

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

EU part

Plant protection products

**Chapter 7 Ecotoxicology: terrestrial; non target
arthropods and plants**

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of plant protection products and biocides**

Chapter 7 Ecotoxicology; terrestrial; non target arthropods and plants

Category: Plant Protection Products

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GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the effects on non target arthropods and plants 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 [1]. The described risk assessment in this chapter can be used for both the approval procedure for active substances as well as for zonal applications for the authorization of plant protection products (i.e. core registration reports).

Substances that are approved under Regulation (EC) No 1107/2009 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 non-target arthropods (I) and a part about non-target plants (II).

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

I NON TARGET ARTHROPODS

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 [3].

1.1 Introduction

This chapter describes the risk assessment of plant protection products for non-target arthropods.

Non-target arthropods play a vital role in the ecosystem. For this reason plant protection products should cause no unacceptable and prolonged effects on populations of non-target arthropods, not in the treated part and not beyond. An agricultural purpose is served at the same time: the protection of natural enemies in integrated pest control.

The risk to non-target arthropods must be assessed in case there is a chance of exposure of these organisms.

Guidelines for the risk assessment for non-target arthropods are given in the Guidance

Document on Terrestrial Ecotoxicology [4] in which the testing procedure is described as elaborated in the report written on the basis of the SETAC/ESCORT 2 workshop [5].

A decision tree with corresponding explanatory notes is presented in Appendix 1. This decision tree summarises the decision scheme for arthropods in non-integrated pest management systems.

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 [3] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [6] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [7] 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 [8].

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.

The data requirements, and the fact whether or not they are required for certain fields of use, and the corresponding guidelines are summarised in the overview table; see Appendix A to Chapter 7.

1.2.1 Data requirements for the active substance

The text below in grey frames has been taken from Commission Regulation (EU) No 283/2013. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given below the headings. The endpoints of the study are given as well, if relevant.

The data requirements regarding the risk of the active substance for arthropods are described in part A of Commission Regulation (EU) No 283/2013, point 8.3 (effects on arthropods).

Introduction

1. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the active substance shall be reported. This shall include all potentially adverse effects found during routine ecotoxicological investigations. Where required by the national competent authorities, additional studies, necessary to investigate the probable mechanisms involved and to assess the significance of these effects, shall be carried out and reported on.
2. The ecotoxicological assessment shall be based on the risk that the proposed active substance used in a plant protection product poses to non-target organisms. In carrying out a risk assessment, toxicity shall be compared with exposure. The general term for

the output from such a comparison is 'risk quotient' or RQ. It shall be noted that RQ can be expressed in several ways, for example, toxicity:exposure ratio (TER) and as a hazard quotient (HQ). The applicant shall take into account the information from Sections 2, 5, 6, 7 and 8.

3. It may be necessary to conduct separate studies for metabolites, breakdown or reaction products derived from the active substance where non-target organisms may be exposed and where their effects cannot be evaluated by the available results relating to the active substance. Before such studies are performed, the applicant shall take into account the information from Sections 5, 6 and 7.

Studies undertaken shall permit characterisation of metabolites, breakdown or reaction products as being significant or not, and reflect the nature and extent of the effects judged likely to arise.

4. In the case of certain study types, the use of a representative plant protection product instead of the active substance as manufactured may be more appropriate, for example testing of non-target arthropods, bees, earthworm reproduction, soil micro-flora and non-target terrestrial plants. In the case of certain plant protection product types (for example encapsulated suspension) testing with the plant protection product is more appropriate to testing with active substance when these organisms will be exposed to the plant protection product itself. For plant protection products where the active substance is always intended to be used together with a safener and/or synergist and/or in conjunction with other active substances, plant protection products containing these additional substances shall be used.
5. The potential impact of the active substance on biodiversity and the ecosystem, including potential indirect effects via alteration of the food web, shall be considered.

6. For those guidelines which allow for the study to be designed to determine an effective concentration (EC_x), the study shall be conducted to determine an EC₁₀, EC₂₀ and EC₅₀, when required, along with corresponding 95% confidence intervals. If an EC_x approach is used, a no observed effect concentration (NOEC) shall still be determined.

Existing acceptable studies that have been designed to generate a NOEC shall not be repeated. An assessment of the statistical power of the NOEC derived from those studies shall be carried out.

7. All of the aquatic toxicity data shall be used when developing a proposal for environmental quality standards (Annual Average EQS, AA-EQS; Maximum Acceptable Concentration EQS, MAC-EQS). The methodology for derivation of these endpoints is outlined in the 'Technical Guidance for Deriving Environmental Quality Standards⁽¹⁾' for the Water Framework Directive 2000/60/EC of the European Parliament and of the Council ⁽²⁾.
8. In order to facilitate the assessment of the significance of test results obtained, including the estimation of intrinsic toxicity and the factors affecting toxicity, the same strain (or recorded origin) of each relevant species shall, where possible, be used in the various toxicity tests specified.
9. Higher tier studies shall be designed and data analysed using suitable statistical methods. Full details of the statistical methods shall be reported. Where appropriate and necessary, higher tier studies shall be supported by chemical analysis to verify exposure

has occurred at an appropriate level.

10. Pending the validation and adoption of new studies and of a new risk assessment scheme, existing protocols shall be used to address the acute and chronic risk to bees, including those on colony survival and development, and the identification and measurement of relevant sub-lethal effects in the risk assessment.

Effect on arthropods
(283/2013; 8.3)

Effects on non-target arthropods other than bees
(283/2013 ; 8.3.2)

8.3. Effects on arthropods
8.3.2. Effects on non-target arthropods other than bees

Circumstances in which required

Effects on non-target terrestrial arthropods shall be investigated for all active substances except where plant protection products containing the active substance are for exclusive use in situations where non-target arthropods are not exposed such as:

- food storage in enclosed spaces that preclude exposure,
- wound sealing and healing treatments,
- enclosed spaces with rodenticidal baits.

Two indicator species, the cereal aphid parasitoid *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) and the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) shall always be tested. Initial testing shall be performed using glass plates and mortality (and reproduction effects if assessed) shall be reported. Testing shall determine a rate-response relationship and LR 50 (1), ER 50 (2) and NOEC endpoints shall be reported for assessment of the risk to these species in accordance with the relevant risk quotient analysis. If adverse effects can be clearly predicted from these studies then testing using higher tier studies may be required (see point 10.3 of Part A of the Annex to the Regulation (EU) No 284/2013 for further details).

With active substances suspected of having a special mode of action (such as insect growth regulators, insect feeding inhibitors) additional tests involving sensitive life stages, special routes of uptake or other modifications, may be required by the national competent authorities. The rationale for the choice of test species used shall be provided.

*Effects on *Aphidius rhopalosiphi**
(283/2013; 8.3.2.1)

8.3.2. Effects on non-target arthropods other than bees

A test shall provide sufficient information to evaluate the toxicity in terms of LR₅₀ and NOEC of the active substance to *Aphidius rhopalosiphi*.

Test conditions

Initial testing shall be performed using glass plates.

Result:

→ LR₅₀

Effects on Typhlodromus pyri
(283/2013; 8.3.2.2)

8.3.2. Effects on non-target arthropods other than bees

A test shall provide sufficient information to evaluate the toxicity in terms of LR 50 and NOEC of the active substance to *Typhlodromus pyri*.

Test conditions

Initial testing shall be performed using glass plates.

Result:

→ LR₅₀

1.2.2 Data requirements for the product

The text below in grey frames has been taken from Commission Regulation (EU) No 284/2013. The numbering in these grey frames follows the section numbering in this Commission Regulation.

Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given below the headings. The endpoints of the study are given as well, if relevant.

The data requirements regarding the risk of the plant protection product for arthropods are described in Commission Regulation (EU) No 284/2013, point 10.5 (effects on arthropods other than bees).

Generally, EU and OECD guidelines for the protocol of experiments are mentioned in Commission Communication 2013/C 95/02 [9].

Introduction

1. Testing of the plant protection product shall be necessary where its toxicity cannot be predicted on the basis of data on the active substance. Where testing is necessary, the aim shall be to demonstrate whether the plant protection product, taking account of content of active substance, is more toxic than the active substance. Thus bridging studies or a limit test may be sufficient. However, where a plant protection product is more toxic than the active substance (expressed in comparable units), definitive testing shall be required. Possible effects on organisms/ecosystems shall be investigated, unless the applicant shows that exposure of the organisms or ecosystems does not occur.

Tests and studies conducted using the plant protection product as test material necessary to assess the toxicity of the active substance shall be reported in the context of the relevant data requirement concerning the active substance.

2. All potentially adverse effects found during routine ecotoxicological investigations shall be reported and such additional studies, which may be necessary to investigate the mechanisms involved and assess the significance of these effects, shall be undertaken and reported.

3. Whenever a study implies the use of different doses, the relationship between dose and adverse effect shall be reported.

4. Where exposure data are necessary to decide whether a study has to be performed, the data obtained in accordance with Section 9 shall be used.

For the estimation of exposure of organisms, all information on the plant protection product and on the active substance shall be taken into account. A tiered approach shall start with default worst-case parameters for exposure and be followed by a parameter refinement based on the identification of representative organisms. Where relevant, the parameters set out in this Section shall be used. Where it appears from available data that the plant protection product is more toxic than the active substance, the toxicity data for the plant protection product shall be used for the calculation of appropriate risk quotients (see point 8 of this introduction).

5. The requirements laid down in this Section shall include certain study types that are set out in Section 8 of Part A of the Annex to Regulation (EU) No 283/2013 (such as standard laboratory tests with birds, aquatic organisms, bees, arthropods, earthworms, soil micro-organisms, soil meso-fauna and non-target plants). While each point shall be addressed, experimental data with a plant protection product shall be generated only if its toxicity cannot be predicted on the basis of data on the active substance. It may be sufficient to test the plant protection product with that species of a group that was most sensitive with the active substance.

6. A detailed description (specification) of the material used as provided for in accordance with point 1.4 shall be provided.

7. In order to facilitate the assessment of the significance of test results obtained, the same strain of each species shall, where possible, be used in the various toxicity tests specified.

8. The ecotoxicological assessment shall be based on the risk that the proposed plant protection product poses to non-target organisms. In carrying out a risk assessment, toxicity shall be compared with exposure. The general term for the output from such a comparison is 'risk quotient' (RQ). RQ may be expressed in several ways, for example, toxicity:exposure ratio (TER) and as a hazard quotient (HQ).

9. For those guidelines which allow for study to be designed to determine an effective concentration (EC_x), the study shall be conducted to determine an EC₁₀ and EC₂₀ along with corresponding 95 % confidence intervals. If an EC_x approach is used, a NOEC shall still be determined.

Existing acceptable studies that have been designed to generate a NOEC shall not be repeated. An assessment of the statistical power of the NOEC derived from those studies shall be carried out.

10. For solid formulations an assessment of the risk from dust drift on to non-target arthropods and plants shall be required. Details on the likely exposure levels shall be presented in accordance with Section 9 of this Annex. For aquatic life, the risk of movement of the whole particle as well as dust particles shall be considered. Until agreed dust dissipation rate assessments are available likely exposure levels shall be used in the risk assessment.

11. Higher tier studies using a plant protection product shall be designed and data

analysed using suitable statistical methods. Full details of the statistical methods shall be reported. Where appropriate, higher tier studies shall be supported by chemical analysis to verify exposure has occurred at an appropriate level.

12. Pending the validation and adoption of new studies and of a new risk assessment scheme, existing protocols shall be used to address the acute and chronic risk to bees, including those on colony survival and development, and the identification and measurement of sub-lethal effects in the risk assessment.

Effects on non-target arthropods other than bees
(284/2013; 10.3.2)

10.3.2 Effects on non target arthropods other than bees

Circumstances in which required

Effects on non-target terrestrial arthropods shall be investigated for all plant protection products except where plant protection products containing the active substance are for exclusive use in situations where non-target arthropods are not exposed such as:

- (a) food storage in enclosed spaces that preclude exposure;
- (b) wound sealing and healing treatments;
- (c) enclosed spaces with rodenticidal baits.

Testing shall be required if:

- the plant protection product contains more than one active substance,
- the toxicity of a plant protection product cannot be reliably predicted to be either the same or lower than the active substance tested, in accordance with the requirements set out in point 8.3.2 of Part A of the Annex to Regulation (EU) No 283/2013.

For plant protection products, two indicator species, the cereal aphid parasitoid *Aphidius rhopalosiphi* (Hymenoptera: Braconidae) and the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae) shall be tested. Initial testing shall be performed using glass plates, and both mortality and effects on reproduction (if assessed) shall be reported. Testing shall determine a rate-response relationship and LR₅₀⁽¹⁾, ER₅₀⁽²⁾ and NOEC endpoints shall be reported for assessment of the risk to these species in accordance with the relevant risk quotient analysis.

For a plant protection product containing an active substance suspected of having a special mode of action (for example insect growth regulators, insect feeding inhibitors) additional tests involving sensitive life stages, special routes of uptake or other modifications, may be required. The rationale for the choice of test species used shall be provided.

Testing shall provide sufficient information to evaluate the toxicity (mortality) of the plant protection product to arthropods in the in-field as well as in the off-field area.

Standard laboratory testing for non-target arthropods
(284/2013; 10.3.2.1)

10.3.2.1. Standard laboratory testing for non-target arthropods

The test shall provide sufficient information to evaluate the toxicity of the plant protection product to the two indicator species (*Aphidius rhopalosiphi* (Hymenoptera: Braconidae) and *Typhlodromus pyri*) (Acari: Phytoseiidae) in accordance with the relevant risk quotient

analysis.

Where adverse effects are indicated, testing using higher tier studies shall be required (see points 10.3.2.2 to 10.3.2.5) for further details. In higher tier assessment the risk quotient analysis used for standard laboratory non-target arthropod testing is not appropriate.

Extended laboratory testing, aged residue studies with non-target arthropods
(284/2013; 10.3.2.2)

10.3.2.2. Extended laboratory testing, aged residue studies with non-target arthropods

The tests shall provide sufficient information to evaluate the risk of the plant protection product for arthropods using a more realistic test substrate or exposure regime.

Circumstances in which required

Further testing shall be required where effects are seen following laboratory testing in accordance with the requirements set out in point 10.3.2.1 and where the relevant risk quotient analysis indicates a risk to the standard indicator non-target arthropod species.

Firstly, the indicator species affected in standard Tier 1 laboratory testing (point 10.3.2.1) shall be tested. In addition, where an in-field risk is indicated to one or both standard indicator species, testing of one additional species shall be required. Where an off-field risk to the standard indicator species is indicated, testing of one further additional species shall be required.

An aged residue study shall be conducted with the most sensitive species to give information on the time scale needed for potential re-colonisation of treated in-field areas.

Test conditions

(a) Extended laboratory studies

Extended laboratory studies shall be carried out under controlled environmental conditions, by exposing laboratory-reared test organisms, or field collected specimens, to fresh and dried pesticide deposits applied to natural substrates, for example leaves, plants or natural soil under laboratory or field conditions.

(b) Aged residue studies

Aged residue studies shall assess the duration of effects on in-field non-target arthropods. They shall involve ageing of plant protection product deposits under field conditions (use of rain protection may be advisable), with exposure of the test organisms on treated leaves or plants either in the laboratory, under semi-field conditions or a combination of both (such as mortality assessment under semi-field conditions and reproduction assessment under laboratory conditions).

Note Ctgb:

The text above shows that under the new data requirements, aged residue tests can not be used for the off-field risk assessment.

Semi-field studies with non-target arthropods
(284/2013; 10.3.2.3.)

10.3.2.3 Semi-field studies with non-target arthropods

The tests shall provide sufficient information to evaluate the risk of the plant protection

product for arthropods taking field conditions into account.

Circumstances in which required

Where effects are seen following laboratory testing in accordance with the requirements set out in point 8.3.2 of Part A of the Annex to Regulation (EU) No 283/2013 or point 10.3.2 of this Annex (for example relevant trigger values are breached), semi-field testing shall be required.

Test conditions

The tests shall be conducted under representative agricultural conditions and in accordance with the proposed recommendations for use, resulting in a realistic worst case study.

In semi-field testing the results from lower tier testing as well as the specific questions to be addressed shall be taken into account. In the selection of species for semi-field testing, the results from lower tier testing as well as the specific questions to be addressed shall be taken into account.

Testing shall include lethal and sub-lethal endpoints (for example integrated parameters in field studies), but such endpoints shall be interpreted with care since they are subject to high variability.

Field studies with non-target arthropods

(284/2103; 10.3.2.4)

10.3.2.4 Field studies with non-target arthropods

The tests shall provide sufficient information to evaluate the risk of the plant protection product for arthropods taking field conditions into account.

Circumstances in which required

Where effects are seen following testing in accordance with the requirements set out in point 8.3.2 of Part A of the Annex to Regulation (EU) No 283/2013 or in accordance with points 10.3.2.2 or 10.3.2.3 of this Annex, and where the relevant risk quotient analysis indicates a risk to non-target arthropods, field testing shall be required.

Test conditions

The tests shall be conducted under representative agricultural conditions and in accordance with the proposed recommendations for use, resulting in a realistic worst case study.

Field trials shall allow the determination of short- and long-term effects on naturally occurring arthropod populations of a plant protection product following application in accordance with the proposed use pattern for the plant protection product under normal agricultural conditions.

Other routes of exposure for non-target arthropods

(284/2013; 10.3.2.5.)

10.3.2.5 Other routes of exposure for non-target arthropods

Where for particular arthropods (such as pollinators and herbivores) testing conducted in accordance with points 10.3.1 and 10.3.2.1 to 10.3.2.4 is not appropriate, additional

specific testing shall be required, where there are indications that exposure by routes other than by contact occur (for example plant protection products containing active substances with systemic activity). Before undertaking such testing, the proposed design to be used shall be discussed with the relevant competent authorities.

1.2.3 Data requirements for metabolites

Except for the active substance and the product, data are also required for metabolites to which non-target arthropods may be exposed.

Arthropods may be exposed to metabolites in/on plants and to metabolites in the soil.

For metabolites in vegetation, standard laboratory tests are normally not required.

Metabolites that are the actually active molecule may be exceptions.

General guidance is given in the general part about metabolites as described under 'birds and mammals' (§1.2.3). Where higher tier studies (cage/tent/tunnel or field tests) have been carried out with the pesticide under realistic exposure conditions it can be assumed that the potential risk of metabolites has been taken into account.

Soil metabolites: these are tested with soil organisms; tests with surface dwelling soil arthropods are therefore not required.

1.3 Risk assessment

The risk assessment methodology for non-target arthropods has in EU context been elaborated in the Guidance Document on Terrestrial Ecology [5], which follows the recommendations of the ESCORT 2 workshop.

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as LR₅₀) are presented in a list of endpoints (see Appendix B to Chapter 7). The risk is assessed against these endpoints.

In Appendix 1 to this chapter, a risk assessment scheme for non-target arthropods in non-integrated pest management systems is included. This decision scheme follows the ESCORT 2 guidance, with additions and clarifications such as they have evolved in risk assessment practice over the years. Since these additions and clarifications are in line with what is currently commonly accepted (and required) during EU-reviews, they are included in the EU-part of this chapter. The scheme for integrated pest management systems is included in Appendix 1 to the NL-part of this chapter.

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

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

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance. The texts specifically applicable to the aspect arthropods are presented below.

3. Criteria for the approval of an active substance

3.1. Dossier

The dossier submitted pursuant to Article 7(1) shall be sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

3.3. Relevance of metabolites

Where applicable the documentation submitted shall be sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.

3.8. Ecotoxicology

3.8.1. An active substance, safener or synergist shall only be approved if the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The assessment must take into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.

3.8.2. An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines, it is not considered to have endocrine disrupting properties that may cause adverse effects on non-target organisms unless the exposure of non-target organisms to that active substance in a plant protection product under realistic proposed conditions of use is negligible.

1.4.1 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 [10]. These are the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects.

The specific principles Environmental effects, part Effect on species that are no target species are as regards beneficial arthropods other than honeybees in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.2.4. Member States shall evaluate the possibility of exposure of beneficial arthropods other than honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they will assess the lethal and sublethal effects on these organisms to be expected and the reduction in their activity after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

- (i) the specific information on toxicity to honeybees and other beneficial arthropods as provided for in the Annex to Regulation (EU) No 544/2011 and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - solubility in water,
 - octanol/water partition coefficient,
 - vapour pressure,

- photodegradation rate and identity of breakdown products,
 - mode of action (e. g. insect growth regulating activity);
- (iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 545/2011 such as:
- effects on beneficial arthropods other than bees,
 - toxicity to honeybees,
 - available data from biological primary screening,
 - maximum application rate,
 - maximum number and timetable of applications;
- (iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues.

1.4.2 Decision making of plant protection products

The principles for decision making as regards the effects on the environment are presented in Commission Regulation (EU) No 546/2011. These are the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects.

The specific principles Environmental effects, part Effect on species that are no target species are as regards beneficial insects other than honeybees in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.2.4. Where there is a possibility of beneficial arthropods other than honeybees being exposed, no authorization shall be granted if more than 30 % of the test organisms are affected in lethal or sublethal laboratory tests conducted at the maximum proposed application rate, unless it is clearly established through an appropriate risk assessment that under field conditions there is no unacceptable impact on those organisms after use of the plant protection product according to the proposed conditions of use. Any claims for selectivity and proposals for use in integrated pest management systems shall be substantiated by appropriate data.

1.5 Developments

In March 2010 a follow-up of ESCORT II was organised, the ESCORT III workshop. It is expected that the risk assessment will change on certain points. The report from this workshop is expected to be input for the revision of the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002), which is taking place at this moment (by EFSA).

II NON TARGET PLANTS

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 [3].

1.1 Introduction

This chapter describes the risk assessment of plant protection products for terrestrial non-target plants. Terrestrial non-target plants are plants positioned outside the treated field without being a crop.

Terrestrial non-target plants play an important role in the ecosystem. This is why plant protection products should cause no unacceptable and prolonged effects on terrestrial non-target plants.

The risk to terrestrial non-target plants must be evaluated if there is a chance of exposure of such plants.

Guidelines for the evaluation of the risk to terrestrial non-target plants are given in the Guidance Document on Terrestrial Ecotoxicology [4].

The decision tree with corresponding explanatory notes is presented in Appendix VI-1. These decision trees summarise the decision scheme for terrestrial non-target plants.

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 in Commission Implementing Regulation (EU) No 540/2011 a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [6] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [7] 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 [8].

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

The data requirements, and the fact whether or not they are required for certain fields of use, and the corresponding guidelines are summarised in the overview table; see Appendix A to Chapter 7.

1.2.1 Data requirements for the active substance

The text below in grey frames has been taken from Commission Regulation (EU) No 283/2013. The numbering in these grey frames follows the section numbering in this

Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given below the headings. The endpoints of the study are given as well, if relevant..

The data requirements regarding the risk of the active substance for non-target plants are described in Commission Regulation (EU) No 283/2013, point 8.6 (effects on terrestrial non-target higher plants).

Introduction

1. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the active substance shall be reported. This shall include all potentially adverse effects found during routine ecotoxicological investigations. Where required by the national competent authorities, additional studies, necessary to investigate the probable mechanisms involved and to assess the significance of these effects, shall be carried out and reported on.
2. The ecotoxicological assessment shall be based on the risk that the proposed active substance used in a plant protection product poses to non-target organisms. In carrying out a risk assessment, toxicity shall be compared with exposure. The general term for the output from such a comparison is 'risk quotient' or RQ. It shall be noted that RQ can be expressed in several ways, for example, toxicity:exposure ratio (TER) and as a hazard quotient (HQ). The applicant shall take into account the information from Sections 2, 5, 6, 7 and 8.
3. It may be necessary to conduct separate studies for metabolites, breakdown or reaction products derived from the active substance where non-target organisms may be exposed and where their effects cannot be evaluated by the available results relating to the active substance. Before such studies are performed, the applicant shall take into account the information from Sections 5, 6 and 7.

Studies undertaken shall permit characterisation of metabolites, breakdown or reaction products as being significant or not, and reflect the nature and extent of the effects judged likely to arise.

4. In the case of certain study types, the use of a representative plant protection product instead of the active substance as manufactured may be more appropriate, for example testing of non-target arthropods, bees, earthworm reproduction, soil micro-flora and non-target terrestrial plants. In the case of certain plant protection product types (for example encapsulated suspension) testing with the plant protection product is more appropriate to testing with active substance when these organisms will be exposed to the plant protection product itself. For plant protection products where the active substance is always intended to be used together with a safener and/or synergist and/or in conjunction with other active substances, plant protection products containing these additional substances shall be used.
5. The potential impact of the active substance on biodiversity and the ecosystem, including potential indirect effects via alteration of the food web, shall be considered.
6. For those guidelines which allow for the study to be designed to determine an effective concentration (EC_x), the study shall be conducted to determine an EC₁₀, EC₂₀ and EC₅₀, when required, along with corresponding 95 % confidence intervals. If an EC_x approach is used, a no observed effect concentration (NOEC) shall still be determined.

Existing acceptable studies that have been designed to generate a NOEC shall not be repeated. An assessment of the statistical power of the NOEC derived from those studies shall be carried out.

7. All of the aquatic toxicity data shall be used when developing a proposal for environmental quality standards (Annual Average EQS, AA-EQS; Maximum Acceptable Concentration EQS, MAC-EQS). The methodology for derivation of these endpoints is outlined in the 'Technical Guidance for Deriving Environmental Quality Standards⁽¹⁾' for the Water Framework Directive 2000/60/EC of the European Parliament and of the Council ⁽²⁾.
8. In order to facilitate the assessment of the significance of test results obtained, including the estimation of intrinsic toxicity and the factors affecting toxicity, the same strain (or recorded origin) of each relevant species shall, where possible, be used in the various toxicity tests specified.
9. Higher tier studies shall be designed and data analysed using suitable statistical methods. Full details of the statistical methods shall be reported. Where appropriate and necessary, higher tier studies shall be supported by chemical analysis to verify exposure has occurred at an appropriate level.
10. Pending the validation and adoption of new studies and of a new risk assessment scheme, existing protocols shall be used to address the acute and chronic risk to bees, including those on colony survival and development, and the identification and measurement of relevant sub-lethal effects in the risk assessment.

Effects on terrestrial non-target higher plants

(283/2013; 8.6)

Summary of screening data

(283/2013; 8.6.1)

8.6 Effects on terrestrial non-target higher plants

8.6.1 Summary of screening data

The information provided shall be sufficient to permit the evaluation of effects of the active substance on non- target plants.

Circumstances in which required

Screening data shall establish whether test substances exhibit herbicidal or plant growth regulatory activity. The data shall include testing from at least six plant species from six different families including both mono- and dicotyledons. The tested concentrations and rates shall be equal or higher than the maximum recommended application rate and at a rate either to simulate use pattern under field conditions, with testing conducted after the final treatment, or at a rate applied directly that takes in to account the accumulation of residues following multiple applications of the plant protection product. If screening studies do not cover the specified range of species or the necessary concentrations and rates, tests as set out in point 8.6.2 shall be carried out.

For assessment of active substances with herbicidal or plant growth regulatory activity

screening data shall not be used. Point 8.6.2 shall apply.

Test conditions

A summary of available data from tests used to assess biological activity and dose range finding studies, whether positive or negative, which may provide information with respect to possible impact on other non- target flora, shall be provided, together with an assessment as to the potential impact on non-target plant species.

These data shall be supplemented by further information, in summary form, on the observed effects on plants during the course of field testing, namely efficacy, residues, environmental fate and ecotoxicological field studies.

Testing on non-target plants (283/2013; 8.6.2)

8.6.2 Testing on non-target plants

A test shall provide the ER₅₀ values of the active substance to non-target plants.

Circumstances in which required

For active substances that exhibit herbicidal or plant growth regulator activity, vegetative vigour and seedling emergence concentration/response tests shall be provided for at least six species representing families for which herbicidal/plant growth regulatory action has been found. Where, from the mode of action, it can be clearly established that either seedling emergence or vegetative vigour is effected, only the relevant study shall be conducted.

Data are not required, where exposure is negligible, for example in the case of rodenticides, active substances used for wound protection or seed treatment, or in the case of active substances used on stored products or in glasshouses where exposure is precluded.

Test conditions

Dose-response tests on a selection of 6 to 10 monocotyledon and dicotyledon plant species representing as many taxonomic groups as possible shall be provided.

Result:

→ ER₅₀

1.2.2 Data requirements for the product

The text below in grey frames has been taken from Commission Regulation (EU) No 286/2013. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given below the headings.

The endpoints of the study are given as well, if relevant.

The data requirements regarding the risk of the plant protection product for non-target plants are described in Commission Regulation (EU) No 286/2013, point 10.8 (available data from biological primary screening in summary form).

Generally, EU and OECD guidelines for the protocol of experiments are mentioned in Commission Communication 2013/C 95/02 [9].

Introduction

1. Testing of the plant protection product shall be necessary where its toxicity cannot be predicted on the basis of data on the active substance. Where testing is necessary, the aim shall be to demonstrate whether the plant protection product, taking account of content of active substance, is more toxic than the active substance. Thus bridging studies or a limit test may be sufficient. However, where a plant protection product is more toxic than the active substance (expressed in comparable units), definitive testing shall be required. Possible effects on organisms/ecosystems shall be investigated, unless the applicant shows that exposure of the organisms or ecosystems does not occur.

Tests and studies conducted using the plant protection product as test material necessary to assess the toxicity of the active substance shall be reported in the context of the relevant data requirement concerning the active substance.

2. All potentially adverse effects found during routine ecotoxicological investigations shall be reported and such additional studies, which may be necessary to investigate the mechanisms involved and assess the significance of these effects, shall be undertaken and reported.

3. Whenever a study implies the use of different doses, the relationship between dose and adverse effect shall be reported.

4. Where exposure data are necessary to decide whether a study has to be performed, the data obtained in accordance with Section 9 shall be used.

For the estimation of exposure of organisms, all information on the plant protection product and on the active substance shall be taken into account. A tiered approach shall start with default worst-case parameters for exposure and be followed by a parameter refinement based on the identification of representative organisms. Where relevant, the parameters set out in this Section shall be used. Where it appears from available data that the plant protection product is more toxic than the active substance, the toxicity data for the plant protection product shall be used for the calculation of appropriate risk quotients (see point 8 of this introduction).

5. The requirements laid down in this Section shall include certain study types that are set out in Section 8 of Part A of the Annex to Regulation (EU) No 283/2013 (such as standard laboratory tests with birds, aquatic organisms, bees, arthropods, earthworms, soil micro-organisms, soil meso-fauna and non-target plants). While each point shall be addressed, experimental data with a plant protection product shall be generated only if its toxicity cannot be predicted on the basis of data on the active substance. It may be sufficient to test the plant protection product with that species of a group that was most sensitive with the active substance.

6. A detailed description (specification) of the material used as provided for in accordance with point 1.4 shall be provided.

7. In order to facilitate the assessment of the significance of test results obtained, the same strain of each species shall, where possible, be used in the various toxicity tests specified.

8. The ecotoxicological assessment shall be based on the risk that the proposed plant protection product poses to non-target organisms. In carrying out a risk assessment, toxicity shall be compared with exposure. The general term for the output from such a comparison is 'risk quotient' (RQ). RQ may be expressed in several ways, for example,

toxicity:exposure ratio (TER) and as a hazard quotient (HQ).

9. For those guidelines which allow for study to be designed to determine an effective concentration (EC_x), the study shall be conducted to determine an EC₁₀ and EC₂₀ along with corresponding 95 % confidence intervals. If an EC_x approach is used, a NOEC shall still be determined.

Existing acceptable studies that have been designed to generate a NOEC shall not be repeated. An assessment of the statistical power of the NOEC derived from those studies shall be carried out.

10. For solid formulations an assessment of the risk from dust drift on to non-target arthropods and plants shall be required. Details on the likely exposure levels shall be presented in accordance with Section 9 of this Annex. For aquatic life, the risk of movement of the whole particle as well as dust particles shall be considered. Until agreed dust dissipation rate assessments are available likely exposure levels shall be used in the risk assessment.

11. Higher tier studies using a plant protection product shall be designed and data analysed using suitable statistical methods. Full details of the statistical methods shall be reported. Where appropriate, higher tier studies shall be supported by chemical analysis to verify exposure has occurred at an appropriate level.

12. Pending the validation and adoption of new studies and of a new risk assessment scheme, existing protocols shall be used to address the acute and chronic risk to bees, including those on colony survival and development, and the identification and measurement of sub-lethal effects in the risk assessment.

Effects on terrestrial non-target higher plants (284/2013; 10.6)

Summary of screening data (284/2013; 10.6.1.)

10.6.1. Summary of screening data

The effects of plant protection products on non-target plants shall be reported, if the toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance, unless the applicant shows that no exposure occurs.

Circumstances in which required

Screening data shall be required for plant protection products other than those exhibiting herbicidal or plant growth regulator activity, and if the toxicity cannot be established from data on the active substance (point 8.6.1 of Part A of the Annex to Regulation (EU) No 283/2013). The data shall include testing from at least six plant species from six different families including both mono- and dicotyledons. The tested concentrations/rates shall be equal or higher than the maximum recommended application rate. If screening studies do not cover the specified range of species or the concentrations/rates necessary, then tests in accordance with point 10.6.2 shall be carried out.

Data are not required, where exposure is negligible, for example in the case of rodenticides, active substances used for wound protection or seed treatment, or in the case

of active substances used on stored products or in glasshouses where exposure is precluded.

Test conditions

A summary of available data from tests used to assess biological activity and dose range finding studies, whether positive or negative, which may provide information with respect to possible impact on other non- target flora, shall be provided, together with an assessment as to the potential impact on non-target plant species.

These data shall be supplemented by further information, in summary form, on the observed effects on plants during the course of field testing, namely efficacy, residues, environmental fate and ecotoxicological field studies.

Testing on non-target plants (284/2013; 10.6.2.)

10.6.2. *Testing on non-target plants*

The test shall provide the ER₅₀ values of the plant protection product to non-target plants.

Circumstances in which required

Studies of effects on non-target plants shall be required for herbicide and plant growth regulator plant protection products and for other plant protection products, where risk cannot be predicted from screening data (see point 10.6.1) or when the risk cannot be reliably predicted on the basis of the active substance data generated in accordance with point 8.6.2 of Part A of the Annex to Regulation (EU) No 283/2013.

For all granules risk from drift of dust during time of application shall be considered.

Data shall not be required, where exposure is not likely (such as in the case of rodenticides, active substances used for wound protection or seed treatment, or in the case of active substances used on stored products or in glasshouses where exposure is precluded).

Test conditions

The test substance used shall be the plant protection product concerned or another relevant formulation, containing the active substance, and other relevant co-formulants.

For plant protection products that exhibit herbicidal or plant growth regulator activity, vegetative vigour and seedling emergence concentration/response tests shall be required for at least six species, representing families for which herbicidal/plant growth regulatory action has been found. Where, from the mode of action, it can be clearly established that either seedling emergence or vegetative vigour is only affected, only the relevant study shall be conducted.

Dose-response tests on a selection of 6 to 10 monocotyledon and dicotyledon plant species representing as many taxonomic groups as possible shall be required.

Where on the basis of screening data or other available information, a specific mode of action is evident, or significant differences in species sensitivities are identified, that information shall be used in the selection of the relevant test species.

Extended laboratory studies on non-target plants (284/2013; 10.6.3.)

10.6.3. Extended laboratory studies on non-target plants

If as a result of conducting studies in accordance with points 10.6.1 and 10.6.2 and carrying out a risk assessment, a high risk has been identified, an extended laboratory study on non-target plants addressing lower tier concerns may be required by the national competent authorities. The study shall provide information regarding the potential effects of the plant protection product on non-target plants following a more realistic exposure.

The type and conditions of the study to be performed shall be discussed with the national competent authorities.

Semi-field and field studies on non-target plants
(284/2013; 10.6.4.)

10.6.4. Semi-field and field studies on non-target plants

Semi-field and field tests to study effects observed on non-target plants following realistic application may be submitted as a basis for a refined risk assessment. Testing shall address effects on plant abundance and biomass production at varying distances from the crop or at exposure levels representing varying distances from the crop.

The type and conditions of the study to be performed shall be discussed with the national competent authorities.

1.2.3 Data requirements for metabolites

Standard laboratory tests are normally not required for metabolites. Exceptions may be formed by metabolites that are the actually active molecule. See the general part about metabolites as described in §1.2.3 of Chapter 7 Ecotoxicology; Terrestrial; Birds and mammals for general guidance. Where higher tier studies have been carried out with the pesticide under realistic exposure conditions, it may be assumed that the potential risk of metabolites has been taken into account.

1.3 Risk assessment

The risk assessment methodology for non-target plants has in EU context been elaborated in the Guidance Document on Terrestrial Ecology [4].

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as ER₅₀) are presented in a list of endpoints (see Appendix B to Chapter 7). Risk is assessed against the endpoints.

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.

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.

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 combination TER can be calculated according to the following formula:

$$\text{TER}_{\text{combi}} = 1 / ((1/\text{TER}_{\text{substance 1}}) + (1/\text{TER}_{\text{substance 2}}) + (1/\text{TER}_{\text{substance 3}}))$$

An acceptable risk is expected when $\text{TER}_{\text{combi}} > \text{trigger}$.

1.4 Approval

1.4.1 Approval of the active substance

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

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance. The texts specifically applicable to the aspect birds and mammals are presented below.

3. Criteria for the approval of an active substance

3.1. Dossier

The dossier submitted pursuant to Article 7(1) shall be sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

3.3. Relevance of metabolites

Where applicable the documentation submitted shall be sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of

metabolites.

3.8. Ecotoxicology

3.8.1. An active substance, safener or synergist shall only be approved if the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The assessment must take into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.

1.4.1 Evaluation

The evaluation, as applied for the risk assessment for non-target plants, has been elaborated in the Guidance Document on Terrestrial Ecotoxicology [4].

1.4.2 Decision making

Decision making, as applied in the risk assessment for non-target plants, has been elaborated in the Guidance Document on Terrestrial Ecotoxicology [4].

1.5 Developments

Revision of the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) is taking place at this moment (by EFSA).

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3 APPENDICES

Appendix 1 Explanatory notes decision tree risk to non-target arthropods 25
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plants 30

Appendix 1 Explanatory notes decision tree risk to non-target arthropods

- 1) A distinction is made between integrated and non-integrated pest management systems because the evaluation for non-target arthropods for these two types of systems is essentially different. In the case of integrated pest management systems natural enemies are deliberately brought into the cropping system to control pests. In the case of non-integrated pest management systems the risk is estimated for non-target arthropods that are present by nature. The scheme for non-integrated systems is dealt with in this chapter. The scheme for integrated pest management systems is included in Appendix 1 to the NL-part of this chapter.
- 2) The applicant should always submit data about the risk to non-target arthropods if there is a chance of exposure of these organisms (question 283/2013 8.3.2 and 284/2013 10.3.2). In case of applications on the soil and on crops there is practically always chance of exposure. It should be noted that some species have overwintering larvae in the soil, which, if relevant, must be taken into account in the risk assessment as well. The chance of exposure is low in case of application of products for sealing and healing of pruning wounds.
- 3) The first step consists of the performance of glass plate tests with the standard test organisms *Aphidius rhopalosiphi* and *Typhlodromus pyri*, preferably dose-response tests so that an LR50 value can be established. When, however, a low toxicity is expected, limit tests can also be carried out with a dose that is equal to the maximum use dose multiplied by the Multiple Application Factor (MAF). These tests should normally be carried out with the formulation. For determination of the MAF reference is made to the ESCORT 2 report [11]

The standard species mentioned above are not suitable for formulations such as granules, seed dressings, baits and IGRs (Insect Growth Regulators) in view of:

- technical reasons: laboratory glass plate tests with the two standard species cannot be carried out with granular formulations, seed dressings and baits;
- the fact that effects cannot be detected in a standard laboratory test with the standard species as result of a different mode of action (e.g. an acute laboratory test with an Insect Growth regulator (IGR) on *A. rhopalosiphi* will probably not show any effect).

The approach described in the Guidance Document on Terrestrial Ecotoxicology is followed for these types of products:

- for products which are applied into the soil (e.g. granules, seed dressings, baits) studies should be carried out with *Hypoaspis aculeifer* or *Folsomia candida*. When considered suitable, studies can be carried out with *Aleochara sp.* (N.B. test compound should be mixed into the soil).
- For products which are applied on (bare) soil, tests with several soil (surface) dwelling species are acceptable (e.g. *Hypoaspis aculeifer*, *Folsomia candida*, *Aleochara bliineata*, *Poecilus cupreus*, *Pardosa sp.*).
- For IGRs and other plant protection products with a special mode of action the tests should be concentrated on those stages of non-target arthropods that are sensitive to the plant protection product in question (e.g. juvenile stages) while taking relevant absorption routes into account. Tests must be carried out with *Typhlodromus pyri* and one other species (e.g. *Coccinella septempunctata*, *Orius laevigatus* or *Chrysoperla carnea*).

There are several examples of special applications such as drenching treatments, application via drip irrigation, etc. Such cases should be dealt with pragmatically, which means that it should be considered case by case which types of organisms are exposed and in which way the test can be conducted.

Except for the active substance and the product, data are also required for metabolites to which non-target arthropods may be exposed. Arthropods may be exposed to metabolites in/on plants and to metabolites in the soil. For metabolites in vegetation standard laboratory tests are normally not required. Metabolites that are the actually active molecule may be exceptions. General guidance is given in the general part about metabolites as described under 'birds and mammals'.

Where higher tier studies (cage/tent/tunnel or field tests) have been carried out with the pesticide under realistic exposure conditions it can be assumed that the potential risk of metabolites has been taken into account.

Soil metabolites are tested with soil organisms; tests with surface dwelling soil arthropods are therefore not required.

- 4) A Hazard Quotient (HQ) must be calculated for both standard species and both the 'in-field' risk as well as the 'off-field' risk are taken into account. For the method according to which the 'in-field' and 'off-field' exposure must be calculated we refer to the Guidance Document on Terrestrial Ecotoxicology, on the understanding that for national risk assessments NL-specific drift figures are used for calculating the 'off-field' exposure, for which we refer to §2.3 (NL-part).

The criterion for both HQ values is that these should be lower than 2 (or effects in limit tests <50%). This criterion is based on available (semi-) field data where lethal, sublethal and reproduction endpoints have been measured for a considerable number of types of substances and species. This means that this first step in the evaluation (in which the criterion $HQ < 2$ is applied) also covers sublethal and reproduction effects and it is not necessary to separately consider sublethal and reproduction endpoints in the first step of the evaluation.

Where also other species than *Aphidius rhopalosiphi* and *Typhlodromus pyri* have been tested in first tier laboratory tests, these cannot be tested against the HQ trigger of 2 because this trigger has only been validated for *Aphidius* and *Typhlodromus*.

The results of these tests will be assessed against the criterion of 50% effect (or HQ of 1, if LR50 and ER50 values are available).

When it concerns tests with the soil organisms *Hypoaspis aculeifer* and *Folsomia candida*, the NOEC (mg/kg soil) is the relevant endpoint. For risk assessment a safety factor of 5 is applied. In the case that artificial soil is used in the test, correction for the percentage of organic matter is necessary (if $\log Kow > 2$).

Off-crop interception:

In cases that only exposure of soil dwelling species is relevant (for example when a reasoned case is made that soil surface spiders are the most sensitive species), interception by the off-crop vegetation may be taken into account in the off-field risk assessment.

For the time being the following interception percentages are applied - till better underpinned percentages come available - which are considered realistic worst-case:

- December – February: 20%
- March: 30%
- April: 40%
- May – September: 50%
- October: 40%

It should be noted that when these percentages are taken into account, the vegetation distribution factor cannot be used in the HQ-calculation (off-field).

- 5) Where the HQ values are ≥ 2 and suitable or desirable risk reduction measures 'in-field' and/or 'off-field' are not possible, higher tier tests must be carried out. First, the sensitive species for which the HQ value is ≥ 2 should be studied in such a higher tier test where extra species are tested: in case that only the HQ for the 'in-field' risk estimate is exceeded, one extra species must be tested; in case the HQ for 'in-field' as well as 'off-field' is exceeded, two extra species. The preferred species are: *Orius laevigatus*, *Chrysoperla carnea*, *Coccinella septempunctata* and *Aleochara bilineata* in view of the fact that the available data indicate that these organisms are relatively sensitive and that good test methods are available. The species *Aleochara bilineata* should in any case be used for products that are applied early in the season and where products are applied on the soil.

Higher tier tests concern extended laboratory tests (with natural substrate) and (semi) field tests. 'Aged-residue' tests also come under the higher tier tests. These tests can be used for establishing the duration of the effect in view of the possible recovery of populations by recolonisation. See also note 6) below.

If the only available data are extended laboratory tests with *A. rhopalosiphi* and *T. pyri*, tests with two additional species will be required, irrespective of the acceptability of the risk for *A. rhopalosiphi* and *T. pyri*. The reason for this is that in this case no first tier risk assessment can be performed to establish the requirements for additional species.

It should be noted that generally, in-crop field studies are considered not acceptable to address off-crop risks. When a field study is chosen as approach to address the off-crop risk to non-target arthropods, it should be demonstrated in this study that no unacceptable effects on a non-target arthropod community that is representative for fauna of off-crop habitats in The Netherlands (e.g. meadow, hay field or (agricultural) verge) will occur as a result from drift exposure. Studies conducted in e.g. Northern France and Germany are also considered representative for The Netherlands. Preferably a multi-dose rate (NOEC) design is used. Before such a study is undertaken, the study protocol may be discussed with the Ctgb.

If an in-crop field test is performed to address an in-crop risk, and *A. rhopalosiphi* and *T. pyri* do not occur in the crop of concern, it is acceptable that these species are not present in the study, as long as a representative fauna for this crop is present.

Further guidance on the evaluation of arthropod field studies can be found in De Jong et al. (2010) (Guidance for summarising and evaluating field studies with non-target arthropods. RIVM report 601712006/2010).

For 'in-field' and 'off-field' the following risk reducing measures are among the options:

'in-field':

- reduction of the dose level;
- changes in application frequency and application interval;
- changes in timing of the application.

'off-field':

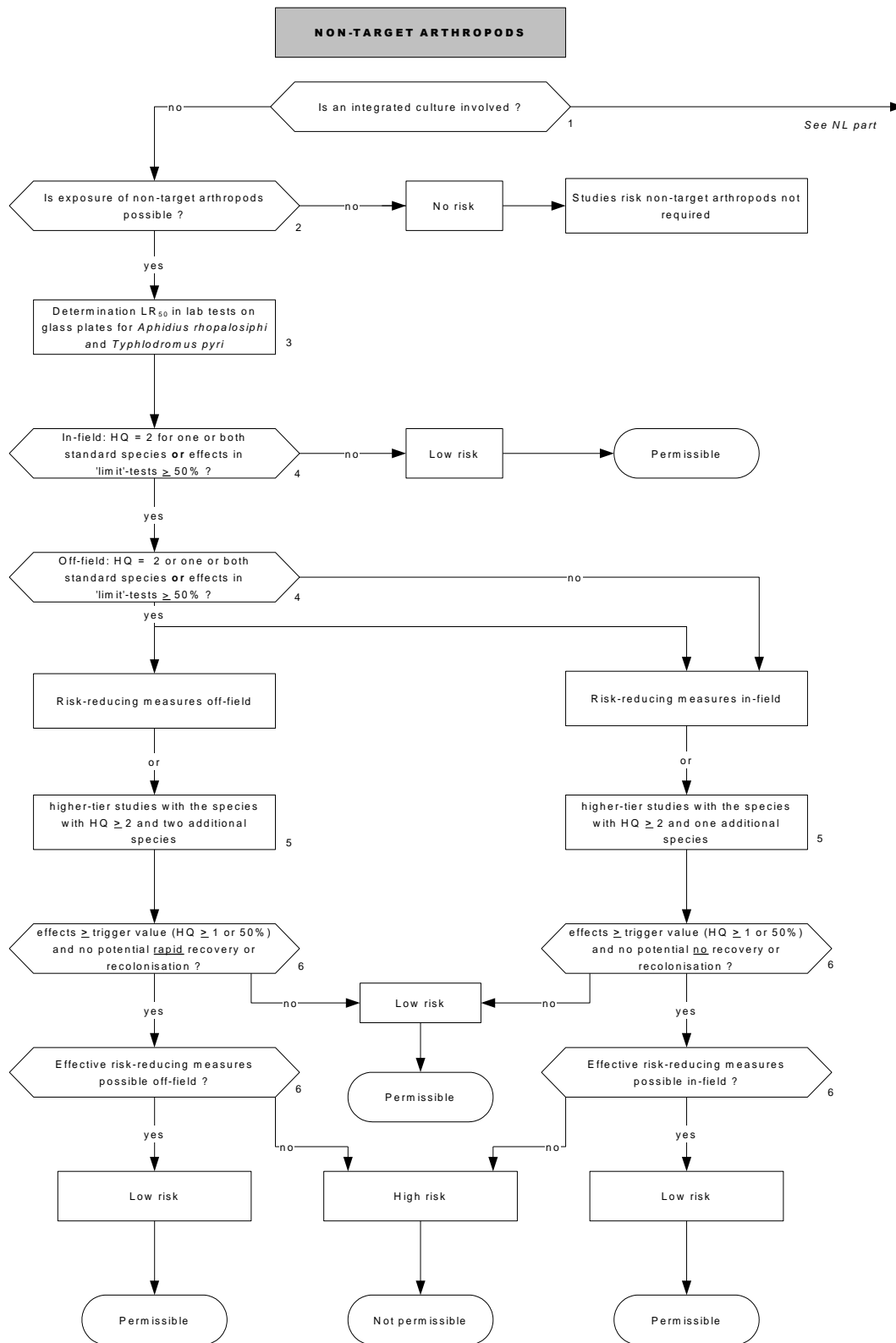
- measures that reduce the amount of drift to the area outside the crop such as:
 - . buffer zones;
 - . wind hedges;
 - . drift-reducing application techniques.

- 6) The risk is unacceptable if the effects found in the extended laboratory tests are equal to or higher than the trigger value (trigger value is 50%¹) and there is no potential (rapid) recovery or recolonisation. When risk-mitigating measures neither lead to an acceptable risk to non-target arthropods, the product cannot be authorised.

The criterion for (potential) recovery or recolonisation for 'in-field' is that this must be the case before the following spraying season. The period for 'off-field' is shorter, for the time being without a specific definition. The Guidance Document on Terrestrial Ecotoxicology [4] mentions an ecologically relevant period. It should be noted however, that under the new data requirements, aged residue tests can no longer be used for the off-field risk assessment. This means that for the off-field risk assessment, studies demonstrating no effects or actual recovery should be provided.

For field tests, ESCORT 2 does not provide fixed trigger values for acceptability of effects.

¹ The trigger value of 50% can be considered equal to an HQ value of 1, provided that only mortality effects occur and no sublethal effects. In case sublethal effects are found, ER50 can be determined and tested against the HQ trigger of 1.



Appendix 2 Explanatory notes decision tree risk to terrestrial non-target plants

- 1) Definition: terrestrial non-target plants are plants positioned outside the field to be treated without being a crop.
- 2) Data on the risk to terrestrial non-target plants are not always required. Where exposure is negligible, no data need to be submitted, e.g., in the case of:
 - Rodenticides
 - Seed treatments
 - Granules
 - Bulb dipping
 - Drenching treatment
 - Substances used to cover and cure pruning wounds
 - Substance that are used in stored products

- 3) This step is based on the already available data, with a preference for screening data. Data on at least 6 species of different taxa tested with the highest nominal dose (1x) should be available. These species should cover monocotyledonous as well as dicotyledonous species. Besides these data, further information available in the biological dossier or obtained from various field experiments such as efficacy studies, residue studies, environmental-behavioural and ecotoxicological studies about efficacy, selectivity, phytotoxicity etc. can be provided.
This first step can be skipped for herbicides and plant growth regulators because these substances will as result of their envisaged effect on plants always reach the second step.

The criterion is that the risk can be considered as acceptable where no data indicate that one or more species experience more than 50% phytotoxic effects at the maximum dose level. If the results show that there is more than 50% effect for one species or that there are clear indications of effects on more than one species, additional research needs to be carried out.

- 4) Where a potential risk is identified (more than 50% effect for one or more species at the maximum dose), specific information must be submitted about the toxicity of the substance for terrestrial plants. These are laboratory experiments on a selection of plants. It is strongly recommended to conduct dose-response tests with 6 –10 plant species representing families for which significant herbicidal effect is claimed. These tests should resemble realistic exposure conditions as much as possible. For applications on leaves, e.g., the tests must be carried out by spraying the pesticide on the plant. Application on soil should be carried out where this is more suitable in view of the mode of action.

Tests must be carried out with the formulations.

Suitable test protocols are available: the new draft version of OECD guideline 208 and the OPPTS guidelines of US EPA.

- 5) This step consists of a quantitative risk assessment according to the exposure/effect approach. Exposure as well as effect are expressed in application dose (g/ha). ER50 values (ER50 = the dose at which 50% effect is observed) are available from the plant tests as mentioned under step 2 of the data requirements. There are two possible approaches for the risk assessment: the deterministic approach and the probabilistic approach. The most suitable approach depends on the dataset.

Deterministic approach

In the deterministic approach the toxicity of the most sensitive species is taken as starting point for the effect. Where the ratio toxicity/exposure is higher than 5, the risk is considered acceptable. This trigger value of 5 is valid where data on at least 6 plant species are available. In case data on significantly more than 6 plant species are available, this trigger value may –where appropriate – be adjusted slightly upward (expert judgement).

Probabilistic approach

Probabilistic methods in which the 'species sensitivity distribution' is used may in principle be applied because data on 6 – 10 species are available. This approach requires a log-normal or a differently defined type of distribution of the data. In case the ER50 for less than 5% of the species (HR5) is below the highest estimated exposure level, the risk to terrestrial non-target plants is considered acceptable. If not, the risk is high.

The initial exposure of non-target plants should be determined at the following distances from the centre of the last crop row:

- field crops (including "soft fruit" and bush and hedge shrubbery) and soil applications, as in the case of herbicides: 2 m (1 m from the edge of the parcel) (evaluation zone 1.5 – 2.5 m);
- 3 m for large fruit (evaluation zone 2.5 – 3.5 m);
- 5 m for lane trees (evaluation zone 4.5 – 5.5 m).

For these distances the following drift percentages apply in the Netherlands:

- outdoor field cultures and soil applications: 4.7%;
- large fruit: 37% before 1 May; 15.9% after 1 May (the latter value (15.9%) is also used for grapes and small fruit (irrespective of application time).);
- lane trees: 'spillen' (closely spaced): 1.8% and 'opzetters' (widely spaced): 6.3% in case of a crop-free zone of 5 m (LOTV)).

Where the crop free zones exceed the standard distances from the centre of the last crop row mentioned here, the 'off-field' area only starts after the crop-free zone and the drift percentage must be determined at a distance as large as the crop-free zone.

Where natural objects have been placed to reduce the amount of drift (e.g. a wind hedge) this object should not be considered as part of the off-field area that needs to be protected. It must be kept in mind that those crop-free zones and natural objects in many cases are only applied on those parts of parcels which borders watercourses. Protection of non-target terrestrial plants is needed for all sides of a parcel.

In cases that only exposure by the soil is relevant (e.g. when an active substance has only adverse effects on pre-emergence stadia of non-target plants), some interception by the off-crop vegetation may be taken into account.

For the time being the following interception percentages are applied - till better underpinned percentages come available - which are considered realistic worst-case:

- December – February: 20%
- March: 30%
- April: 40%
- May – September: 50%
- October: 40%

If a Plant protection product contains several active substances, the combination toxicity must be determined 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 are compared with the combination toxicity on the basis of toxicity research with the separate active substances. The risk of combination products is determined on the basis of the lowest TER as calculated based on the toxicity of the separate active substances or the toxicity of the product.

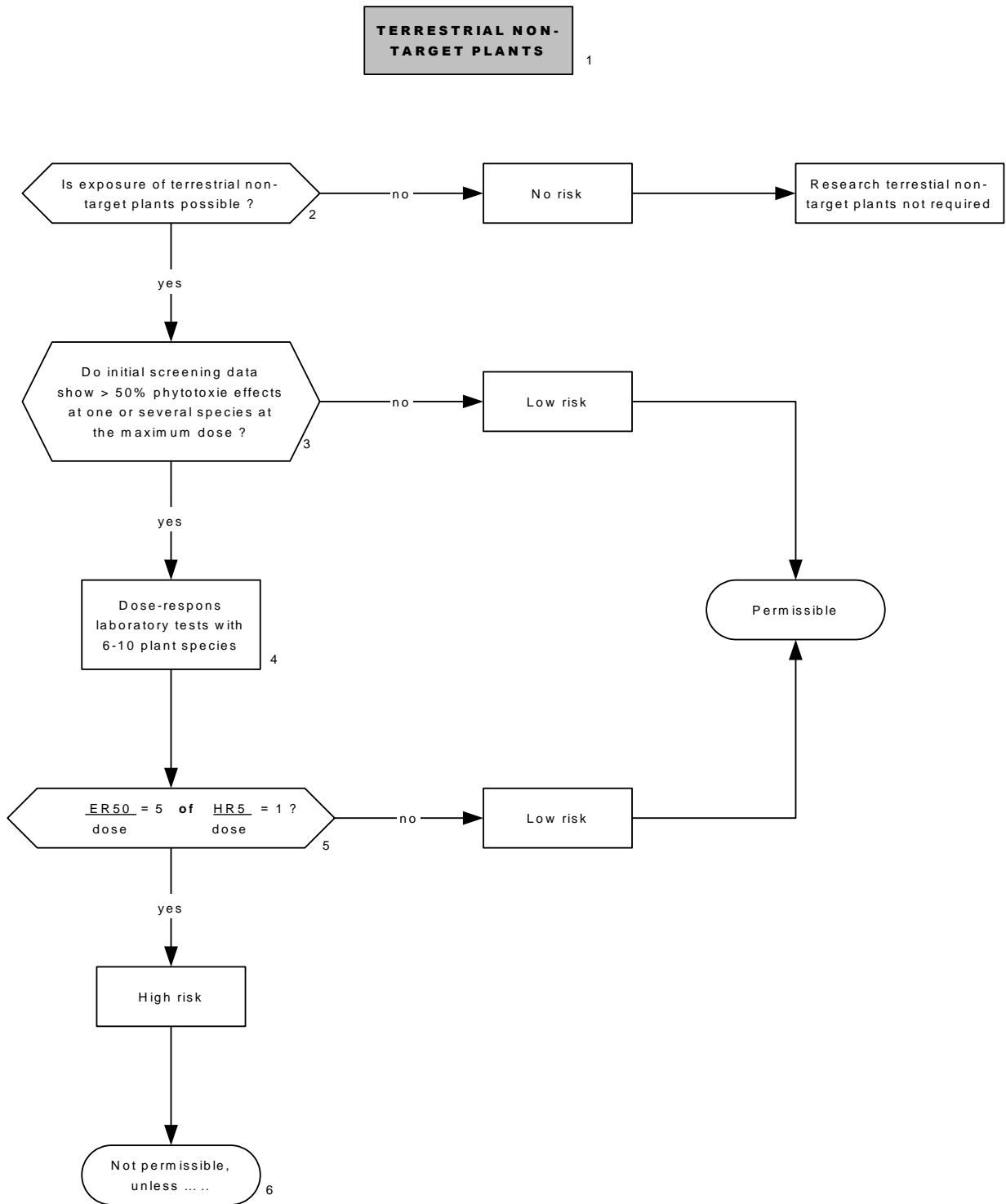
The combination toxicity is determined on the basis of concentration addition. For the calculation method see Appendix C of Chapter 7.

- 6) Where on the basis of the previous step a high risk is concluded to exist, the use is not permissible unless it can be demonstrated by means of adequate risk evaluation that there are no unacceptable direct or indirect effects for terrestrial non-target plants.

An adequate risk evaluation may consist of the performance of a (semi) field study to investigate the effects on non-target plants under realistic application conditions. Because such studies take a long time and are expensive, it is recommended to investigate whether options exist for refinement of the exposure and/or effects. In addition, (semi) field studies are not required if the risk identified in step 2 can sufficiently be reduced by means of risk-mitigating measures.

Field and semi-field studies with non-target plants have not been standardised. It is therefore recommended to contact the Ctgb beforehand to discuss the protocol. Generally, it can be stated that in such tests effects on plant abundance and biomass production at different distances from the crop or at exposure levels representing exposure at different distances from the crop, need to be analysed.

Because the exposure of terrestrial non-target plants is mainly caused by drift of pesticides, possible measures to reduce the risk to these plants are based on reduction of the amount of drift. In principle, all already existing drift-mitigating measures can be applied. The drift reduction of drift reducing measures, which are easy to realise in practice are mentioned in paragraph 2.3 of the NL part.



4 REFERENCES

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