

SANTE-10832-2015 rev. 2 18 May 2022

## Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products

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This guidance has been developed in co-operation with the Member States. It does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State within the implementation prerogatives under Regulation (EC) No 1107/2009, nor any case law developed with regard to this provision. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

## 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 updated guidance document:

EFSA (European Food Safety Authority), Charistou A, Coja T, Craig P, Hamey P,Martin S, Sanvido O, Chiusolo A, Colas M and Istace F, 2022. Guidance on the assessment of exposureof operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032, 134 pp. <u>https://doi.org/10.2903/j.efsa.2022.7032</u> ISSN:1831-4732

This GD is an update of a previous version<sup>1</sup> published in 2014 which was endorsed by the Standing Committee on Plants, Animals, Food and Feed on 29 May 2015 and its implementation schedule amended 1<sup>st</sup> March 2017.

## **Implementation schedule**

The updated guidance document should apply from <u>**1** January 2023</u> onwards to dossiers submitted in the context of (renewal of ) approval of active substances or (renewal of) authorisation of plant protection products under Regulation (EC) No. 1107/2009.

However, when this document was endorsed in the Standing Committee on Plants, Animals, Food and Feed on 29 May 2015, it was decided it should apply with exception of some unresolved issues.

While users became used to the derivation of the AAOEL and its use for risk assessment even in the absence of guidance, the following issues are not yet resolved because of the limited dataset for bystanders and residents, and the lack of acute exposure estimates for the workers at the time of the update of the document:

- 1. The guidance does not set out fully detailed higher-tier risk assessment schemes for bystanders or residents. However several risk management options are available for ad-hoc approaches for controlling risk or conducting a more refined assessment (note the EUROPOEM, old DE and UK models are not considered refinements);
- 2. The guidance does not contain suitable information to estimate acute worker exposure so without further development worker risks should only consider the longer risk assessment, using the AOEL.

<sup>&</sup>lt;sup>1</sup> EFSA, 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014, 12(10):3874, 55pp., doi:10.2903/j.efsa.2014.3874