EFSA ACTIVITIES FOCUSED ON PROTECTING BIODIVERSITY

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GUIDANCE DOCUMENTS FOR RISK ASSESSMENTS

The GD for pesticides currently in place (SANCO, 2002)

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: plant health, animal health and welfare, international questions
E1 - Plant health

SANCO/10329/2002 rev 2 final

17 October 2002

DRAFT
Working Document

Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC

This document has been conceived as a working document of the Commission Services which was elaborated 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 Annex II, III and VI of Commission Directive 91/414/EEC, 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.

covers 4 groups of non-target organisms

EFSA, 2013 GD for bees; this GD was never endorsed

EFSA, 2023 GD for bees; waiting for endorsement

Mandate in 2024 to review the guidance

Note: Scientific Opinion is available for each non-target organism group

EFSA, 2023 GD FOR BEES

GUIDANCE

efsa JOURNAL

APPROVED: 30 March 2023

doi: 10.2903/j.efsa.2023.7989

Revised guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

European Food Safety Authority (EFSA),
Pauline Adriaanse, Andres Arce, Andreas Focks, Brecht Ingels, Daniela Jölli, Sébastien Lambin, Maj Rundlöf, Dirk Süßenbach, Monica Del Aguila, Valeria Ercolano, Franco Ferilli, Alessio Ippolito, Csaba Szentes, Franco Maria Neri, Laura Padovani, Agnès Rortais, Jacoba Wassenberg and Domenica Auteri

Abstract

The European Commission asked EFSA to revise the risk assessment for honey bees, bumble bees and solitary bees. This guidance document describes how to perform risk assessment for bees from plant protection products, in accordance with Regulation (EU) 1107/2009. It is a review of EFSA's existing guidance document, which was published in 2013. The guidance document outlines a tiered approach for exposure estimation in different scenarios and tiers. It includes hazard characterisation and provides risk assessment methodology covering dietary and contact exposure. The document also provides recommendations for higher tier studies, risk from metabolites and plant protection products as mixture.

Keywords: bees, pesticides, risk assessment, higher tier studies

Requestor: European Commission

Question number: EFSA-Q-2019-00308

Correspondence: pesticidespeerreview@efsa.europa.eu

- EFSA, 2023 is for the EC REGULATION No. 1107/2009
- Considers specific protection goals agreed by the RMs
- Complex and comprehensive guidance document covering:
  - ✔ multiple application methods
  - ✔ multiple exposure routes
  - ✔ multiple exposure scenarios
  - ✔ multiple bee groups
  - ✔ multiple risk cases (acute, chronic, brood development)

In addition, it addresses some special issues:

- ✔ risk from time reinforced toxicity
- ✔ risk from sublethal effects
- ✔ risk from metabolites
- ✔ risk from mixtures

REVISION OF SANCO TERRESTRIAL GUIDANCE – TORs OF M-2024-00086

- Review the risk assessment for non-target arthropods

Consider the possibility for recovery/recolonisation

- Revise the risk assessment for in-soil organisms

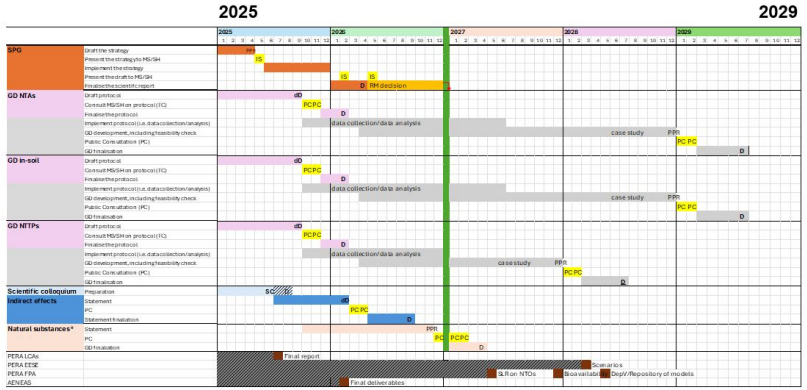
In soil meso and macrofauna and nitrogen transformation rate

- Review the risk assessment for non-target plants

NTTPs outside the treated area

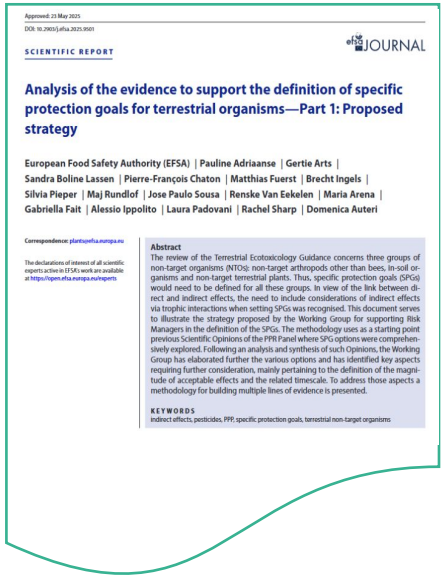
STEPS ALREADY DONE/ONGOING FOR THE REVISION OF THE TERRESTRIAL GD

- An outline of the work program published in January 2025



- A working group was established (academia and MS's experts) and 9 meetings already held

- Strategic document collecting potential lines of evidence and potential methods to set SPG was presented to COM and SH on 8th May. The final document (part 1) was published on 23rd of June



SCIENTIFIC REPORT

efsa JOURNAL

Analysis of the evidence to support the definition of specific protection goals for terrestrial organisms—Part 1: Proposed strategy

European Food Safety Authority (EFSA) | Pauline Adriaanse | Gertie Arts | Sandra Boline Lassen | Pierre-François Chaton | Matthias Fuerst | Brecht Ingels | Silvia Pieper | Maj Rundlof | Jose Paulo Sousa | Renske Van Eekelen | Maria Arena | Gabriella Fait | Alessio Ippolito | Laura Padovani | Rachel Sharp | Domenica Auteri

- Protocol for review of the guidance document is under development. It includes conceptual models for the problem formulation, identifies needs and methods for data collection, includes plans and ideas to shape the future GDs

- Organizing data collection is ongoing (calls for FPA contracts, links to relevant on-going projects, interaction with EU Agencies and international organisations)

INDIRECT EFFECTS

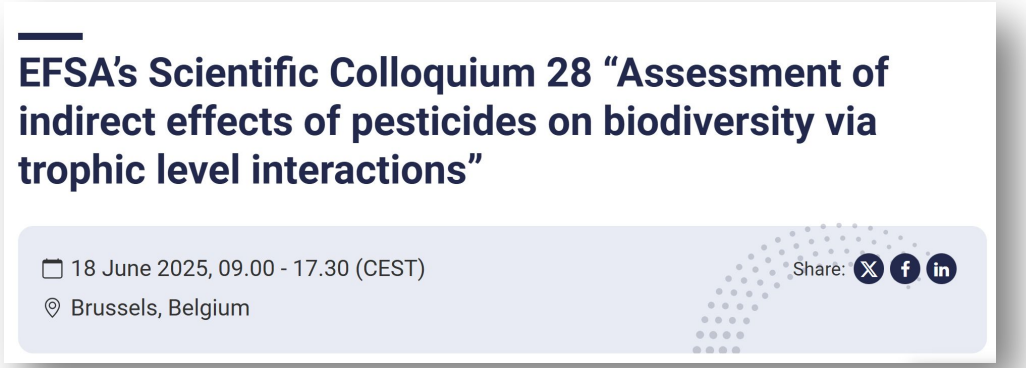
With the mandate for the review of the terrestrial GD, a second mandate was received (M-2024-00101)

The TORs are:

Develop a methodology for risks from indirect effects on biodiversity via trophic interactions under agro-environmental conditions

Include recommendations for measures and agronomic practices

- Discussions with the WG is ongoing
- A PPR Panel Statement is under preparation and is anticipated to be published in Q4 of 2026
- Scientific colloquium was held in June 2025



RELATED PROJECTS (INITIATED IN THE PRECEDING YEARS)

EESE

Development of EU Environmental Scenarios for ERA of Non-Target Organisms

- to collect and generate data for characterising landscape structure;
- to characterise ecological communities in terrestrial ecosystems;
- to develop environmental scenarios using these data;
- to gather information on existing food webs and ecological interaction models

AENEAS

Advancing the ERA of non-target arthropods for PPPs by accounting for the impact on ecosystem services and on the ecological function

- to establish a quantitative link between the direct effects of PPPs on NTAs and pollinators other than managed bees and their ecological consequences;
- to investigate the interspecies sensitivity of key driver species for various ecosystem services;
- to characterise the exposure of these key driver species

PERA

Advancing the ERA of Plant Protection Products towards a system-based approach

- to enhance exposure characterisation for terrestrial non-target organisms;
- to improve hazard characterisation across different levels of biological organisation and species;
- to collect and evaluate methodologies and tools (e.g., mechanistic effect models) for regulatory risk assessment;
- to explore the integration and interconnection of data from various sources, methods, tools, and objectives through the development of a common platform for risk assessments

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