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

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.

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 Appendix A.

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%. This conclusion applies to EU a.s. dossiers.

In line with the Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms - - 2017 - EFSA Journal - Wiley Online Library , Ctgb notes that the factor of two has no scientific basis for assessments at the European level because it is based on the ratio of the organic matter content of the test medium (10%) and the organic matter content of the old Dutch standard soil (4.7%) and not on that of the proposed exposure scenarios. This also means that for national risk assessments for The Netherlands, using the correction factor of 2 for studies with an organic matter % of 5% is scientifically not justified.

Therefore, for zonal dossiers Ctgb will use a pragmatic approach:
- When Ctgb is zRMS, Ctgb will apply the factor of 2 irrespective of %OM, referring to the agreement from the general Expert meeting 133. However, when the trigger is not met, the factor is lowered to 1 for studies with 5% OM as a ‘ higher tier’ approach, since we assume an organic matter % of 4.7% for standard Dutch agricultural soils. Whether this is acceptable for other MS in the Central Zone can be adressed in the commenting round.

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 .

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 Appendix A.

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).