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

NL part

Plant protection products

Chapter 7 Ecotoxicology; terrestrial; soil organisms

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Board for the Authorisation of plant protection products and Biocides

Chapter 7 Ecotoxicology; terrestrial; soil organisms

Category: Plant protection products

Important changes in the Evaluation Manual

Evaluation manual PPP NL part Chapter 7 Ecotoxicology; terrestrial;Soil organisms			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014		
2.1	October 2016		No major changes, only formatting and updating references to Regulation (EC) No 1107/2009
2.2	March 2019	2	Bgb link updated
		All paragraphs	Links checked and updated

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).

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 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 are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) . The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 implementing Regulation (EC) No 1107/2009 (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 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 when it is demonstrated that it can be ruled out that the active substance reaches the soil (see Chapter 6 Fate and behaviour in the environment; Persistence).
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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).
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.

2.3 Risk assessment

The national evaluation methodology for earthworms follows the EU framework (see §1.3 of the EU part).

2.4 Approval

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

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 (§1.4.1and §1.4.2).

2.5 Developments

No Dutch specific developments. See EU-part for EU 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 Commission Implementing Regulation (EU) No 540/2011 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 are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree). The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 implementing Regulation (EC) No 1107/2009 (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 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 Chapter 6 Fate and behaviour in the environment; Persistence).

For the aspect soil micro-organisms there are no deviations from the EU evaluation methodology.

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.

2.3 Risk assessment

The national evaluation methodology for soil micro-organisms follows the EU framework (see §1.3 of the EU part).

2.4 Approval

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

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

No Dutch specific developments. See EU-part for EU developments.