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 1.0; January 2013

ctgb

Board
for the Authorisation
of plant protection products and Biocides

Chapter 7 Ecotoxicology; terrestrial; soil organisms

Category: Plant protection products

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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].

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

I EARTHWORMS

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 pesticide 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 544/2011 [5] and Commission Regulation (EU) 545/2011 [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.

The decision tree with corresponding explanatory notes is presented in Appendix 2.
This decision tree summarises the decision scheme for earthworms.
The decision tree is in line with EU guidance, except for the part with the triggers for a sublethal toxicity test (see §2.2).

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.

Further elaboration EU data requirements
The following is relevant for earthworms in as far as the trigger for the sublethal toxicity test is concerned:
The following situation is not mentioned in the Guidance Document on Terrestrial Ecotoxicology [7]: 100 d ≤ DT_{90} (field) ≤ 365 d and the number of applications per season is **1** or **2**. In addition, according to the Guidance Document a case-by-case decision must be made for the situation DT_{90} (field) between 100 and 365 days and/or the number of applications per season between 3 and 6. For the NL evaluation the situations above are therefore elaborated. The sublethal toxicity test should in case of these situations be carried out if the following applies:

- 100 d ≤ DT90(field) ≤ 365 d and 3 ≤ frequency ≤ 6 and the acute TER (toxicity exposure ratio = LC50/PIEC) is higher than 10 and lower than or equal to 1000;
- 100 d ≤ DT90(field) ≤ 365 d and frequency = 1 or 2 and the acute TER is higher than 10 and lower than or equal to 100;
- DT90(field) < 100 d and 3 ≤ frequency ≤ 6 and the acute TER is higher than 10 and lower than or equal to 100.

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.

Further elaborations of the EU evaluation methodology:

Combination toxicity
Combination toxicity must be determined when plant protection products contain several active substances. Combinations of plant protection products of which the combination (tank mix) is recommended in the directions for use are also considered as combination products.

When evaluating the side effects of combination products on non-target organisms, the question arises whether the risk estimate must be based on 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.

It is possible to base the risk assessment of a combination product on toxicity tests with the formulation.
The *acute* toxicity test can lead to varying results because the quantity and the quality of the co-formulants may not be constant and the formulation may change the availability of the active substances. For the acute risk assessment, the combination toxicity on the basis of the tests with the product is compared with the combination toxicity based on the toxicity research with the separate active substances.

In the assessment the risk of the combination products is determined on the basis of the lowest TER value, as calculated by the toxicity of the separate active substances or the toxicity of the product.

The fact that the ratio between the active substances changes by differences in sorption and degradation rate plays a role in establishing *chronic* toxicity. This means that the concentration of the combination product in the environment (the PEC) cannot be predicted because the separate active substances may behave differently after application.
For chronic risk assessment it is therefore preferred to determine the toxicity of the combination product on the basis of toxicity research with the separate active substances.

Combination toxicity is determined on the basis of concentration addition.
In theory, three different effects are to be expected when two or more substances are used in a mixture:
- the substances may weaken each others' toxic effects (antagonism)
- the effects of the substances may be additive
- the substances may potentiate each others' toxic effects (synergism).

Although the effects of mixtures of active substances in plant protection products have only been studied to a very limited extent and not for all relevant species and toxicological endpoints it is expected that active substances in a combination product or tank mix together contribute to the toxicity of that product or that tank mix. The extent to which the active substances are contributing is poorly known. The available data indicate that also in case of partial addition the extent of combination toxicity does not deviate strongly from concentration addition. In view of these considerations the evaluation of the toxicity data of combination products or tank mixes is based on concentration addition. In case of concentration addition each substance contributes to the total toxicity of a mixture in proportion to its concentration. The calculation method is given Appendix C.

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 (§1.4.1and §1.4.2).

2.5 Developments

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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 pesticide 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 544/2011 [5] and Commission Regulation (EU) 545/2011 [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). 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 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 (§1.4.1and §1.4.2).

2.5 Developments

None.

3 APPENDICES

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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.

Appendix 2 Explanatory notes decision tree earthworms

1) Data about the effects on earthworms are required for each active substance/product unless it is demonstrated that it can be ruled out that the active substance reaches the soil. See Appendix IV-1 for answering this question.

   Data about the effects on earthworms are also required for metabolites 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.

2) Suitable guidelines for the acute toxicity test for earthworms are ISO guideline 11268-1 and OECD 207. The test yields an LC_{50} value over 14 d for the test substance. LC_{50} values determined in another way, e.g. those obtained in the filter paper contact-test or in the so-called artisol (a silica-gel medium) are not suitable.
   Exposure in these studies deviates strongly from that in soil, which makes extrapolation of such results to soil impossible.

   The availability. and thus the toxicity, of the active substance in the soil may depend on the amount of organic matter in the soil (f_{OC}) because the active substance may adsorb to organic matter. The standard test soil in earthworm laboratory tests has a higher f_{OC} than many natural soils, which may result in a higher LC_{50} or NOEC than when the test had been carried out in natural soil. The value of the LC_{50} is therefore adjusted for the difference between organic matter in the test soil and in the reference soil. This means that the LC_{50} value is divided by the percentage organic matter in the test soil (usually 10 %), and multiplied by the percentage organic matter in the reference soil (4.7 %). The adjustment is only carried out where $K_{ow} > 2$ [1].

3) The acute endpoint must be tested against the initial concentration in the soil (PIEC), because this is a static test in which the substance is applied once at the start of the test.

   For substances that are sprayed, the concentration in the soil immediately after a single application is determined by (see also Chapter 6 Behaviour and fate in the environment; Behaviour in soil; Persistence):

   $$PIEC_{soil} = D * (1- f_{int} – 0.1) / (100 * d * \rho) \quad (1)$$

   where:
   $PIEC_{soil}$ = Predicted Initial Environmental Concentration (mg a.s./kg soil)
   D = dose (g/ha)
   f_{int} = crop interception (fraction)
   d = depth (cm)
   ρ = dry bulk density of the soil (g/cm^3)

[1] The proposed conversion only applies for products/substances that are totally or mainly bound to the organic matter fraction of the soil. Such a conversion based on differences in organic matter concentrations are less suitable for substances or products of which the behaviour strongly depends on pH (e.g. for dissociating substances) or the clay content of the soil.

A dry bulk density of the soil of 1.5 g/cm^3 and the dose reaching the top 5 cm of the soil (d = 5 cm) is assumed. For substances that are incorporated into the soil, the $PIEC_{soil}$ is determined for the top 20 cm of the soil. In addition, 10% spraying loss is assumed.

Further information on the determination of the fraction intercepted by the crop (f_{int}) is given in Appendix 4 in the EU part to Chapter 6 Behaviour and fate in the environment; Behaviour in soil; Persistence).

For substances that are applied several times per season, the following equation is used to determine the $PIEC_{soil}$ immediately after the last application:

$$PIEC_{soil}(\text{last application}) = PIEC_{soil}(\text{first application}) * (1-e^{-nki})/(1-e^{-ki})$$

where:
n = number of applications
k = ln2/DT50 (day^{-1})
i = interval between two subsequent applications (days)
DT50 = half-life value in the soil (days)

Degradation of the substance in the period between applications is taken into account on the basis of DT50, interval between applications and frequency. Where adequate field data are available, these may be applied for the half-life value (see the FOCUS document for further details, to which reference is made in chapter 6 Behaviour and fate in the environment; Behaviour in soil; Persistence [8]

Combination toxicity must be determined for a plant protection product with several active substances as well as for combinations of plant protection products of which the combination (tank mix) is recommended in the directions for use. For the acute risk assessment, the combination toxicity on the basis of the tests with the product is compared with the combination toxicity on the basis of toxicity research with the separate active substances. The lowest combination toxicity value is then used for risk assessment.

Combination toxicity is determined on the basis of concentration addition. For the calculation method see Appendix C.

4) The sublethal toxicity test must be carried out in accordance with A8.4.2a of the application form. Where log K_{ow} > 2, the endpoint (NOEC) must be adjusted for the difference in organic matter content in the test soil and the standard soil (see 2).
An ISO guideline (ISO 11268-2) is available for guidance on this study. The sublethal test must be carried out where the acute criterion is not met and this is also a trigger for certain exposure conditions (repeated or continuous exposure).

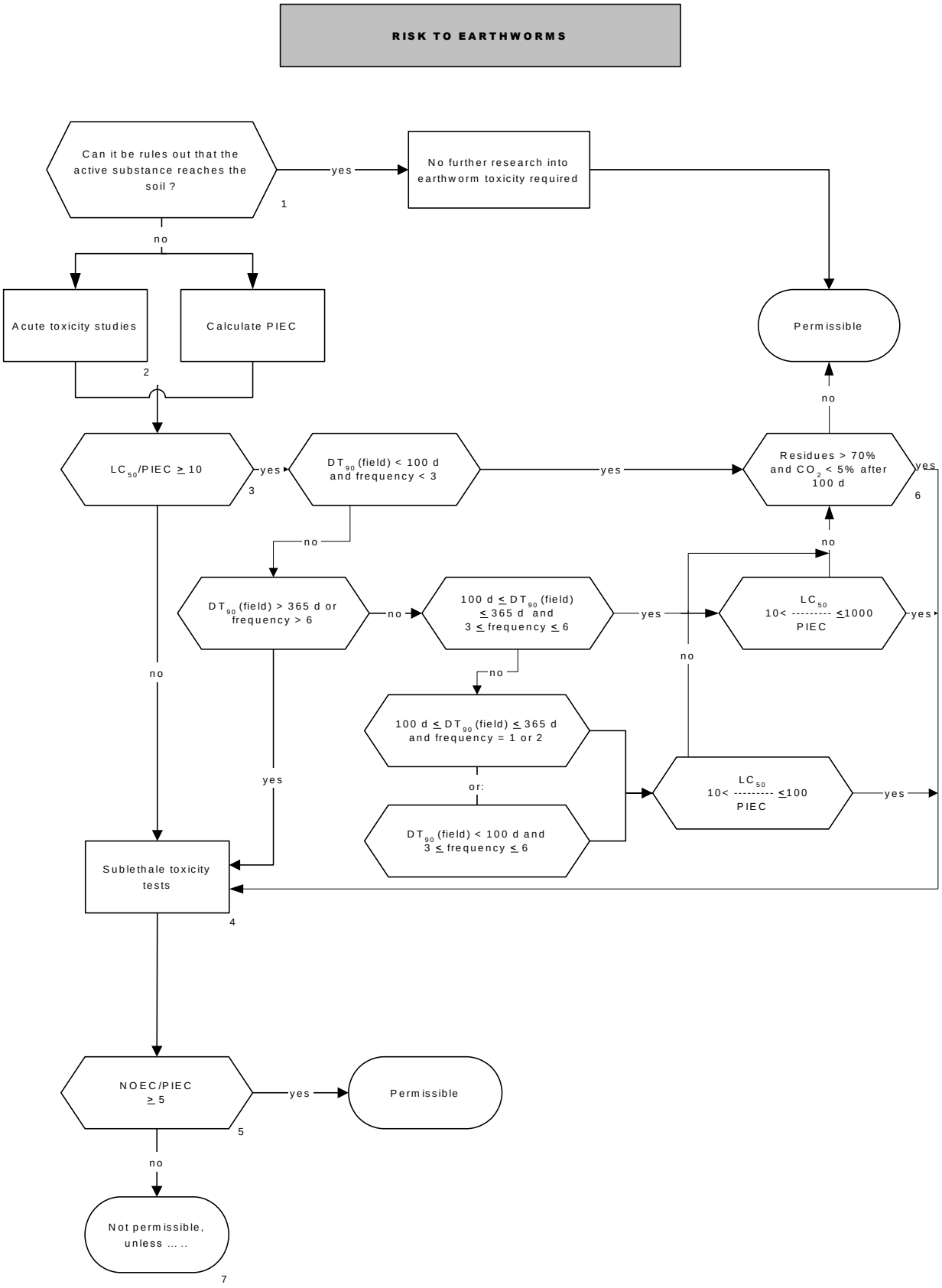
5) The sublethal endpoint must be tested against the initial concentration in the soil (PIEC), because this is a static test where the test substance is applied once at the start of the experiment.

Combination toxicity must be determined for a plant protection product with several active substances as well as for combinations of plant protection products of which the combination (tank mix) is recommended in the directions for use. For the chronic risk assessment, determination of the toxicity of the combination product through toxicity research with the separate active substances is preferred.

Combination toxicity is determined on the basis of concentration addition. For the calculation method see Appendix C.

6) The sublethal test does not need to be carried out in the case of bound residues if it can be made plausible that the bound residue will not be released.

7) A further adequate risk assessment can still demonstrate that the risk is acceptable. The further adequate risk assessment can consist of a refinement of the first-tier tests (e.g., recalculation of the effects on the basis of actual concentrations, or use of field data, or more extensive models to determine exposure). Another possibility is the performance of higher-tier studies such as (semi) field tests. An ISO guideline (ISO 11268-3) is available for the performance of field tests with earthworms. Evaluation is based on expert judgement. Where effects occur in the field test, recovery may be taken into account.
The product can be authorised if complete recovery occurs within a year.


RISK TO EARTHWORMS
Can it be rules out that the active substance reaches the soil ?
1
yes
No further research into earthworm toxicity required
no
Acute toxicity studies
Calculate PIEC
2
Permissible
LC50/PIEC ≥ 10
3
yes
DT90 (field) < 100 d and frequency < 3
yes
Residues > 70% and CO2 < 5% after 100 d
6
yes
no
no
DT90 (field) > 365 d or frequency > 6
no
100 d ≤ DT90 (field) ≤ 365 d and 3 ≤ frequency ≤ 6
yes
LC50 10< -------- ≤1000 PIEC
yes
no
no
100 d ≤ DT90 (field) ≤ 365 d and frequency = 1 or 2
or:
DT90 (field) < 100 d and 3 ≤ frequency ≤ 6
LC50 10< -------- ≤100 PIEC
yes
no
yes
Sublethale toxicity tests
4
NOEC/PIEC ≥ 5
5
yes
Permissible
no
Not permissible, unless ….
7

4 REFERENCES

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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
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4 Bgb: Plant protection products and Biocides Decree. See www.overheid.nl/wetten
5 Commission Regulation (EU) No 544/2011 of Regulation (EC) No 1107/2009, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574584%3Acs&pos=2&page=1&lang=en&pgs=10&nbl=2&list=607696%3Acs%2C574584%3Acs&hwords=&action=GO&visu=%23texte
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