Evaluation Manual for the Authorisation of plant protection products according to Regulation (EC) No 1107/2009

EU part

Plant protection products

Chapter 7 Ecotoxicology; terrestrial; soil organisms

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ctgb

Board for the Authorisation of plant protection products and biocides

Chapter 7 Ecotoxicology; terrestrial; soil organisms

Category: Plant Protection Products

Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 7 Ecotoxicology; terrestrial; soil organisms			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014		
2.1	October 2016		Text from data requirements deleted from the Manual, replaced with reference/links to Regulations (EU) No 283/2013 and 284/2013. Short list of data requirements included in the text.
			No major changes, only formatting, updating references to Regulation (EC) No 1107/2009
2.2	May 2018		Correction factor for organic matter
2.3	January 2020	Chapter 1.3	Conclusions from the Pesticides Peer review Meeting 185 on Recurring Issues on Ecotoxicology in held 2019 (EFSA Supporting publication 2019:EN-1673)
		I.1 and II.1	Sentence included on the administrative EFSA guidance
2.4	July 2020	Chapter 1.3.1	Added paragraph structure for 'Recurring issues meetings' and 'Zonal harmonization workshops' agreements.
		Chapter 1.3.1.2	Bullet point from the final agreements from the 4th CZHW in Ecotoxicology, Dessau, Sept 20-21 2018 on 'Natural soils in the refined risk assessment for in-soil organisms' included.
2.5	September 2023	I.1 Chapter 1.3.1.1:	Sections copied from the EFSA Supporting publication 2019:EN-1673, Appendix I on the evaluation of earthworm field studies removed and replaced with only a reference to the report.
		I.1 Chapter 1.3.2.1	Removal point for correction factor for organic matter. This is due to the fact that none of the other MS accepts this refinement.
		I.1 and II.1 Chapter 1.3.1.2	Bullet points from the final agreements from the 6th CZHW in Ecotoxicology, Ede, June 2022.

GENERAL INTRODUCTION

This chapter shortly describes the data requirements for estimation of the effects on soil organisms of a plant protection product and its active substance and how reference values are derived in the EU framework (§1 - §1.5) under Regulation (EC) No 1107/2009.

This chapter consists of two parts: a part about earthworms (I) and a part about soil micro-organisms (II).

I EARTHWORMS AND OTHER NON-TARGET SOIL MESO- AND MACROFAUNA

1. EU FRAMEWORK

In this document, the procedures for the evaluation and re-evaluation of active substances as laid down in the EU are described; the NL procedure for evaluation of a substance is reverted to when no EU procedure has been laid down. The NL-procedure for the evaluation of a substance is described in §2 - §2.5 of part 2 of the Evaluation Manual (plant protection products). This document aims to give procedures for the approval of active substances and inclusion in Commission Implementing Regulation (EU) No 540/2011.

Notifiers preparing an assessment report for active substances need to comply with the relevant guidance, instructions and format laid down in the EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances

1.1. Introduction

Effects of plant protection products on earthworms are included in the assessment where it cannot be ruled out that the substance or the product reach the soil (see Chapter 6 Fate and behaviour in the environment; Persistence).

Guidelines for the risk assessment for earthworms are described in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).

Earthworms play a vital role in the ecosystem. For this reason plant protection products should cause no unacceptable and prolonged effects on earthworm populations, not in the treated part and not beyond. The risk assessment of the use of pesticides for earthworms serves to prevent that products that present an unacceptable risk to the environment will reach the market. The risk to earthworms must be evaluated in case there is a chance of exposure of these organisms.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the NL part (§2 - §2.5). The national further provisions can also be used for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011.

1.2. Data requirements

In order to qualify for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011 [2] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the protocol of experiments are mentioned in Commission Communication 2013/C 95/01 .

When according to the applicant a certain study is not necessary, a relevant scientific justification can be provided for the non-submission of the particular study.

1.2.1. Data requirements for the active substance

The data requirements regarding the risk of the active substance for earthworms are described in Commission Regulation (EU) No 283/2013 , point 8.4 (Effects on non-target soil meso- and macrofauna).

Point 8.4 consists of the following data requirements:
8.4.1 Earthworm – sub-lethal effects
8.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms):
8.4.2.1 Species level testing with *Folsomia candida* and *Hypoaspis aculeifer*

- *Note on 8.4.2 (and 10.4.2):*

The text of point 8.4.2 (and 10.4.2) leaves open for the national competent authorities a choice on how to require the fulfillment of this data requirement in case of foliar applications. (i.e. due to the (multiple) use of the word 'may' in the second alinea). The text therefore leaves room for two options in case of foliar applications:

A) Studies with *Folsomia candida* and *Hypoaspis aculeifer* are always required

B) Studies with *Folsomia candida* and *Hypoaspis aculeifer* are only required when:
- no data is available for *Aphidius rhopalosiphi* and *Typhlodromus pyri,* or:
- a risk is identified for *Aphidius rhopalosiphi* or *Typhlodromus pyri.*

The Ctgb working approach will be option A. The reason for this choice is as follows:

- The tests and risk assessment for *Typhlodromus* and *Aphidius* are considered not a good indicator for the risk to in-soil species, due to the different exposure route (in soil versus residues on plant leaves) and due to the different triggers that are used for risk assessment (HQ based on ER50 with trigger value 2 versus TER based on NOEC with trigger 5).
- The risk assessment for soil organisms based solely on earthworms and soil micro-organisms is, from a scientific point of view, considered as limited.

The above will be used by Ctgb in the role of EU Rapporteur Member State for Annex I listing of an active substance, or as Zonal Rapporteur Member State for authorisation of a plant protection product.

1.2.2. Data requirements for the product

The data requirements regarding the risk of the plant protection product for earthworms are described in Commission Regulation (EU) No 284/2013, point 10.4 (Effects on non-target soil meso- and macrofauna).

Point 10.4 consists of the following data requirements:
10.4.1 Earthworms
10.4.1.1 Earthworms - sublethal effects
10.4.1.2 Earthworms - field studies
10.4.2 Effects on non-target soil meso- and macrofauna (other than eartworms)
10.4.2.1 Species level testing with *Folsomia candida* and *Hypoaspis aculeifer*
10.4.2.2 Higher tier testing (soil organisms other than earthworms)

- *Note on 10.4.2:*

See note on 8.4.2 above.

1.2.3. Data requirements for metabolites

Data about the effects on earthworms are required for metabolites formed in the laboratory study into the (an)aerobic transformation route in soil. For a general discussion about metabolites see §1.2.3 in Chapter 7 Ecotoxicology; Terrestrial; Birds and mammals.

1.3. Risk assessment

The risk assessment methodology for earthworms has in EU context been elaborated in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as 56d NOEC) are presented in a list of endpoints.
The risk is assessed against the endpoints and a relevant trigger value.

Further elaborations of the EU evaluation methodology:

Persistent substances:
When in the section on fate and behaviour in the environment (Chapter 6, Persistence) it is concluded that the active substance is persistent in soil, the risk for earthworms is assessed by using the sum of the PIECsoil and PECaccumulation.

Combination toxicity
Combination toxicity must be determined when plant protection products contain several active substances. The issue of combined toxicity is further described in G 7. general introduction.

1.3.1. Agreements from 'Pesticide peer review meetings on recurring issues on ecotoxicology' and from 'Zonal harmonization workshops'

1.3.1.1 Pesticides Peer review Meetings on Recurring Issues on Ecotoxicology

Pesticides Peer review Meeting 133 on Recurring Issues on Ecotoxicology held in 2015:

Correction factor of 2 for organic matter in soil organism toxicity tests
In the general pesticides peer review meeting on general recurring issues in ecotoxicology (Pesticide Peer Review Meeting 133, 23-25 September 2015) it was concluded to retain the correction factor of 2 for all first tier soil organism studies when relevant (i.e. LogPow>2), i.e. also for studies with organic matter % lower than 5%.

Pesticides Peer review Meeting 185 on Recurring Issues on Ecotoxicology held in 2019:

In the Pesticides Peer review Meeting 185 on Recurring Issues on Ecotoxicology (EFSA Supporting publication 2019:EN-1673), the agreements that were reached are presented below. These agreements apply to EU active substance dossiers submitted from 7 July 2019 and national product assessment submitted from 1 january 2020:

- Minimum detectable difference in higher tier field studies:
  It was overall considered premature to recommend calculating the MDD for higher tier studies with soil organism, as criteria to help interpret these MDD values are currently lacking (e.g. classes of MDD, minimum number of taxa with an acceptable MDD).

According to Ctgb, this agreement does not exclude the possibility that an MDD analysis could provide useful information on a case-by-case basis.

- Evaluation of earthworm field studies:

It was agreed to follow the guidance from De Jong et al. (2006) for reporting the studies in the RARs/DARs, but some modifications were proposed. The elements agreed upon have been in included in a template in Appendix I from the report of the meeting (EFSA Supporting publication 2019:EN-1673). It was recommended by the meeting that the template in this Appendix is followed when reporting the studies in the RARs/DARs. It was also noted that the agreed approaches on how to assess the reliability of earthworm field tests might need to be adjusted once the new OECD guideline comes into force.

1.3.1.2 Zonal harmonisation workshops

Bullet points from the final agreements from the 4th CZHW in Ecotoxicology, Dessau, Sept 20-21 2018

Bullet point 6: Soil organisms: Natural soils in the refined risk assessment for in-soil organisms (4thCZHW topic #34)

At the 4th CZHW in ecotoxicology, Sept 20-21 2018 the MS experts in ecotoxicology agreed that testing one single natural soil additionally to an artificial soil is not suitable for:

i) skipping the correction factor of 2 for the endpoints of lipophilic substances and
ii) overwriting toxicity endpoints based on artificial test soils by the test result of a natural soil

The meeting could not agree in a minimal number of different test soils, which would be appropriate in order to refine the risk for soil organisms. MS concluded on not using natural soils for the risk assessment as long as no further results from ongoing research projects are available.

Bullet points from the final agreements from the 6th CZHW in Ecotoxicology, Ede, June 8-10 2022

The agreements of this 6th CZHW in Ecotoxicology apply for product dossiers (point 7) and product and active substance dossiers (point 8) submitted from 1 September 2023.

Bullet point 7: Field studies with soil mesofauna The MS agreed:

(1) It is recommended that the study will be started in spring, however, exceptions are possible (e.g. summer) when it is proven that the community is adequately representative in terms of abundance and species diversity (see point 2) and that exposure was sufficient. It is further noted that the study should adequately represent the realistic field effects considering the GAP. In particular, the potential for recovery after application during autumn is potentially lower. For a GAP with applications in autumn, the study may therefore need to be performed in autumn, depending upon e.g. the types of effects observed.

(2) It is recommended that Oribatid and Gamasid mites must be included in the determination. If possible, other Co-horts like Prostigmata (Trombidiformes), Astigmata and Uropodina should be included. Determination should be done at species level, if possible.
(3) It is recommended two soil layers will be included: 0-5 and 0-10 cm. In some cases, it might be necessary to check other soil layers of 0-1 or 0-2.5 cm, e.g., in case of (a) highly adsorptive substances and (b) substances with a high potential for accumulation.

Bullet point 8: Analytical measurements toxicity studies with soil organisms

1) The majority of CZ MS agreed to consider the substance “unstable” if the tier 1 (laboratory) DT90 does not cover the exposure phase of the test. This decision will be used at the active substance and product level.
2) The analytical measurements must be performed at least at the start, middle, and end of the study. The intermediate measurements should be designed to capture the degradation of the substance (i.e., substance property dependent). Depending upon substance degradation it could be concluded that an “end” measurement is not relevant/necessary.
3) The TWA or geometric mean measured concentration should be calculated over the duration of the test and used if the concentration falls under 80% of nominal.
4) If analytical measurements are not available when they should be according to the aforementioned criteria, the reliability of the test would be lower and in most cases a new study including analytical measurements would be required.
5) For products containing multiple actives where only “unstable” substance(s) is (are) measured, appendix J of EFSA (2019)[1] shall be followed to calculate the appropriate endpoint.

[1] EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, June 2019

1.4. Approval

This section describes the approval criteria for active substances (section 1.4.1) and plant protection products (section 1.4.2 and 1.4.3). For the EU approval procedure of active substances a representative formulation has to be included in the dossier. Therefore section 1.4.1 to 1.4.3 apply. For the zonal applications of plant protection products only section 1.4.2 and 1.4.3 apply.

1.4.1. Approval of the active substance

Annex II of Regulation (EC) No 1107/2009 provides the procedure and criteria for the approval of an active substances, safeners and synergists.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance.

1.4.2. Evaluation of plant protection products

The principles for the evaluation regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles

for evaluation for earthworms and other non target soil macro-organisms are included in Part B Evaluation, point 2.5.2.5.

1.4.3. Decision making for plant protection products

The principles for the decision-making regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles for decision making for soil micro-organisms are included in Part C Decision making, point 2.5.2.5.

Note on 2.5.2.5:
Soil meso- and macro organisms other than earthworms are not explicitly mentioned under 2.5.2.5, however the common approach in EU-risk assessment for these organisms is to use the same triggers for the toxicity/exposure ratio as for earthworms (i.e. a trigger value of 5 for chronic effects).

1.5. Developments

New guidance is in development at EFSA with the revisions of the Guidance documents on Persistence (9188/VI/97 rev.8) and Terrestrial Ecotoxicology (SANCO/10329/2002). An EFSA opinion on the science behind the soil risk assessment has recently been published on the EFSA website for public consultation (Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms). Until the revision of these guidance documents is finished, the methods as described in 1.3 and 1.4 are used for risk assessment.

II SOIL MICRO-ORGANISMS

1 EU FRAMEWORK

In this document, the procedures for the evaluation and re-evaluation of active substances as laid down in the EU are described; the NL procedure for evaluation of a substance is reverted to when no EU procedure has been laid down. The NL-procedure for the evaluation of a substance is described in §2 - §2.5 of part 2 of the Evaluation Manual (plant protection products). This document aims to give procedures for the approval of active substances and inclusion in Commission Implementing Regulation (EU) No 540/2011 .

Notifiers preparing an assessment report for active substances need to comply with the relevant guidance, instructions and format laid down in the EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances.

1.1. Introduction

Effects of plant protection products on soil micro-organisms are included in the assessment if the substance or product reaching the soil cannot be ruled (see Chapter 6 Fate and behaviour in the environment; Persistence).

Guidelines for the risk assessment for soil micro-organisms are described in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).

Soil micro-organisms play a vital role in the ecosystem. For this reason plant protection products should cause no unacceptable and prolonged effects on soil micro-organism populations, not in the treated part and not beyond. The risk assessment of the use of pesticides for soil micro-organisms serves to prevent that products which present an unacceptable risk to the environment will reach the market. The risk to soil micro-organisms must be evaluated in case there is a chance of exposure of these organisms.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described under NL framework (§2 - §2.5). The national further provisions can also be used for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011.

1.2. Data requirements

In order to qualify for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011 a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the protocol of experiments are mentioned in Commission Communication 2013/C 95/01.

When according to the applicant a certain study is not necessary, a relevant scientific justification can be provided for the non-submission of the particular study.

1.2.1. Data requirements for the active substance

The data requirements regarding the risk of the active substance for soil micro-organisms are described in Commission Regulation (EU) No 283/2013, point 8.5 (effects on soil non-target micro-organisms).

Point 8.5 consists of the following data requirement:
Effects on soil nitrogen transformation

1.2.2. Data requirements for the product

The data requirements regarding the risk of the plant protection product for soil micro-organisms are described in Commission Regulation (EU) No 284/2013, point 10.5 (Effects on soil nitrogen transformation).

Point 10.5 consists of the following data requirement:
Effects on soil nitrogen transformation

1.2.3. Data requirements for metabolites

Data about the effects on soil micro-organisms are required for metabolites that are formed in the laboratory study into the (an)aerobic transformation route in the soil. For a general discussion about metabolites, see §1.2.3 in Chapter 7 Ecotoxicology; Terrestrial; Birds and mammals.

1.3. Risk assessment

The risk assessment methodology for soil micro-organisms has in EU context been elaborated in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final).

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (nitrogen formation rate in comparison with the untreated control) are presented in a list of endpoints. Risk is assessed against the endpoints.

Persistent substances:
When in the section on fate and behaviour in the environment (Chapter 6, Persistence) it is concluded that the active substance is persistent in soil, the risk for soil micro-organisms is assessed by using the sum of the PIECsoil and PECaccumulation.

Combination toxicity
Combination toxicity must be determined when plant protection products contain several active substances. The issue of combined toxicity is further described in G 7. general introduction.

1.3.1.1 Zonal harmonisation workshops

Bullet points from the final agreements from the 6th CZHW in Ecotoxicology, Ede, June 8-10 2022

The agreements of this 6th CZHW in Ecotoxicology apply for product dossiers submitted from 1 September 2023.

Bullet point 9: Soil nitrification studies-time intervals for effect calculations

The MS agreed to always use the intermediate time intervals for expression of the effect endpoints for risk assessment.

1.4. Approval

This section describes the approval criteria for active substances (section 1.4.1) and plant protection products (section 1.4.2 and 1.4.3). For the EU approval procedure of active substances a representative formulation has to be included in the dossier. Therefore section

1.4.1 to 1.4.3 apply. For the zonal applications of plant protection products only section 1.4.2 and 1.4.3 apply.

1.4.1. Approval of the active substance

Annex II of Regulation (EC) No 1107/2009 provides the procedure and criteria for the approval of an active substances, safeners and synergists.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance.

1.4.2. Evaluation of plant protection products

The principles for the evaluation regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles for evaluation for soil micro-organisms are included in Part B Evaluation, point 2.5.2.6.

1.4.3. Decision making for plant protection products

The principles for the decision-making regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles for decision making for soil micro-organisms are included in Part C Decision making, point 2.5.2.6.

1.5. Developments

New guidance is in development at EFSA with the revisions of the Guidance documents on Persistence (9188/VI/97 rev.8) and Terrestrial Ecotoxicology (SANCO/10329/2002). An EFSA opinion on the science behind the soil risk assessment has recently been published on the EFSA website for public consultation (Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms). Until the revision of these guidance documents is finished, the methods as described in 1.3 and 1.4 are used for risk assessment.

2. REFERENCES

1. SETAC (1995) Procedures for assessing the environmental fate and ecotoxicity of pesticides (ISBN 90-5607-002-9).