on Plants, Animals, Food and Feed (Sections Phytopharmaceuticals - Legislation and Pesticide Residues) between December 2018 and February 2021. This implementation document has been adopted in the Standing Committee on Plants, Animals, Food and Feed on 23 February 2021.

¹ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1.

³ <https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements>

Implementation schedule

The Standing Committee on Plants, Animals, Food and Feed agreed that the EFSA guidance applies to all applications submitted to the competent authority of a Member State **as of 27 March 2021** and should be used for the preparation of applications intended to be submitted from that date onwards. Consequently, the guidance applies to all assessment reports concerning applications submitted **as of 27 March 2021**.