

**Evaluation Manual
for the Authorisation
of Plant protection products and Biocides
according to Regulation No 1107/2009**

NL part

Plant protection products

Chapter 7 Ecotoxicology: terrestrial; soil organisms

version 2.0; January 2014

ctgb

**Board
for the Authorisation
of plant protection products and Biocides**

Chapter 7 Ecotoxicology; terrestrial; soil organisms

Category: Plant protection products

General introduction	3
I Earthworms and other non-target soil meso- and macrofauna.....	3
2. NL framework	3
2.1. Introduction	4
2.2 Data requirements	4
2.3 Risk assessment.....	4
2.4 Approval.....	4
2.4.1 Trigger values, criteria and decision on approval	5
2.5 Developments	5
II soil micro-organisms	6
2 NL framework	6
2.1 Introduction	6
2.2 Data requirements	7
2.3 Risk assessment.....	7
2.4 Approval.....	7
2.4.1 Trigger values, criteria and decision on approval	7
2.5 Developments	7
3 Appendices.....	8
4 References	10

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the effects on soil organisms of a plant protection product and its active substance in the NL framework (§2 - §2.5).

Substances that are approved under Regulation (EC) No 1107/2009 [1] and were approved under Directive 91/414/EEC [2] are included in Commission Implementing Regulation (EU) No 540/2011 [3].

The chapter describes the procedures following the data requirements as laid down in Commission Regulation (EU) No 283/2013 for active substances and in Commission Regulation (EU) No 284/2013 for plant protection products. These data requirements apply for active substances submitted after 31 December 2013 and for plant protection products submitted after 31 December 2015.

A concept guidance is available on the interpretation of the transitional measures for the data requirements for chemical active substances according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509/2013 – rev. 0.1).

For further information on the former data requirement as laid down in Commission Regulation (EU) No 544/2011 for active substances and in Commission Regulation (EU) No 545/2011 we refer to the Evaluation Manual for Authorisation of plant protection products according to Regulation (EC) No 1107/2009 version 1.0

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

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for plant protection products based on existing substances, included Commission Implementing Regulation (EU) No 540/2011 [3] and new active substances.

A new substance is a substance not authorised in any of the Member States of the EU on 25 July 1993.

The plant protection product that contains such substances may be authorised if the criteria laid down in the Regulation (EC) No 1107/2009 [1] are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) [4]. The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) 284/2013 [6] implementing Regulation (EC) No 1107/2009 [1] (see Application Form and corresponding instructions).

A Member State may deviate from the EU evaluation on the basis of agricultural, phytosanitary and ecological, including climatological, conditions which are specific for the Netherlands.

The NL framework describes the data requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national approval framework or when the national framework has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter can also be used for evaluation of a substance for approval, and consequently inclusion in Commission Implementing Regulation

(EU) No 540/2011 [3] in case no European procedure has been described.

2.1. Introduction

This chapter describes the data for earthworms for which specific rules apply in the national approval framework or when the national framework has been elaborated in more detail than the EU framework.

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 which 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. The risk to earthworms does not need to be evaluated (see Appendix 1) when it is demonstrated that it can be ruled out that the active substance reaches the soil.

The sublethal data on earthworms are used in the higher tier risk assessment for persistence (see Chapter 6 Behaviour and fate in the environment; Behaviour in soil; Persistence).

The calculated concentration in soil (PEC_{soil}) is also used for the risk assessment for earthworms. The calculation method for the PEC_{soil} is presented in Chapter 6 Behaviour and fate in the environment; Behaviour in soil; Persistence.

The aspect earthworms does not deviate from the EU evaluation methodology.

The points described in this chapter concern further elaborations of the EU procedure.

2.2 Data requirements

The data requirements for chemical plant protection products are in agreement with the provisions in EU framework (see §1.2 of the EU part). The question numbering of the NL Application Form has also been included in §1.2 of the EU part.

NL-specific data requirements and further interpretations of the EU data requirements are given in the text below.

Experiments carried out after 25 July 1993 must have been carried out under GLP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

The studies must be carried out in compliance with the applicable guidelines. A review of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 7.

2.3 Risk assessment

The national evaluation methodology for earthworms follows the EU framework (see §1.3 of the EU part). In addition, the text below elaborates specific aspects that have not been elaborated in EU framework.

2.4 Approval

The evaluation of products on the basis of existing active substances already included in Commission Implementing Regulation (EU) No 540/2011 [3] or new substances, has been laid

down in Regulation (EC) No 1107/2009 [1]. Where no European methodology is agreed upon, a national methodology is applied as described in the Plant protection product and Biocides Decree (Bgb) [4]. .

2.4.1 *Trigger values, criteria and decision on approval*

For the criteria, trigger values and decision on approval for earthworms for the national authorisation for the national authorisation reference is made to the EU part (§1.4.1 and §1.4.2).

2.5 Developments

-

II SOIL MICRO-ORGANISMS

2 NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for plant protection products based on existing substances, included in Commission Implementing Regulation (EU) No 540/2011 [3], and new active substances.

A new substance is a substance not authorised in any of the Member States of the EU on 25 July 1993.

The plant protection product that contains such substances may be authorised if the criteria laid down in Regulation (EC) No 1107/2009 [1] are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) [4]. The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) 284/2013 [6] implementing Regulation (EC) No 1107/2009 [1] (see Application Form and corresponding instructions).

A Member State may deviate from the EU evaluation on the basis of agricultural, phytosanitary and ecological, including climatological, conditions which are specific for the Netherlands.

The NL framework describes the data requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national approval framework or when the national framework has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter can also be used for evaluation of a substance for approval, and consequently inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] in case no European procedure has been described.

2.1 Introduction

This chapter describes the data for soil micro-organisms for which specific rules apply in the national approval framework or when the national framework has been elaborated in more detail than the EU framework.

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-organisms, 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 that 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. Where it is demonstrated that it is ruled out that the active substance reaches the soil, the risk to soil micro-organisms needs no evaluation (see Appendix 1).

The data on soil micro-organisms are used in the higher tier risk assessment for persistence (see Chapter 6 Fate and behaviour in the environment; Behaviour in soil; Persistence).

There is for the aspect soil micro-organisms no deviation from the EU evaluation methodology.

The decision tree with corresponding explanatory notes is presented in Appendix 3 to the EU-part of this chapter.

2.2 Data requirements

The data requirements for chemical plant protection products are in accordance with the provisions in EU framework (see §1.2 of the EU part).

NL-specific data requirements and further interpretations of the EU data requirements are given in the text below.

Experiments carried out after 25 July 1993 must have been carried out under GLP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

The studies must be carried out in compliance with the applicable guidelines. A review of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 7.

2.3 Risk assessment

The evaluation methodologies for chemical plant protection products comply with the description under EU framework (see §1.3 of the EU part).

NL-specific evaluation elaborations of the EU procedure are presented in the text below.

Further elaborations of the EU evaluation methodology

Combination toxicity

Combination products are formulated plant protection products that contain more than one active substance. Combinations of plant protection products of which the combination (tank mix) is recommended in the directions for use are also considered as combination products.

In the evaluation of the side-effects of combination products on non-target organisms the question arises whether the risk must be estimated on the basis of a toxicity test with the combination product or whether a reasonable risk estimate can be made on the basis of the toxicity data of the separate active substances.

There is no European guidance in the field of combination toxicology.

In the case of soil micro-organisms the endpoints from the toxicity tests are expressed in effect percentages, at a certain dose. It is not possible to determine the combination toxicity with these endpoints.

For products with several active substances it is therefore in principle preferred to conduct the tests for soil micro-organisms with the product instead of the active substance.

2.4 Approval

The evaluation of products on the basis of existing active substances already included in Commission Implementing Regulation (EU) No 540/2011 [3], or new substances, has been laid down in Regulation (EC) No 1107/2009 [1]. Where no European methodology is agreed upon, a national methodology is applied as described in the Plant protection product and Biocides Decree (Bgb) [4].

2.4.1 Trigger values, criteria and decision on approval

For the criteria, trigger values and decision on approval for non-target soil micro-organisms for the national authorisation reference is made to the EU part (§1.4.1 and §1.4.2).

2.5 Developments

None.

3 APPENDICES

Appendix 1 Can it be ruled out that the substance reaches the soil? 9

Appendix 1 Can it be ruled out that the substance reaches the soil?

To answer the above question it is important whether the substance, during or after the application in a not entirely closed system consistent with good agricultural practice, comes into contact with the soil or not.

The first thing that matters is whether the application takes place in the open, or in enclosed spaces (greenhouses (cultures on substrate), barns, bee hives etc.). During applications in enclosed spaces, it is not ruled out *a priori* that the product reaches the soil. This can only be ruled out if the applied water is collected for re-use, or is discharged to a sewage treatment plant in a controlled manner. In the other cases of treatment in enclosed spaces, persistence is relevant.

During outdoor use, the aspect persistence is relevant for nearly all applications. Only for a number of specific application techniques (treatment of wounds by pasting, injection of trees etc.), and applications where the water is collected for re-use or is discharged to a sewer, can it be ruled out that the product reaches the soil.

There are uses where the actual use of the plant protection product takes place at another location, other than the crop cultivation itself (seed treatment, treatment of propagation material, tray treatment etc.). In those cases, the situation of the crop cultivation itself should serve as a basis. This means that, in the case of treated seed or other propagation material, it is not ruled out that the substance reaches the soil.

4 REFERENCES

- 1 Regulation (EC) No 1107/2009, <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=504604%3Acs&pos=1&page=1&lang=en&pgs=10&nbl=1&list=504604%3Acs%2C&hwords=&action=GO&visu=%23texte>
- 2 Directive 91/414/EEC, <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=172911%3Acs&pos=3&page=1&lang=en&pgs=10&nbl=3&list=447073%3Acs%2C185439%3Acs%2C172911%3Acs%2C&hwords=&action=GO&visu=%23texte>
- 3 Commission Implementing Regulation (EU) No 540/2011, <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574460%3Acs&pos=6&page=1&lang=en&pgs=10&nbl=6&list=646199%3Acs%2C628324%3Acs%2C615541%3Acs%2C607847%3Acs%2C607130%3Acs%2C574460%3Acs%2C&hwords=&action=GO&visu=%23texte>
- 4 Bgb: Plant protection products and Biocides Decree. See www.overheid.nl/wetten
- 5 Commission Regulation (EU) No 283/2013, <http://eur-lex.europa.eu/Notice.do?val=724582:cs&lang=en&list=729945:cs,724582:cs,&pos=2&page=1&nbl=2&pgs=10&hwords>
- 6 Commission Regulation (EU) No 284/2013, <http://eur-lex.europa.eu/Notice.do?val=724566:cs&lang=en&list=729902:cs,724566:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=>