

National risk assessment for the authorization of plant protection products (PPP) in Austria:

Ecotoxicology Effects on biodiversity

Information for notifier/applicants and other interested parties

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This document is intended to give background information on the ecotoxicological risk assessment for plant protection products, active ingredients and metabolites currently considered necessary for the national authorisation of plant protection products (PPP) in Austria. The approaches for **risk assessments of negative effects on biodiversity** are shortly described hereafter.

The ecotoxicological risk assessment for plant protection products is legally based on the Commission Regulation (EU) No 283/2013 of 1 March 2013, setting out the data requirements for active substances and (EU) No 284/2013 of 1 March 2013, setting out the data requirements for plant protection products as well as Commission Regulation (EU) No 546/2011 of 10 June 2011 regarding uniform principles for evaluation and authorisation of plant protection products in accordance with Regulation (EC) No 1107/2009 of 21 October of the European Parliament and of the Council.

8 Assessment of negative effects on biodiversity

As laid out in Commission Regulation (EC) No 1107/2009¹ plant protection products shall have no unacceptable effects on the environment. In order to address this demand, potential impacts on (i) non-target organisms and (ii) biodiversity and the ecosystem shall be assessed with appropriate scientific methods that are accepted by EFSA. For the latter (i.e. impacts on biodiversity and the ecosystem), an evaluation of indirect effects, resulting from trophic interactions within the food web of organisms, need to be included in the risk assessment. An evaluation of these complex ecological interactions is also required according to the data requirements for active substances defined in Commission Regulation (EU) No 283/2013², where it is stated that „*the potential impact of the active substance on biodiversity and the ecosystem, including potential indirect effects via alteration of the food web, shall be considered.*”. Further, in the Uniform Principles for evaluation and authorisation of plant protection products (Commission Regulation (EU) No 546/2011)³ it is acknowledged that the evaluation of effects has to be based on data derived by a limited amount of representative species, yet it is stated that “*Member States shall ensure that use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.*”. However, currently no EU-harmonised approach and no method officially accepted by EFSA for the assessment of indirect effects on biodiversity (including trophic interactions) is available. Hence, for the time being the potential impact on biodiversity cannot be considered as mandatory part of the ecotoxicological risk assessment. As a consequence, based on the present risk assessment, negative effects on biodiversity (including trophic interactions) cannot be ruled out.

¹ Commission Regulation (EC) 1107/2009, Chapter II, Section 1, Subsection 1, Article 4, (3) e (ii) & (iii)

² Annex of Commission Regulation (EU) No 283/2013, Part A, Section 8, Introduction 5.

³ Commission Regulation (EU) No 546/2011, Part I, C. Decision-Making, 1. General principles 1.5