MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES

CSIC Consejo Superior de Investigaciones Científicas

INIA Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria

Risk assessment of PPP for NTA, Soil organisms and NTTP: Current knowledge, expectations and data availability.

'Workshop for the Revision of the Terrestrial Ecotoxicology Guidance Document'

Joint presentation of the Southern Zone

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Layout

- Existing documents reviewing the current risk assessment schemes

- Limitations of the current risk assessment:

  NON TARGET ARTHROPODS

  NON TARGET TERRESTRIAL PLANTS

  SOIL ORGANISMS

- Conclusions and expectations for the revision of the guidance

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European Food Safety Authority
EFSA Journal 2015;13(2):3996

SCIENTIFIC OPINION

Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods[1]

EFSA Panel on Plant Protection Products and their Residues (PPR)[2,3]

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EFSA Journal

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Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms

www.efsa.europa.eu/efsajournal
EFSA Journal 2017;15(2):4690

- **EFSA Technical Reports on ecotoxicology (2015, 2019):**

TECHNICAL REPORT

APPROVED: 18 December 2015
PUBLISHED: 22 December 2015

Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology

European Food Safety Authority

TECHNICAL REPORT

APPROVED: 28 June 2019
doi:10.2903/sp.efsa.2019.EN-1673

Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology

European Food Safety Authority

Maria Arena, Domenica Auteri, Stefania Barmaz, Eugenia Chaideftou, Lucie Ctverackova, Chloe De Lentdecker, Alessio Ippolito, Dimitra Kardassi, Chris Lythgo, Tunde Molnar, Laura Padovani, Rachel Sharp, Franz Streissl, Juergen Sturma, Csaba Szentes, Benedicte Vagenende, Joanke Van Dijk and Laura Villamar-Bouza

2023

South Member States

Revision 8 October 2023

WORKING DOCUMENT ON THE WORK-SHARING OF THE SOUTHERN ZONE MEMBER STATES UNDER REGULATION EC 1107/2009

Revision history

When	What
Rev. 7.1 of 06.08.2018	Update of table of the national requirements for Spain – Efficacy Section. Clarification on the deposition data
Rev 8 of 27.10.2023	Update of National Data Requirements Update of contact points

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NON-TARGET ARTHROPODS – Limitations of current RA

1.- Routes of exposure

- Contact exposure to dried and fresh residues on plant and soil surfaces (SANCO/10329/2002 rev 2 final, ESCORT 2)
- Direct overspray and exposure through ingestion are not covered.
- The risk for metabolites should be taken into account in all tiers as is done in other NTO.

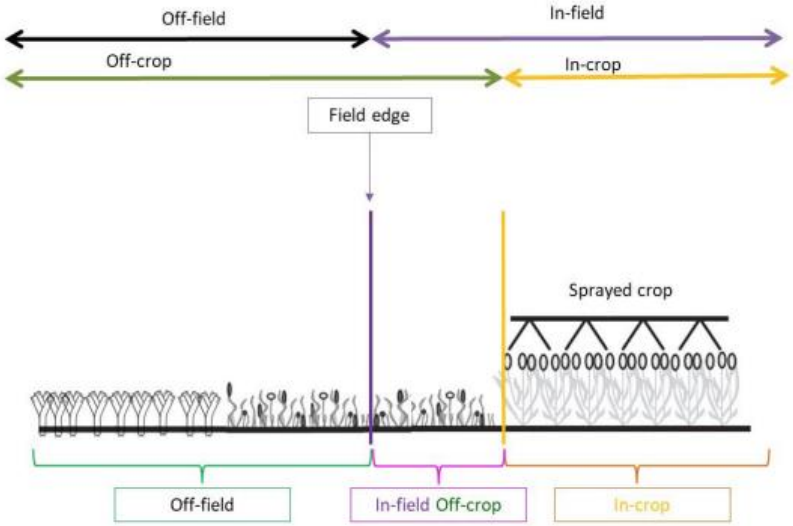
NON-TARGET ARTHROPODS – Limitations of current RA

2.- Exposure assessment (cont.):

- Exposure scenarios

External Scientific Report on Exposure Assessment for NTOs refering to the ExAGs development (refer to Adriaanse PI et al., 2022, EFSA Supporting publication 2022: EN-7661):

> *The current use of the application rate (in-crop) or drift deposition rate (off-crop) is a poor surrogate for their exposure, both in the environment and in the ecotoxicological experiments.*



Picture taken from: EFSA Supporting publication 2022: EN-7661

NON-TARGET ARTHROPODS – Limitations of current RA

2.- Exposure assessment (cont.):

- ESCORT 2, exposure calculation based on default values or limited numbers of experimental:

In-field PER = application rate * MAF

Off-field PER = application rate * MAF * (drift factor / VDF)* correction factor

MAF	Default MAF values: → Appendix V of the ESCORT 2 leaf substrates (= 2.3:1) soil substrates (= 6:1) Refinement possible when foliar dissipation data 'half life' (DT50) available (refer to EFSA Technical Report (2019))
DRIFT	Rautmann *et al.* (2001) → Appendix IV of ESCORT 2.  Under revision → spray drift should be harmonised
VDF	Defaults – Not reliable!!! (refer to Appendix E of EFSA Technical Report 2019) VDF = 10 (toxicity endpoints from 2D exposure test) VDF = 1 (toxicity endpoints from 3D exposure test)
CF	Defaults: CF = 10 (Tier 1) and CF= 5 (Tier 2 and 3)

NON-TARGET ARTHROPODS – Limitations of current RA

3.- Assessment of effects:

- In EFSA Scientific Opinion on NTA (EFSA Journal 2015;13(2):3996) it was concluded that the present first tier risk assessment is not protective for the occurrence of effects in the field situations in all cases:
  - ➢ Current risk assessment methodology is focused on beneficial arthropods. Important groups and feeding guilds were not represented in the sensitivity analyses performed for defining current standard indicator species.
  - ➢ Tier 1 – assessment of mortality, unless effects on reproduction are expected. Effects on reproduction should be taken into account at all tiers.
  - ➢ Insect growth regulators or other compounds with particular modes of action (e.g. insect feeding inhibitors, ovicides, …), plant protection products applied to soil (as granules, seed treatments and pellets) are potentially not covered.

- No guidance on how to implement the recovery/recolonization in the risk assessment available (refer to EFSA Technical Report 2019; EFSA Supporting publication 2019:EN-1673).

NON-TARGET ARTHROPODS – Limitations of current RA

3.- Assessment of effects:

- No harmonized guidance on how to assess field studies available. However, there are a number of documents currently used for evaluation of field studies:

  - ‘Principles for regulatory testing and interpretation of semi-field and field studies with non-target arthropods’ (Candolfi *et al*., 2001)

  - De Jong *et al.,* 2010. Guidance for summarising and evaluating field studies with non-target arthropods. RIVM report 601712006/2010.

  - Appendix H of the “Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology” (EFSA supporting publication 2019:EN-1673)

  - Annex H/H2 of the “proposal of critical appraisal tools for the evaluation of ecotoxicology studies” (refer to Lahr et al., 2022, EFSA Supporting publication 2023:EN-7787)

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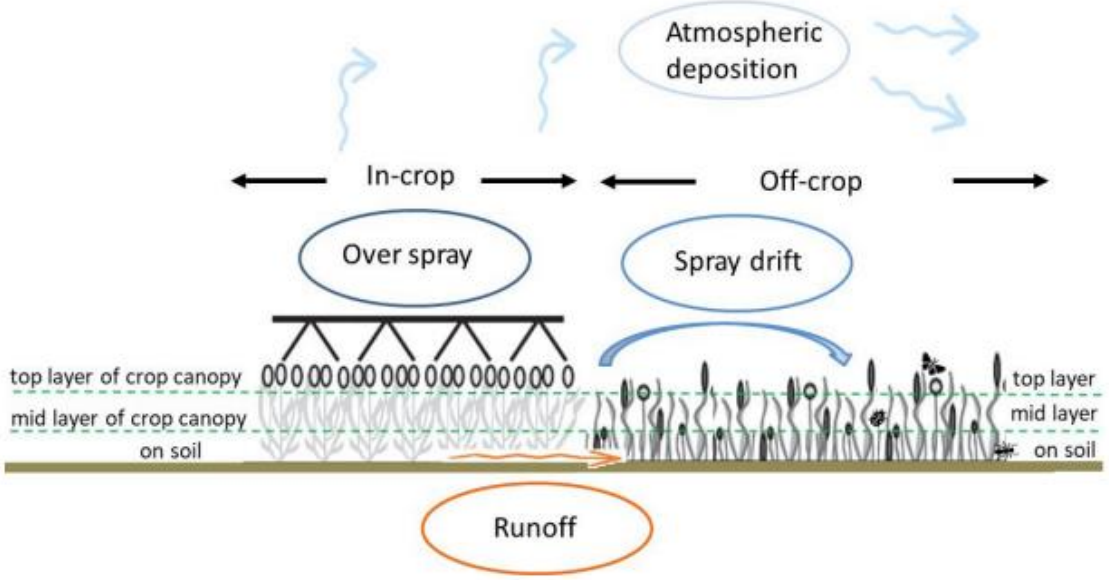
NTTPs– Limitations of current RA

1.- Routes of exposure

- Drift is considered the most important route of exposure for off-field areas.

- Other relevant routes could also impact the off field area: runoff (if the mode of entry is uptake by the plant root system), deposition (volatile substances) and dust drift (granular applications and seed treatments).



Picture taken from: EFSA Supporting publication 2022: EN-7661

NTTPs– Limitations of current RA

2.- Exposure scenarios

Definition of NTTP:

- SANCO/10329/2002 rev 2: non-crop plants located outside the treatment area
- EFSA Opinion on NTTPS (EFSA PPR 2014, EFSA Journal 2014;12(7):3800): all plants growing outside fields, and those growing within fields that are not the intended pesticide target.

A change in the definition on non-target plants implies a change in the exposure protection goals and the exposure scenarios.

Harmonization and alignment of the risk assessment of the different NTO groups.

NTTPs– Limitations of current RA

3.- Multiple application factor

- Only single application is considered in the current guidance
- A multiple application factor in case of repeated applications is not applied/harmonized until a guidance document is developed (as suggested in EFSA Supporting publication 2015:EN-924).

4.- Assessment of effects

- Current RA is conducted on crop species → Wild species are covered in RA?
- The endpoints measured do not include the overall effect on the whole life cycle (germinating seeds, seedling, juvenile stages, flowering, and seed production and germinability) → Standard and validated guidelines to test effects on reproduction of NTTP are not available.
- In EFSA Technical report 2019 (EFSA Supporting publication 2019:EN-1673), it was agreed that the phytotoxicity endpoint should be reported in the study summary and in the list of endpoints → no guidance for the visual injury assessment is available.
- Guidelines and guidance on harmonized and fully accepted semi-field and field studies are needed.

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SOIL ORGANISMS – Limitations of current RA

1.- Limited number of species tested:

- Test with *Folsomia* and *Hypoaspis* are always required for soil applications.
- For foliar spray applications, test with *Folsomia* and *Hypoaspis* are not always required:

  "If data are available on both *Aphidius rhopalosiphi* and *Typhlodromus pyri* these may be used in an initial risk assessment. If concern is raised with either species tested under point 8.3.2, data on both *Folsomia candida* and *Hypoaspis aculeifer* shall be provided" (Commission Regulation (EU) No 283/2013).
- Earthworms might not be the most sensitive species of the in-soil fauna.
- Effects on soil microorganisms are evaluated via functional responses nitrogen turnover. For chemicals with a fungicidal mode of action, no adequate non-target organisms is included in ERA.

⇩

Further species should be tested

2.-Routes of exposure

- Exposure via food uptake is only partly included in the standard laboratory tests, since normally uncontaminated food is often provided.

SOIL ORGANISMS – Limitations of current RA

3.- No intermediate refinement options are available when lower tier fails

4.- No guidance on how to assess field studies available:

- Earthworm field tests are carried out according to ISO 11268-3 (2014). A draft OECD guideline which is based on the current ISO guideline, is under development.
- In 2006, guidance on how to summarize those studies was published by de Jong *et al.* (2006).
- The elements agreed for the evaluation of earthworm field studies were included in a template that is provided in Appendix I of EFSA Technical report (2019).
- The statistical power of field studies is an issue requiring further consideration.

5.- No standardized test guideline on how to perform field studies for mesofauna are available.

Field studies available to date mainly follow recommendations of the ISO 11268-3 (2014) guideline. However, it not known if this methodology is appropriate for soil mesofauna

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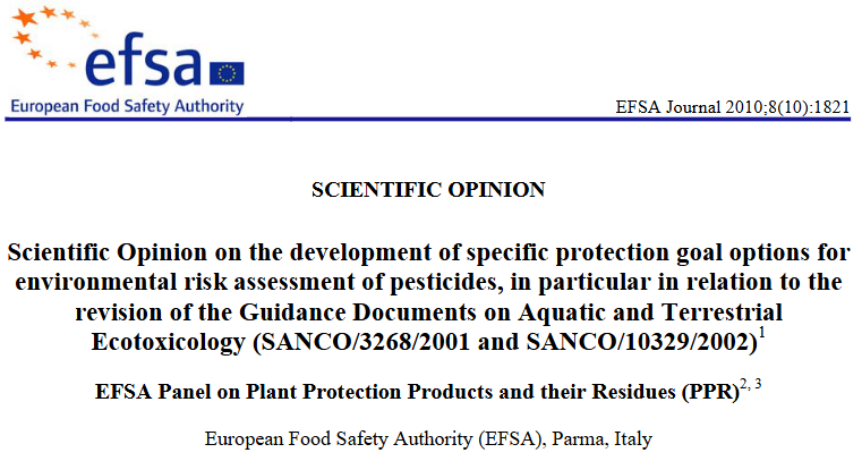
Conclusions and expectations for the revision of the guidance

- Definition of Specific Protection Goals for each organisms group in line with current EFSA methodology.



efsa
European Food Safety Authority
EFSA Journal 2010;8(10):1821

SCIENTIFIC OPINION

Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002)[1]

EFSA Panel on Plant Protection Products and their Residues (PPR)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

GUIDANCE

EFSA Journal

ADOPTED: 21 April 2016

doi: 10.2903/j.efsa.2016.4499

Guidance to develop specific protection goals options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services

EFSA Scientific Committee

EXTERNAL SCIENTIFIC REPORT

WAGENINGEN UNIVERSITY & RESEARCH

APPROVED: 13 September 2022

doi:10.2903/sp.efsa.2022. EN-7661

Supporting the development of exposure assessment scenarios for Non-Target Terrestrial Organisms to plant protection products

Development of Exposure Assessment Goals

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Wageningen University and Research (WUR)

Conclusions and expectations for the revision of the guidance

- Relevant exposure routes and scenarios should be revised.
- Realistic agronomical situations (IPM) should be considered in the definition of scenarios.
- The risk assessment should be considered the different application techniques (foliar spray, granular application, application to bare soil, seed treatment, ..) and MoA of PPP (systemic active substances, contact or oral activity, …).
- It is necessary to identify key species that are drivers for ecosystem services and to have standard and validated methods to test them.

Conclusions and expectations for the revision of the guidance

- Further guidance on how to include recovery and how to conduct and assess higher tier studies should be developed to avoid inconsistencies in assessments.
- If the use of models are introduced in the ERA of PPP, these models should be agreed in the new guidance (with an appropriate analysis of sensitivity and uncertainty) and training provided.
- Development of new methodologies to assess the potential impacts of PPP on biodiversity and the ecosystem, including indirect effects via alteration of the food web.
- A change in the paradigm of the risk assessment might imply a revision of the Uniform Principles and EU data requirements.

Thank you for your attention!