

**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; aquatic

version 2.0; January 2014

ctgb

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

Chapter 7 Ecotoxicology; aquatic

Category: Plant Protection Products

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GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the effects of a plant protection product and its active substance on the aquatic environment and STP, 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].

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

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

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

This chapter consists of two parts: a part about effects on aquatic and sediment dwelling organisms (I), and a part about effects on sewage treatment plants (STPs) (II),

I AQUATIC AND SEDIMENT DWELLING ORGANISMS

1. EU FRAMEWORK

In this document, the procedures for the evaluation and re-evaluation of active substances as laid down in the EU are described; the NL procedure for evaluation of a substance is reverted to when no EU procedure has been laid down. The NL-procedure for the evaluation of a substance is described in §2 - §2.5 of part 2 of the Evaluation Manual (plant protection products). This document aims to give procedures for the approval of active substances and inclusion in Commission Implementing Regulation (EU) No 540/2011 [3]

1.1. Introduction

This chapter describes the risk assessment of plant protection products for aquatic and sediment dwelling organisms.

This chapter is related to Chapter 6 Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plant (STP). This chapter describes the determination of estimated or measured concentrations in the sediment.

Data requirements, evaluation methodologies, criteria and trigger values that deviate

from, or further elaborate, the provisions under EU framework (§1), are described in the NL part (§2 - §2.5). The national further provisions can also be used for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011.

1.2. Data requirements

In order to qualify for inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [4] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [5] must be submitted for the active substance as well as for the product,.

Generally, EU and OECD guidelines for the execution of experiments are mentioned in Commission Communication 2013/C95/01 [6].

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 aquatic organisms are described in part A of Commission Regulation (EU) No 283/2013, point 8.2 (effects on aquatic organisms).

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 microflora 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 aquatic organisms
(283/2013; 8.2)

8.2. Effects on aquatic organisms

Reports of the tests referred to in points 8.2.1, 8.2.4 and 8.2.6 shall be submitted for every active substance and supported with analytical data on concentrations of the substance in the test media.

When aquatic toxicity studies are conducted with a poorly soluble substance, limit concentrations lower than 100 mg substance/L may be acceptable, however precipitation of the substance in the test medium shall be avoided and a solubiliser, auxiliary solvent or dispersing agent shall be used when appropriate. Testing using the plant protection product may be required by the national competent authorities if no biological effects occur at the solubility limit of the active substance.

Toxicity endpoints (such as LC₅₀, EC₁₀, EC₂₀, EC₅₀ and NOEC) shall be calculated on the basis of nominal or mean/initial measured concentrations.

Acute toxicity to fish
(283/2013 ; 8.2.1)

8.2.1. Acute toxicity to fish

A study shall be provided on the acute toxicity to fish (LC₅₀) and details of observed effects.

Circumstances in which required

A test on rainbow trout (*Oncorhynchus mykiss*) shall be carried out.

Test conditions

The acute toxicity of the active substance to fish shall be determined. In order to minimise fish testing, a threshold approach to acute toxicity testing on fish shall be considered. An acute toxicity fish limit test shall be conducted at 100 mg substance/L or at an appropriate concentration selected from aquatic endpoints (points 8.2.4, 8.2.6 or 8.2.7) following consideration of the threshold exposure. When mortality is detected in the fish limit test an acute fish dose-response toxicity study shall be required to determine an LC 50 for use in the risk assessment conducted in accordance with the relevant risk quotient analysis (see point 2 of the introduction of this Section).

Result:

→ LC₅₀ fish

Long term and chronic toxicity to fish.
(283/2013; 8.2.2)

8.2.2. Long-term and chronic toxicity to fish

Circumstances in which required

A long-term or chronic toxicity study on fish shall be provided for all active substances where exposure of surface water is likely and the substance is deemed to be stable in water, that is to say there is less than 90 % loss of the original substance over 24 hours via hydrolysis (see point 7.2.1.1). A fish early life stage study shall be provided in these circumstances. However, if a fish full life cycle study is provided an early life stage study shall not be required.

Fish early life stage toxicity test
(283/2013 ; 8.2.2.1)

8.2.2.1. Fish early life stage toxicity test

A fish early life stage toxicity test shall determine effects on development, growth and behaviour, and details of observed effects on fish early life stages. The EC₁₀ and EC₂₀ shall be reported together with the NOEC. Where EC₁₀ and EC₂₀ cannot be estimated, an explanation shall be provided.

Result:

→ NOEC fish

Fish full life cycle test
(283/2013 ; 8.2.2.2)

8.2.2.3. Fish full life cycle test

A fish full life cycle test shall provide information on the effects on reproduction of the parental and the viability of the filial generation. The EC₁₀ and EC₂₀ shall be reported together with the NOEC.

For active substances that are not considered as potential endocrine disruptors, a fish full life cycle test may be required depending upon the persistence and bioaccumulative potential of the substance.

For active substances that fulfil the screening criteria on either of the fish screening assays, or for which there are other indications of endocrine disruption (see point 8.2.3), appropriate additional endpoints shall be included in the test and discussed with the national competent authorities.

Test conditions

Studies shall be designed to reflect concerns identified through lower tier testing, mammalian and bird toxicology studies and other information. The exposure regime shall be selected accordingly, taking account of the rates of application proposed.

Result:

→ NOEC fish

Bioconcentration in fish

(283/2013 8.2.2.3)

8.2.2.3. Bioconcentration in fish

The test on bioconcentration in fish shall provide the steady-state bioconcentration factors, uptake rate constants and depuration rate constants, incomplete excretion, metabolites formed in fish and, if available, information on organ-specific accumulation.

All data shall be provided with confidence limits for each test substance. Bioconcentration factors shall be expressed as a function of both total wet weight and of the lipid content of the fish.

Data provided under point 6.2.5 shall be considered, where relevant, in addressing this point.

Circumstances in which required

The bioconcentration of the substance, shall be assessed where:

- the log Pow is greater than 3 (see point 2.7) or there are other indications of bioconcentration, and
- the substance is considered stable, that is to say there is less than 90 % loss of the original substance over 24 hours via hydrolysis (see point 7.2.1.1).

Endocrine disrupting properties

(283/2013; 8.2.3)

8.2.3. Endocrine disrupting properties

Consideration shall be given to whether the active substance is a potential endocrine disruptor in aquatic non- target organisms according to Union or internationally agreed

guidelines. In addition, other available information on toxicity profile and mode of action shall be taken into account. If as a result of this assessment, the active substance is identified as a potential endocrine disruptor, the type and conditions of the studies to be performed shall be discussed with the national competent authorities.

Result

→ BCF

Acute toxicity to aquatic invertebrates (283/2013 ; 8.2.4)

8.2.4. Acute toxicity to aquatic invertebrates

Circumstances in which required

The acute toxicity shall be determined for a *Daphnia* species (preferably *Daphnia magna*). For active substances with an insecticidal mode of action or which show insecticidal activity a second species shall be tested, for example Chironomid larvae or Mysid shrimps (*Americamysis bahia*).

*Acute toxicity to *Daphnia magna** (283/2013; 8.2.4)

8.2.4. Acute toxicity to *Daphnia magna*

A test shall be provided on the 24- and 48-hour acute toxicity of the active substance to *Daphnia magna*, expressed as the median effective concentration (EC₅₀) for immobilisation, and where possible, the highest concentration causing no immobilisation.

Test conditions

Concentrations up to 100 mg substance/L shall be tested. A limit test at 100 mg substance/L may be performed where the results of a range finding test indicate that no effects are to be expected.

Result:

→ EC₅₀ *Daphnia*

Acute toxicity to an additional aquatic invertebrate species (283/2013; 8.2.4.2)

8.2.4. Acute toxicity to additional aquatic invertebrate species

A test shall be provided on the 24- and 48-hour acute toxicity of the active substance to an additional aquatic invertebrate species, expressed as the median effective concentration (EC₅₀) for immobilisation, and where possible, the highest concentration causing no immobilisation.

Test conditions

The conditions as set out in point 8.2.4.1 shall apply.

Long-term and chronic toxicity to aquatic invertebrates (283/2013 ; 8.2.5)

8.2.5. Long-term and chronic toxicity to aquatic invertebrates

Circumstances in which required

A long-term or chronic toxicity study on aquatic invertebrates shall be provided for all active substances where exposure of surface water is likely and the substance is deemed to be stable in water, that is to say there is less than 90 % loss of the original substance over 24 hours via hydrolysis (see point 7.2.1.1).

A chronic toxicity study shall be submitted on one aquatic invertebrate species. If acute toxicity tests have been conducted on two aquatic invertebrate species the acute endpoints shall be taken into account (see point 8.2.4) in order to determine the appropriate species to be tested in the chronic toxicity study.

If the active substance is an insect growth regulator, an additional study on chronic toxicity shall be carried out using relevant non-crustacean species such as *Chironomus* spp.

Result:

→ NOEC *Daphnia*

Reproductive and developmental toxicity to Daphnia magna
(283/2013; 8.2.5.1)

8.2.5.1. Reproductive and developmental toxicity to *Daphnia magna*

The aim of the test on reproductive and development toxicity to *Daphnia magna* shall be to measure adverse effects such as immobilisation and loss of reproductive capacity and to provide details of observed effects. The EC₁₀, and EC₂₀ shall be reported together with the NOEC. Where EC₁₀ and EC₂₀ cannot be estimated, an explanation shall be provided.

Reproductive and developmental toxicity to an additional aquatic invertebrate species
(283/2013; 8.2.5.2)

8.2.5.2. Reproductive and developmental toxicity to an additional aquatic invertebrate species

The test on reproductive and development toxicity to an additional aquatic invertebrate species shall measure adverse effects such as immobilisation and loss of reproductive capacity and provide details of observed effects. The EC₁₀, and EC₂₀ shall be reported together with the NOEC. Where EC₁₀ and EC₂₀ cannot be estimated, an explanation shall be provided.

Developmental and emergence in Chironomus riparius
(283/2013; 8.2.5.3)

8.2.5.3. Developmental and emergence in *Chironomus riparius*

The active substance shall be applied to the water overlying sediment and effects on survival and development of *Chironomus riparius*, including effects on emergence of adults, shall be measured to provide endpoints for those substances considered to interfere with insect moulting hormones or that have other effects on insect growth and development. The EC₁₀ and EC₂₀ shall be reported together with the NOEC.

Test conditions

Concentrations of active substance in the overlying water and the sediment shall be

measured to establish an EC₁₀, EC₂₀ and a NOEC. The active substance shall be measured often enough to allow the calculation of test endpoints based on nominal as well as time-weighted average concentrations.

Sediment dwelling organisms
(283/2013; 8.2.5.4)

8.2.5.4. Sediment dwelling organisms

When accumulation of an active substance in aquatic sediment is indicated or predicted by environmental fate studies, the impact on a sediment-dwelling organism shall be assessed. The chronic risk to *Chironomus riparius* or *Lumbriculus* spp. shall be determined. An appropriate alternative test species may be used where a recognised guideline is available. The active substance shall be applied to either the water or the sediment phase of a water/sediment system and the test shall take account of the major route of exposure. The key endpoint from the study shall be presented in terms of mg substance/kg dry sediment and mg substance/L water and the EC₁₀ and EC₂₀ shall be reported together with the NOEC.

Test conditions

Concentrations of active substance in the overlying water and the sediment shall be measured to establish an EC₁₀, EC₂₀ and a NOEC.

Effects on algal growth
(283/2013; 8.2.6)

8.2.6. Effects on algal growth

Circumstances in which required

Testing shall be carried out on one green alga (such as *Pseudokirchneriella subcapitata*, synonym *Selenastrum capricornutum*).

For active substances that exhibit herbicidal activity a test on a second species from a different taxonomic group shall be performed such as a diatom, for example *Navicula pelliculosa*.

The EC₁₀, EC₂₀, EC₅₀ and corresponding NOEC values shall be provided.

Result:

→ NOEC algae/EC50 algae

Effects on growth of green algae
(283/2013; 8.2.6.1)

8.2.6.1. Effects on growth of green algae

A test shall be provided establishing EC₁₀, EC₂₀, EC₅₀ for green algae and corresponding NOEC values for algal growth rate and yield, based on measurements of biomass or surrogate measurement variables.

Test conditions

Concentrations up to 100 mg substance/L shall be tested. A limit test at 100 mg substance/L may be performed when results of a range-finding test indicate that no effects are to be expected at lower concentrations.

Effects on growth of an additional algal species
(283/2013; 8.2.6.2)

8.2.6.2. Effects on growth of an additional algal species

A test shall be provided establishing EC₁₀, EC₂₀, EC₅₀ for an additional algal species and corresponding NOEC values for algal growth rate and yield, based on measurements of biomass (or surrogate measurement variables).

Test conditions

The test conditions as set out in point 8.2.6.1 shall apply.

Effects on aquatic macrophytes
(283/2013; 8.2.7)

8.2.7. Effects on aquatic macrophytes

A test shall be provided establishing EC₁₀, EC₂₀, EC₅₀ and corresponding NOEC values for *Lemna* species growth rate and yield, based on measurements of number of fronds and at least one additional measurement variable (dry weight, fresh weight or frond area).

For other species of aquatic macrophytes, a test shall provide sufficient information to evaluate impact on aquatic plants and provide EC₁₀, EC₂₀, EC₅₀ and corresponding NOEC values based on measurement of appropriate biomass parameters.

Circumstances in which required

A laboratory test with *Lemna* species shall be performed for herbicides and plant growth regulators and for substances where there is evidence from information submitted under point 8.6 of Part A of this Annex or point 10.6 of Part A of the Annex to Regulation (EU) No 284/2013 that the test substance has herbicidal activity. Additional testing may be required by the national competent authorities on other macrophyte species depending on the mode of action of the substance, or if clear indications of higher toxicity are apparent to dicotyledonous (for example auxin inhibitor, broad leaf herbicides) or other monocotyledonous (for example grass herbicides) plant species from efficacy or terrestrial non-target plants tests (see point 8.6 of Part A of this Annex and point 10.6 of Part A of the Annex to Regulation (EU) No 284/2013).

Additional aquatic macrophyte species tests may be undertaken on a dicotyledonous species, such as *Myriophyllum spicatum*, *Myriophyllum aquaticum* or a monocotyledonous species, such as aquatic grass *Glyceria maxima*, as appropriate. The need to perform such studies shall be discussed with the national competent authorities.

Test conditions

Concentrations up to 100 mg substance/L shall be tested. A limit test at 100 mg substance/L may be performed when results of a range-finding test indicate that no effects are to be expected.

Further testing on aquatic organisms
(283/2013; 8.2.8)

8.2.8. Effects on aquatic macrophytes

Further studies on aquatic organisms may be conducted to refine the identified risk and shall provide sufficient information and data to evaluate potential impact on aquatic organisms under field conditions.

Studies undertaken may take the form of additional species testing, modified exposure testing, microcosm or mesocosm studies.

Circumstances in which required

The need to perform such studies shall be discussed with the national competent authorities.

Test conditions

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

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 aquatic and sediment dwelling organisms are described in Commission Regulation (EU) No 284/2013, point 10.2 (effects on aquatic organisms).

Generally, EU and OECD guidelines for the execution of experiments are mentioned in Commission Communication 2013/C95/02 [7].

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 EC 10 and EC 20 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 aquatic organisms
(284/2013; 10.2)

10.2. Effects on aquatic organisms

Possible effects on aquatic species (fish, aquatic invertebrates, algae and in the case of herbicides and plant growth regulators, aquatic macrophytes) shall be investigated except where the possibility that aquatic species will be exposed can be ruled out.

A risk assessment for aquatic organisms shall be conducted in accordance with the relevant risk quotient analysis.

Acute toxicity to fish, aquatic invertebrates or effects on algal growth and macrophytes
(284/2013 ; 10.2.1)

10.2.1. Acute toxicity to fish, aquatic invertebrates or effects on algal growth and macrophytes

Circumstances in which required

Testing shall be performed where:

- (a) the acute toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance; or
- (b) the intended use includes direct application on water;
- (c) extrapolation on the basis of available data for a similar plant protection product is not possible.

Tests shall be carried out on one species from each of the three/four groups of aquatic organisms, that is to say fish, aquatic invertebrates, algae and, where relevant, macrophytes as referred to in point 8.2 of Part A of the Annex to Regulation (EU) No 283/2013, if the plant protection product itself may contaminate water.

However, where the available information permits to conclude that one of these groups is clearly more sensitive, tests on only the relevant group shall be performed.

If the plant protection product contains two or more active substances, and the most sensitive taxonomic groups for the individual active substances are not the same, testing on all three/four aquatic groups, that is to say fish, aquatic invertebrates, algae and, where relevant macrophytes, shall be required.

Test conditions

The relevant provisions as under points 8.2.1, 8.2.4, 8.2.6 and 8.2.7 of Part A of the

Annex to Regulation (EU) No 283/2013 apply. In order to minimise fish testing a threshold approach shall be considered for testing acute toxicity in fish (see point 8.2.1 of Part A of the Annex to Regulation (EU) No 283/2013)

Result:

→ NOEC algae/EC50 algae

→ EC₅₀ *Daphnia*

→ LC₅₀ fish

Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms
(284/2013; 10.2.2)

10.2.2. Additional long-term and chronic toxicity on fish, aquatic invertebrates and sediment dwelling organisms

The studies referred to in points 8.2.2 and 8.2.5 of Part A of the Annex to Regulation (EU) No 283/2013 shall be conducted for particular plant protection products, where it is not possible to extrapolate from data obtained in the corresponding studies on the active substance (for example the plant protection product is more acutely toxic than the active substance as manufactured by a factor of 10), unless it is demonstrated that exposure will not occur.

If chronic toxicity studies with the plant protection product are required, the type and conditions of the studies to be provided shall be discussed with the national competent authorities.

Further testing on aquatic organisms
(284/2013; 10.2.3)

10.2.3. Further testing on aquatic organisms

The studies referred to in point 8.2.8 of Part A of the Annex to Regulation (EU) No 283/2013 may be required for particular plant protection products where it is not possible to extrapolate from data obtained in the corresponding studies for the active substance or another plant protection product.

1.2.3. Data requirements for metabolites

Except for the active substance and the product, data about metabolites formed in the water and sediment phase of water/sediment systems are required as well. A distinction is made between *minor* and *major* metabolites.

Major metabolites in the aqueous phase are metabolites of which in the laboratory study into the transformation in a water/sediment system the concentration in the aqueous phase is at any point in time higher than or equal to 10% of the added amount of active substance.

Data on transformation rate, bioconcentration and acute toxicity to algae, daphnia and fish are required for such metabolites.

Major metabolites in the sediment phase are metabolites of which in the laboratory study into the transformation in a water/sediment system the concentration in the sediment phase after 14 days is higher than or equal to 10% of the added amount of active substance.

Data on the toxicity to sediment dwelling organisms are required for such metabolites. *Minor* metabolites (formed in a concentration lower than 10% of the amount of added active substance) should be taken into consideration as well.

The data requirements mentioned in these sections do not always need to be met by means of experimental studies. Applicants may also answer the open questions by means of other available information in support of a scientific and rational risk assessment.

Valuable sources of information are e.g.:

- consideration of molecular structure of the metabolite (active part intact?);
- the occurrence of metabolites in the medium in existing tests with the active substance or major metabolites;
- general knowledge on the relationship between the toxicity of the metabolite and its parent substance (e.g. from the aquatic base set (fish, daphnia, algae);
- information on pesticidal activity from biological screening data;
- available knowledge on related compounds;

Further information is given in the Guidance Document on Aquatic Ecotoxicology [5].

1.3. Risk assessment

Each study is analysed and evaluated separately. The final conclusion and the endpoint per aspect (such as LC₅₀ fish and NOECecosystem) are presented in a list of endpoints (see Appendix B to Chapter 7).

Risk assessment is based on comparison with endpoints. The risk evaluation for aquatic and sediment dwelling organisms follows a tiered approach. The first tier is based on model data as regards exposure and on laboratory data as regards toxicity. This is a general conservative evaluation of the behaviour and toxicity of the substance in the environment.

Where the criteria of the first tier of the evaluation are not met, there is the possibility to submit supplementary data for conducting a refined risk evaluation (higher tier).

Further information about the method to determine the exposure concentration is given in Chapter 6 Fate and behaviour in the environment; Behaviour in surface water, sediment and sewage treatment plant (STP), §1.3.

The estimated exposure concentration is then compared with the toxicity data for the different aquatic and sediment organisms.

Detailed information about the evaluation methodology is given in the Guidance Document on Aquatic Ecotoxicology [5].

Higher tier methods like the SSD approach and micro-/mesocosm studies are more elaborated in the national assessment in comparison to what is mentioned in the Guidance Document on Aquatic Ecotoxicology [5]. For that reason these higher-tier methods are described in more detail below.

Higher tier risk assessment

The higher tier assessment is carried out according to Regulation (EC) 1107/2009 guidance document Aquatic Ecotoxicology [5]. Here one can think of a higher tier assessment based on the SSD approach or micro-/mesocosm studies (with or without recovery).

For further information regarding the performance of micro-/mesocosm studies reference is made to the Guidance Document on Aquatic Ecotoxicology [5] and the Guidance for summarizing and evaluating aquatic micro- and mesocosm studies [8]. With regard to the

SSD approach and the acceptability of effects seen in micro-/mesocosm studies only very limited information is available in the Guidance Document on Aquatic Ecotoxicology [5]. In NL the SSD approach is developed much more in detail and guidance about acceptability of effects is available. The information is presented below.

SSD approach

General introduction

A frequently used higher-tier effect assessment procedure for the administration of PPPs is the Species Sensitivity Distribution (SSD) approach. According to the HARAP Guidance document [9] the toxic mode-of-action should be taken into account when constructing SSDs to derive acceptable concentrations. If the lower-tier indicates that one species of the basic set is considerably more sensitive an SSD should be constructed representative for the sensitive taxonomic group. According to the HARAP guidance document, toxicity data for at least 8 different species from the sensitive taxonomic group are recommended to construct SSDs. In case of herbicides usually vascular plants and algae comprise the most sensitive group, while in case of insecticides arthropods usually are most sensitive. For fish the HARAP guidance document recommends the use of a minimum number of 5 toxicity data to construct SSDs specific for fish.

This lower number of toxicity data is chosen, amongst other reasons, to address animal welfare considerations. For PPPs with biocidal properties, such as several fungicides for which the basic set of standard test species shows a more or less equal sensitivity, at least toxicity data for 8 different taxonomic groups should be used. The HARAP Guidance document, however, does not specify the taxonomic groups and level of taxonomic resolution when selecting toxicity data for this generic SSD. According to the Guidance Document on Aquatic Ecotoxicology [5] the lower-tier Assessment Factors may be reduced if additional sensitive species are tested. A statistical extrapolation technique (e.g. the method described in Aldenberg and Jaworska [10]) can also be used to calculate the concentration at which a specified proportion of species (p) are expected to suffer direct toxic effects, referring to as the Hazardous Concentration (HC) to p% of the species (HC_p). The Species Sensitivity Distribution from which the HC_p is derived can be based on either acute or chronic toxicity data. However, the smaller the number of data available for the calculation, the larger the confidence interval around the SSD (and the HC_p) will be (Figure 1).

The HARAP guidance document [9] mentions HC₅ and HC₁₀ values as possible assessment endpoints. However, in the Guidance Document on Aquatic Ecotoxicology [5] currently no established guidance is provided on which HC_p is appropriate for assessments under Regulation (EC) No 1107/2009 [1].

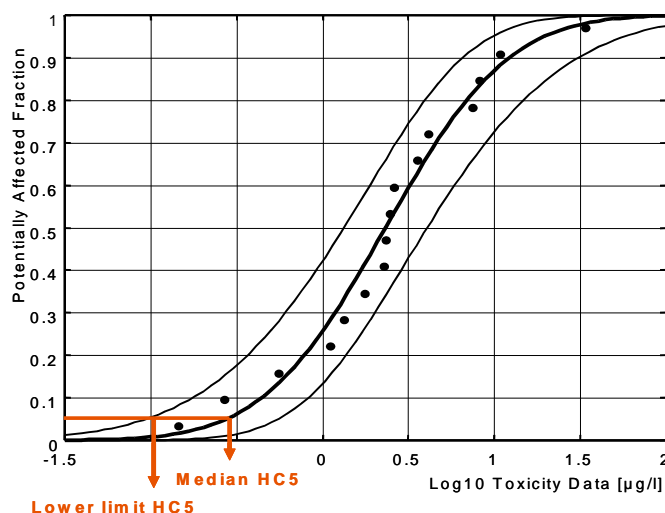


Figure 1: Graphical presentation of the Species Sensitivity Distribution curve, its 95% confidence interval, and the derivation of the lower limit and median Hazardous Concentration to 5% of the species (HC5).

For construction of SSDs, the programme ETX2.0 can be used (Van Vlaardingen et al., 2004)[11]. This programme also contains several statistical tools to test the assumptions of normality (see Point 7 above). It should be noted, however, that the performance of these tests strongly depends on the number of data. With a relatively low number of data, a distribution is often accepted as normal, whereas for large datasets deviations from normality will be more easily detected. The outcome of the tests as such should therefore not be used as a single criterion to decide whether or not the SSD can be applied, or to split datasets to construct specific SSDs for particular taxonomic groups. A thorough evaluation of the individual data points and visual inspection of the fit may reveal whether or not violation of the assumptions concerning the distribution is acceptable. For example, violation of the goodness-of-fit test may be acceptable from a regulatory point of view when the fitted distribution in the tail of the SSD is relatively worst case compared to the data points (in the sense that most of the toxicity data around the HC5 and lower are on the right side of the fitted curve).

In Brock et al (2011) (Alterra report 2235) [12] the SSD approach is presented in very much detail. This report is not yet accepted as official guidance to be used in risk assessment of PPPs. However, for information about how to perform the SSD approach for different types of compounds reference can be made to this report, because it is standard practice. The report contains also proposals for safety factors which has to be applied on the HC5 values. These proposals are accepted by Ctgb and are presented below. A difference is made between aquatic invertebrates/primary producers and fish, because for vertebrates a higher protection level is required than for invertebrates and primary producers.

Table 1: Safety factors on acute and chronic HC5 values derived from Species Sensitivity Distributions with aquatic invertebrates and/or primary producers (from Brock et al (2011), Alterra report 2235)

Field exposure regime in drainage ditch scenario	Relevant PEC	Hazardous concentration	AF
Single pulse exposure of short duration (or repeated pulse exposures that are	PEC _{max}	Median acute HC ₅ (based on acute LC ₅₀ or EC ₅₀ data)	1

toxicologically independent*) of which the water dissipation DT_{50} in predicted field exposure profile is lower than 10 days			
Toxicologically dependent repeated pulse exposures (water dissipation $DT_{50} < 10d$ in predicted field exposure profile) or single pulse with a water dissipation DT_{50} in predicted field exposure profile that is larger than 10 days	PEC_{max}	Median acute HC_5 (based on acute LC_{50} or EC_{50} data)	3
More or less constant chronic exposure	PEC_{max} or PEC_{TWA}	Median chronic HC_5 (based on chronic NOEC and/or EC_{10} data)	1-2#

* For tests to demonstrate that repeated pulses are toxicologically (in)dependent see sections 3.3.3

The range of 1 to 2 is proposed to address the higher uncertainty in availability of chronic SSDs

Table 2: Safety factors on acute and chronic HC_5 values derived from Species Sensitivity Distributions with fish (and other aquatic vertebrates) (from Brock et al (2011), Alterra report 2235)

Field exposure regime in drainage ditch scenario	Relevant PEC	Hazardous concentration	AF
Single pulse exposure of short duration (or repeated pulse exposures that are toxicologically independent) of which the water dissipation DT_{50} in predicted field exposure profile is lower than 10 days	PEC_{max}	Median acute HC_5 (based on acute NOEC and/or acute LC_{10} data)	1
		or Median acute HC_5 (based on acute LC_{50} or EC_{50} data)	3
Toxicologically dependent repeated pulse exposures (water dissipation $DT_{50} < 10d$ in predicted field exposure profile) or single pulse with a water dissipation DT_{50} in predicted field exposure profile that is larger than 10 days	PEC_{max}	Median acute HC_5 (based on acute NOEC and/or acute LC_{10} data)	3
		or Median acute HC_5 (based on acute LC_{50} or EC_{50} data)	5
Chronic exposure: more or less constant chronic exposure	PEC_{max} or PEC_{TWA}	Median chronic HC_5 (based on chronic NOEC and/or EC_{10} data)	1 - 3

Micro-mesocosm studies

In the Guidance Document on Aquatic Ecotoxicology [13] the information regarding micro-/mesocosm studies is mainly directed on the performance of these studies and some information concerns the interpretation of the studies. Little information is presented about the acceptability of effects seen in these studies.

In Brock et al (2011) (Alterra report 2235) [12] many details are given regarding the interpretation of the effects and also proposals for safety factors to be applied to the

endpoints of the micro/mesocosm studies. For the interpretation of the effects reference is made to this report. The proposals for safety factors in the Alterra report are accepted by Ctgb and are presented below.

Table 3: Safety factors applied on endpoints from appropriate micro-/mesocosm experiments

	Assessment factor	Field exposure concentration
Ecological threshold option		
Effect class 1** (based on nominal or measured peak concentration)	1 – 2*	PEC _{max}
Effect class 2*** (based on nominal or measured peak concentration)	2 - 3*	PEC _{max}
Ecological recovery option		
Effect class 3A**** (based on nominal or measured peak concentration)	3 - 4*	PEC _{max}

* The height of the AF is based on expert judgement considering all available lower and higher-tier information. If several adequate micro/mesocosm studies are available the AF is applied to the highest Effect class 1, 2 or 3 value or a lower AF than reported in the table may be applied. If in the same study several treatments resulted in the same 'Effect class'- response the highest concentration within the same Effect class is selected.

** **Effect class 1** (*No treatment-related effects demonstrated; NOEC_{micro/mesocosm}*).
No (statistically and ecologically significant) effects observed as a result of the treatment. Observed differences between treatment and controls show no clear causal relationship.

*** **Effect class 2** (*Slight effects*).
Effects reported as "slight", "transient", or other similar descriptions. It concerns a short-term and/or quantitatively restricted response of one or a few sensitive endpoints, usually observed at individual samplings only.

**** **Effect class 3A** (*Pronounced short-term effects (< 8 weeks, followed by recovery)*).
Clear response of sensitive endpoints, but full recovery of affected endpoints within 8 weeks after the 1st application or, in case of delayed responses and repeated applications, the duration of the effect period is less than 8 weeks and followed by full recovery. Effects observed at some subsequent sampling instances.

A decision tree with corresponding explanatory notes is presented in Appendix 1. This decision tree summarises the decision scheme for aquatic and sediment dwelling organisms.

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 aquatic organisms 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.

1.4.2. Evaluation of plant protection products

The principles for evaluation of the effects on the environment are presented in Commission Regulation (EU) No 546/2011 [14]. 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 aquatic organisms, in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.2.2. Member States shall evaluate the possibility of exposure of aquatic organisms to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the degree of short-term and long-term risk to be expected for aquatic organisms after use of the plant protection product according to the proposed conditions of use.

(a) This evaluation will take into consideration the following information:

(i) the specific information relating to the effects on aquatic organisms 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,
- volatilization rate,
- KOC,
- biodegradation in aquatic systems and in particular the ready biodegradability,
- photodegradation rate and identity of breakdown products,
- hydrolysis rate in relation to pH and identity of breakdown products;

(iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 545/2011 and in particular the effects on aquatic organisms;

(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;

(b) This evaluation will include:

(i) the fate and distribution of residues of the active substance and of relevant metabolites, breakdown and reaction products in water, sediment or fish;

(ii) a calculation of the acute toxicity/exposure ratio for fish and Daphnia. This ratio is defined as the quotient of respectively acute LC50 or EC50 and the predicted short-term environmental concentration;

(iii) a calculation of the algal growth inhibition/exposure ratio for algae. This ratio is defined as the quotient of the EC50 and the predicted short-term environmental concentration;

(iv) a calculation of the long-term toxicity/exposure ratio for fish and Daphnia. The long-term toxicity/exposure ratio is defined as the quotient of the NOEC and the predicted long-term environmental concentration;

(v) where relevant, the bioconcentration in fish and possible exposure of predators of fish, including humans;

(vi) if the plant protection product is to be applied directly to surface water, the effect on the change of surface water quality, such as pH or dissolved oxygen content.

1.4.3. Decision making for plant protection products

The principles for decision making as regards the effects on the environment are presented in Commission Regulation (EU) No 546/2011 [14]. 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, as regards aquatic organisms, are in the text below printed in a grey frame.

This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.2.2. Where there is a possibility of aquatic organisms being exposed, no authorisation shall be granted if:

- the toxicity/exposure ratio for fish and Daphnia is less than 100 for acute exposure and less than 10 for long-term exposure, or
 - the algal growth inhibition/exposure ratio is less than 10, or
 - the maximum bioconcentration factor (BCF) is greater than 1 000 for plant protection products containing active substances which are readily biodegradable or greater than 100 for those which are not readily biodegradable,
- unless it is clearly established through an appropriate risk assessment that under field conditions no unacceptable impact on the viability of exposed species (predators) occurs -

directly or indirectly - after use of the plant protection product according to the proposed conditions of use.

1.5. Developments

- In the framework of the WG Water, the Effects assessment working group has produced a draft report (Brock et.al. 2011) [12]. In this report new proposals for the aquatic effects assessment of plant protection products in the Netherlands are described for edge-of-field surface waters (drainage ditches) falling under the domain of the Plant protection Product Regulation (pre-registration) and for water bodies falling under the domain of the Water Framework Directive (post-registration). This report is not officially handed yet to Ctgb.
- Hormone-disturbing substances
It is known that substances may disturb endocrine systems of organisms. Endocrine substances may in an early life stage cause damage of which the effects only manifest themselves later, possibly only in a next generation. It is recognised that the current available chronic toxicity tests are not adequate to demonstrate potential endocrine effects. This is why in an international programme, organised by OECD, toxicity tests (including fish) are being developed to identify endocrine-disturbing substances. For the time being, data on mammals may give an indication. In the process of revision of 544/2011 and 545/2011 data requirements regarding endocrine disruption will be taken into account by setting several data requirements.
- Macrophytes
In the process of revision of 544/2011 and 545/2011 a test with an additional plant species will be required in case if Lemna is not a representative species.
- Invertebrates
In the process of revision of 544/2011 and 545/2011 a test with a second invertebrate species will be required as a standard requirement.
- Amphibians
In the process of revision of 544/2011 and 545/2011 data requirements probably data requirements regarding the toxicity to amphibians will be implemented.
- Acute fish testing
For fish, the draft revised OECD guideline recommends reducing the number of test animals in the limit test. It is proposed to perform the limit test with a minimum of 7 fish including for the control, as when zero mortality is recorded in 7 to 9 fish there is 99% confidence that the LC50 is above 100 mg/L. In the main test of OECD no. 203, there should be seven fish per concentration tested.
- Organisms in groundwater
Studies of the biological groundwater ecosystem have led to the notion that the groundwater ecosystem is a system as such which needs protection [15,16]. Active substances and/or metabolites should for this reason be evaluated for their effects on the groundwater ecosystem in the future.
In the absence of more specific information and harmonised test guidelines, it may be assumed that groundwater organisms have the same sensitivity as taxonomically and physiologically related organisms in surface water. Crustaceans represent the most important groundwater taxa and – from a provisional scientific point of view – data on crustaceans in surface water are considered as suitable and adequate to cover the

risk to groundwater organisms. Recovery observed in higher tier tests, however, is possibly not relevant for organisms in groundwater. Currently, harmonised schemes for exposure and risk assessment are not available. Further research should therefore be carried out in this field, as is also recommended in the Guidance Document on Aquatic Ecotoxicology [13].

- Revision Guidance Document on Aquatic Ecotoxicology
There will be a revision of the Guidance Document on Aquatic Ecotoxicology in the coming years by EFSA. It is not yet clear when this revision will be available.
- The Water Framework Directive came into force on 23 October 2000 (Directive 2000/60/EC). This Directive aims at mapping the chemical and ecological water quality by means of a standardised monitoring and reporting protocol.
In addition, the desired future water quality is described, together with the path to reach this new situation. There is a link with Plant Protection Directive 91/414/EC in view of the burdening of surface water by pesticides.
The consequences for the authorisation policy of plant protection products are not yet fully clear.
- Ecological modelling
Individual-level effects of pesticides may depend on factors such as toxicokinetics and toxicodynamics, exposure history and adaptation, the developmental stage of the organism and avoidance behaviour. On the population-level, effects of pesticides not only depend on exposure and toxicity profiles, but also on factors such as biological traits (e.g. life history characteristics), demographic structure of the populations of concern, food web interactions, ecological infrastructure (e.g. connectivity of waterways), spatio-temporal aspects of multi-stress and the presence of refuges in space and time. Since it is practically not feasible to perform experiments that address all these factors, computer simulation models may be the appropriate tools to integrate the results of focussed ecotoxicological experiments.
Promising individual-level models in the future risk assessment to extrapolate time-variable exposure regimes of pesticides comprise toxicokinetic/toxicodynamic (TK/TD) models. These models, however, have been developed for a limited number of aquatic species only so that it primarily concerns a research activity up till now. Whether the parameters and model concepts derived with TK/TD models for these focal species can be easily extrapolated to other aquatic species is an important research activity (Rubach, 2010)[17]. So far TK/TD models do not consider distribution and metabolism of the toxicant within the organism. Thus, the description of the TK is usually restricted to the process of uptake and elimination only, and the models differ mainly in their assumptions on the TD. The TD concepts differ in the range of toxic mechanisms for which they are valid. Consequently, another important research activity is to further develop TK/TD models for pesticides that differ in toxic mode-of-action (Hommen *et al.*, 2010b)[18].
To date, a broad range of ecological models to predict population and community responses is available in the scientific literature. However, ecological models in support of the regulatory risk assessment for pesticides not often have been used because of lack of understanding of model assumptions, uncertainties about model inputs and outputs, and lack of validation and good modelling practice (Schmolke *et al.*, 2010) [19]. Nevertheless, currently considerable research efforts take place to address these drawbacks and to further improve modelling approaches in the effect assessment procedures for pesticides (Grimm *et al.*, 2009)[20].
- Risks of fungicides to aquatic fungi
Almost no information is available concerning the potential risks of fungicides (or

PPPs in general) to aquatic fungi. Maltby *et al.* (2009)[21] compiled aquatic ecotoxicity data for a series of fungicides. The dataset included acute single-species data for 42 fungicides, semi-field data for 12 fungicides and covered seven modes of action and different exposure regimes. SSDs were constructed for separate taxonomic groups (*i.e.* fish, invertebrates, and primary producers) and for all groups together. They conclude that there is no evidence to suggest that derived threshold values based on hazardous concentrations (HC_p) from acute aquatic SSDs would pose a risk to aquatic hyphomycetes. However, laboratory toxicity data on fungi were not included in the datasets, since they were not available. In the micro/mesocosm studies reviewed, only functional responses of micro-organisms in the form of litter decomposition received attention. None of the semifield studies specifically studied structural endpoints of fungi. Maltby *et al.* (2009)[21] therefore also concluded that the underlying data is limited in number and that further research on nontarget fungi should be conducted. The relevance of further research into the sensitivity of aquatic fungi was demonstrated recently in screening studies by Dijksterhuis *et al.* (2009, 2011)[22, 23] and CBS (2009)[24]. Their data indicate that HC_5 concentrations derived by Maltby *et al.* (2009)[21] for ergosterol inhibitors may show an effect on aquatic fungi. Further research is needed to address the relevance of aquatic fungi as additional non-target groups in the risk assessment of PPPs. Special attention should be paid to the selection of appropriate test species, given the enormous diversity within the kingdom of fungi. When these data are collated, it will be a risk manager decision to set the specific protection goal for aquatic fungi (e.g. structure and/or function).

- Multiple stress and mixture toxicity

In many crops during the growing season more than one compound will be used. In some crops this can add up to more than 50 applications and some of these compounds will be applied together, e.g. an herbicide together with an insecticide and/or fungicide. Sometimes even two or three herbicides or two or three fungicides or two insecticides may be applied simultaneously, up to 5 or 6 compounds at the same time. When these combinations (e.g. tank mixes) are not sold as a formulation the legislative process does not take account for the potential combined effects of the use of these tank mixes. Neither does the legislative process take into account that different compounds of the same group (e.g. insecticides) or of different groups (e.g. insecticides, herbicides, fungicides) are used over time in the same growing season. When a compound is allowed on the market this decision is sometimes based on the potential of recovery. Whether under different crop scenarios the recovery option is appropriate to use in the derivation of the RAC needs to be evaluated from an ecological point of view, since during the growing season drainage ditches may be affected multiple times by the use of plant protection products. The EFSA working group dealing with the update of the Guidance Document on Aquatic Ecotoxicology will take this topic into account.

II EFFECTS ON A SEWAGE TREATMENT PLANT (STP)

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 serves to estimate the risk to micro-organisms in the STP.

This chapter is related to Chapter 6 Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plant (STP).

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 540/2011.

1.2. Data requirements

In order to qualify for inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [4] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [5]. must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the execution of experiments are mentioned in Commission Communication 2013/C 95/01 [6].

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 effects of the active substance on sewage treatment plants (STPs) are described in part A of Commission Regulation (EU) No 544/2011, point 8.8 (effects on biological methods for sewage treatment).

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 microflora 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 biological methods for sewage treatment
(283/2013; 8.8)

8.8. Effects on biological methods for sewage treatment

A test shall provide an indication as to the potential of the active substance on biological sewage treatment systems.

Circumstances in which required

Effects on biological methods for sewage treatment shall be reported where the use of plant protection products containing the active substance can give rise to adverse effects on sewage treatment plants.

→ L(E)C₅₀ STP

1.2.2. Data requirements for the product

According to Commission Regulation (EU) No 284/2013 [5], no data are required for the risk assessment for an STP.

1.3. Risk assessment

Risk assessment is carried out as described in §1.3 of Chapter 6 Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plant (STP).

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 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.

1.4.2 Evaluation of plant protection products

Commission Regulation (EU) No 546/2011, the Uniform Principles (Directive 97/57/EC), contains no specific criteria for risk assessment as regards sewage treatment.

1.4.3 Decision making for plant protection products

Commission Regulation (EU) No 546/2011, the Uniform Principles (Directive 97/57/EC), contains no specific criteria for decision making as regards sewage treatment..

However, for the national assessment the threshold level used for risk assessment is 0.1 * EC50 STP value.

1.5. Developments

There is a draft new EFSA guidance document for aquatic organisms: Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013; 11(7):3290. This guidance document has to be implemented still. The implementation is expected somewhere in the second half of 2014.

2. APPENDICES

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Appendix 1 Explanatory notes decision tree Risk to aquatic and sediment dwelling organisms based on Regulation (EC) 1107/2009

- 1) For each active substance, information concerning toxicity to aquatic organisms (Commission Regulation (EU) No 283/2013: point 8.2) [4] must be provided, unless it can be demonstrated that it can be ruled out that the substance reaches surface water during good (agricultural) use of the product, in compliance with the WG/GA (Statutory Use Instructions/Directions for Use). For the purposes of labelling in the European framework, data concerning acute toxicity of the active substance to algae, daphnia and fish, and the ready biodegradability of the active substance must always be provided. For each product in principle data concerning toxicity to aquatic organisms must be provided if the toxicity of the plant protection product cannot be predicted on the basis of the data for the active substance (Commission Regulation (EU) No 284/2013, point 10.2).
- 2) The acute toxicity research (283/2103 point 8.2.1/8.2.4/A8.2.6) must be carried out in accordance with standardised methods with representatives of at least 3 different trophic levels, i.e., algae, crustaceans and fish.
For fish acute toxicity data are always required for rainbow trout (*Oncorhynchus mykiss*). Also a test with a warm water species is required, unless it can be justified that exposure is not likely to occur.
For herbicides and growth regulators a standard test with higher aquatic plants must be submitted (283/2013 point 8.2.7) as well as a test with a second algal species from a different taxonomic group. If the toxicity of an insecticide to *Daphnia* is low (48 h EC50 > 1 mg/L; 21 d NOEC > 0.1 mg/L), this may indicate selectivity. An acute toxicity test should then be carried out with first instar (2-3 d old) *Chironomus riparius* (48 h water-only study).
If a long-term/chronic study on insects is already available there is no need to require additionally an acute one.
Except for the active substance and the product, data about metabolites formed in the water and sediment phase of water/sediment systems are required as well, where a distinction is made between *minor* and *major* metabolites.
Major metabolites in the aqueous phase are metabolites of which in the laboratory study into the transformation in a water/sediment system the concentration in the aqueous phase is at any point in time higher than or equal to 10% of the added amount of active substance.
Data on transformation rate, bioconcentration and acute toxicity to algae, daphnia and fish are required for such metabolites. Metabolites should in general also be tested with *Lemna*, *Chironomus* or other species if these taxa have been the most sensitive with the active substance. If it can be demonstrated that certain taxonomic groups are clearly less sensitive to the active substance (by a factor of 100) than other groups, testing can be limited to those which are the most sensitive ones. If testing reveals that the toxicity of the metabolite to one taxonomic group is similar to the parent or higher then testing may be required on all taxonomic groups.
Major metabolites in the sediment phase are metabolites of which in the laboratory study into the transformation in a water/sediment system the concentration in the sediment phase after 14 days is higher than or equal to 10% of the added amount of active substance. Data on the toxicity to sediment dwelling organisms are required for such metabolites.
Minor metabolites should be taken into consideration as well.
The data requirements mentioned in this section do not always need to be met by

means of experimental studies.

Applicants may also answer the open questions by means of other available information in support of a scientific and rational risk assessment. Valuable sources of information are e.g.:

- consideration of molecular structure of the metabolite (active part intact?);
- the occurrence of metabolites in the medium in existing tests with the active substance or major metabolites;
- general knowledge on the relationship between the toxicity of the metabolite and its parent substance (e.g. from the aquatic base set (fish, daphnia, algae);
- information on pesticidal activity from biological screening data;
- available knowledge on related compounds;

Further information is given in the Guidance Document on Aquatic Ecotoxicology [13].

- 3) In case of chronic or repeated exposure (more than 1 application according to WG/GA), chronic toxicity data (283/2013 point 8.2.2/8.2.5) must be submitted. Where DT_{50} in the aqueous phase < 2 days and the applicant demonstrates clearly that prolonged/chronic exposure does not occur as result of the application interval, chronic toxicity studies do not need to be provided. The risk of repeated acute exposure must be determined in this case. The DT_{50} value must be determined in a water/sediment study at an environmentally relevant pH value (283/2013 point 7.2.2.3..
- 4) Chronic toxicity studies (283/2013 point 8.2.2/A8.2.5) should in any case be submitted for the active substance. This concerns chronic tests with fish and daphnia. If the 48 h EC_{50} for *Chironomus* sp is at least ten times lower than the Daphnia 48 h EC_{50} (see point 2), then a chronic study should also be conducted with *Chironomus* sp. For transformation products data must be provided if:
 - the transformation product was found to be more toxic than the active substance in acute toxicity tests, and
 - $DT_{50} \geq 2$ days for the transformation of the transformation product in the aqueous phase, determined in a water/sediment study.Where for these metabolites acute toxicity data are available for fish and daphnia, a chronic test only needs to be carried out with the most sensitive group.
- 5) Where in a water/sediment study (283/2013 point 7.2.2.3.) after 14 days (283/2013 point 8.2.7) $\geq 10\%$ of the active substance and/or metabolite is found in the sediment, a chronic toxicity test with sediment dwelling organisms (*Chironomus* sp.) (283/2013 point 8.2.7) must be provided unless the NOEC from the chronic daphnia test (or a comparable study with aquatic insects if this group of organisms is more sensitive) ≥ 0.1 mg a.s./L.
- 6) Further information on the calculation and determination of the PEC is given in Chapter 6 Behaviour and fate in the environment; behaviour in surface water, sediment and sewage treatment plant (STP).
- 7) The following criteria must be met:
An active substance and each of its transformation products have in surface water a concentration lower than:
 - 0.01 of the LC_{50} for acute toxicity to fish
 - 0.01 of the EC_{50} for acute toxicity to daphnia
 - 0.1 of the EC_{50} for algae
 - 0.1 of the EC_{50} for aquatic plants
 - 0.1 of the NOEC for long-term toxicity to fish and daphnia

- 0.1 of the NOEC for long-term toxicity to sediment dwelling organisms
The risk is low if these criteria are met. The product can be authorised in as far as the risk to aquatic and sediment dwelling organisms is concerned.

8&9) A risk is present if the criteria as given under 7) are not met. Such a use is considered as not permissible, unless a further (adequate) risk evaluation shows that there are no unacceptable direct or indirect effects for aquatic and sediment dwelling organisms and organisms that depend on aquatic ecosystems (higher tier). The higher tier risk assessment is performed according to Regulation (EC) 1107/2009 and hence the Guidance Document on Aquatic Ecotoxicology [13]. For further information reference is made to the decision tree on the higher tier risk assessment for aquatic and sediment organisms (Appendix 1B).

10) Research is requested to determine species accumulation and elimination, i.e., the extent to which the substances in question are directly absorbed from the water, retained (bioconcentration factor BCF), and excreted by the organism. The octanol/water partition coefficient (Kow) (283/2013 point 2.7) of a substance gives information about the bioaccumulating capacity of a substance. Where the logKow of a substance < 3, experimental research is not required. For such organic substances sufficient insight into the bioaccumulating capacity can be obtained from the octanol/water partition coefficient (Kow) (283/2013 point 2.7), for which the following formula (Veith et al., 1979¹) is used:

$$\log\text{BCF} = 0.85 \cdot \log\text{Kow} - 0.70 \text{ (L/kg)}$$

Experimental research with fish is required for substances with a logKow > 3 (283/2013 point 8.2.2.3), unless the substance is considered not stable, i.e. DT90 in the whole system is < 10 days in a water/sediment study. But if in the case of an unstable substance the proposed use of the active substance includes multiple applications at intervals short enough to result in significant long-term exposure, then experimental research is again necessary.

- 11) An active substance of a plant protection product and each of its transformation products have a maximum bioconcentration factor lower than:
- a. 1000 for readily biodegradable active substances, or
 - b. 100 for active substances that are not readily biodegradable.
- 12) Where this is not the case, a risk is present and the use is not permissible, unless a further (adequate) risk evaluation shows that there are no unacceptable direct or indirect effects for aquatic and sediment dwelling organisms and organisms that depend on aquatic ecosystems (higher tier). The higher tier risk assessment is performed according to Regulation (EC) 1107/2009 and hence the Guidance Document on Aquatic Ecotoxicology [13].

As bioaccumulation processes often are slow and substances could be persistent a chronic risk assessment is appropriate. The following exposure routes should be considered:

- direct long term effects in fish due to bioconcentration;
- secondary poisoning for birds and mammals;

¹ Veith, G.D., D.L. Defoe and B.V. Bergstedt. 1979. Measuring and estimating the bioconcentration factor of chemicals on fish. J. Fish. Res. Board Can. 36: 1040-1048.

- biomagnification in aquatic food chains.

For more information about the triggers regarding the different possible tests and information on the risk assessment reference is made to the Guidance Document on Aquatic Ecotoxicology [13].

If the risk from bioaccumulation is still not acceptable, drift reduction measures may be applied. If these are sufficient the risk from bioaccumulation in the edge-of-field ditch is acceptable.

For the higher tier risk assessment triggered by exceeding of the first tier TER values several possibilities exist, e.g.:

- SSD approach;
- micro-/mesocosm studies.

For more information about these studies and approaches reference is made to the Guidance Document on Aquatic Ecotoxicology [13], the Guidance for summarizing and evaluating aquatic micro- and mesocosm studies [8] and paragraph 2.3. In this paragraph also information is presented with regard to the acceptability of effects.

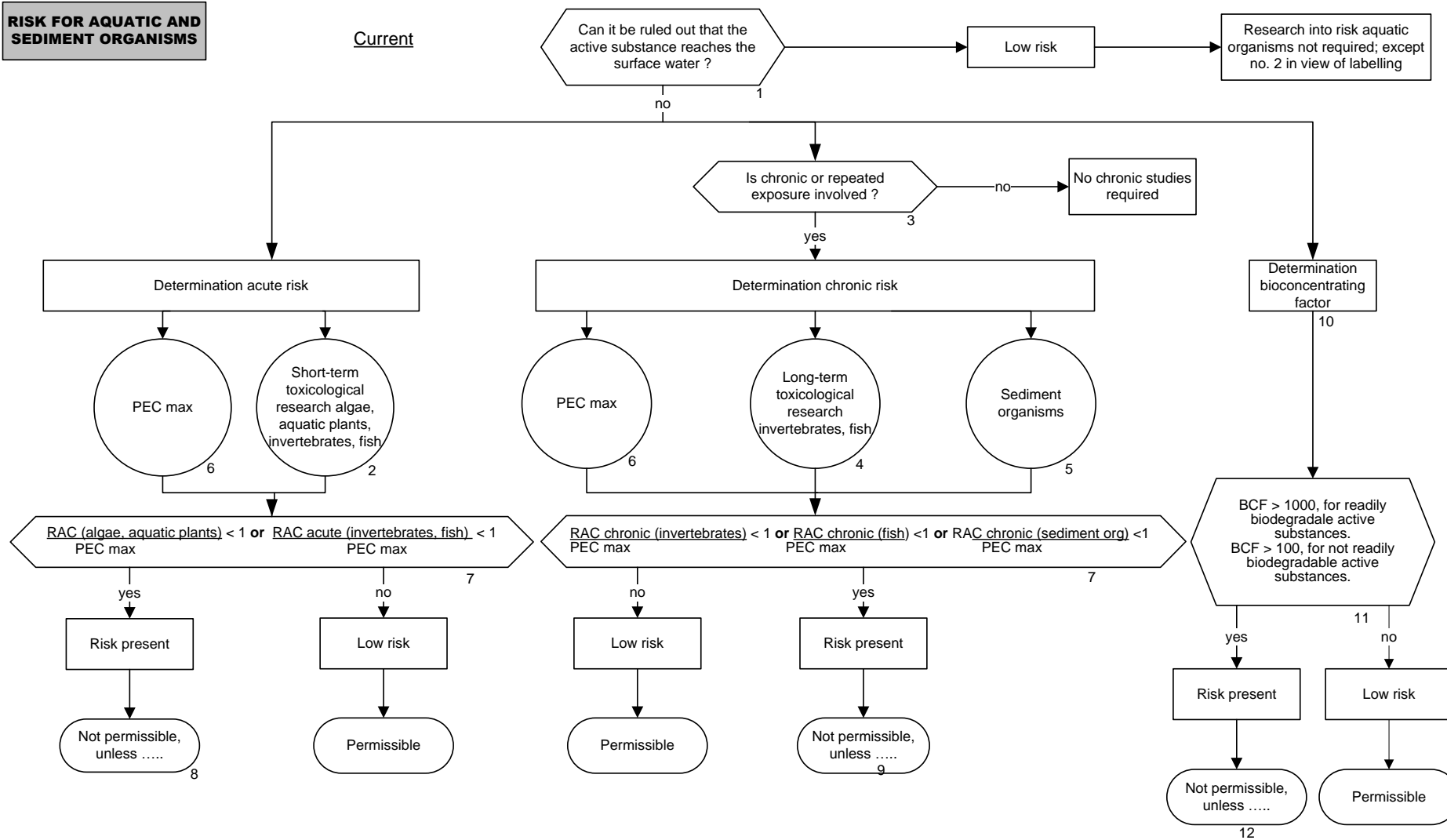
A TER is calculated based on the relevant higher tier Regulation (EC) 1107/2009 toxicity endpoint and the relevant PEC in the edge-of-field ditch. The toxicity endpoint depends on the higher tier approach which is chosen; modified exposure studies are directed on taking into account fate processes under natural conditions; the endpoint will change but in principle the same safety factor will be applied as in the first tier risk assessment. The SSD approach yields an endpoint which can be a mean HC5 value with a certain safety factor. More information can be found in paragraph 2.3.

A micro-/mesocosm study yields a NOEC or NOEAEC. For risk assessment a safety factor is applied (trigger value). The safety factor depends on the endpoint and on the number of studies available. For more information see paragraph 2.3.

If the TER is lower than the trigger value, a risk is still present; drift reduction measures may be applied. If these are sufficient the risk in the edge-of-field ditch is acceptable.

RISK FOR AQUATIC AND SEDIMENT ORGANISMS

Current



Appendix 2 Risk evaluation crop protection products in mushroom culture

Emission from mushroom rearing facilities to surface water and STP
The Dutch Approach

(information from Dutch Handbook for risk assessment of pesticides translated for PRAPeR 62, January 2009)

NB emission values have been established based on monitoring data in The Netherlands in the 1980's and early '90's. Approach was established in 1993.

Two scenarios were developed:

1. direct emission to surface water
2. indirect emission of surface water (via STP)

Those scenarios are described below.

1. direct emission to surface water (only settling in presettlement tank).

- 1) most (realistic) critical situation (direct emission via settlement tank to surface water)

input values/parameters:

substance: X

application rate: D kg/ha

application: per event 1 cell of 200 m²

emission percentage: maximum 3,5% per day

sewage water discharge: Q = 1,5 m³/day per facility (1.000 m²)

efficiency settlement tank: 50%

receiving surface water: standard NL ditch
i.e. semi-stagnant
dilution factor 3 (12)

calculation of initial PEC (t=0) is based on next steps/assumptions:

- a) applied amount per company/cell (200 m²): 0,02*D
- b) emission to raw sewage water: 0.035 * amount applied
- c) concentration in raw sewage water: emission/daily discharge
- d) concentration in sewage water after settlement: 0.5 * concentration in raw sewage water
- e) concentration in receiving surface : concentration in sewage water after settlement /dilution factor of 3
- f) in short:

$$PEC_{aq} (\mu\text{g/l}) = \frac{0.02 * 0.035 * 0.5 * D * 10^6}{1.5 * 3} = 78 * D$$

2. situation where emission occurs through an STP

- 2) least critical situation (emission via purification facility on STP)

input values/parameters:

substance: X

application rate: D kg/ha

application: per event 1 cell of 200 m²

emission percentage: maximum 3,5% per day

sewage water discharge: Q = 1,5 m³/day per facility (1.000 m²)

efficiency settlement tank: 50%

standard STP properties 'Maasdriel': 13.700 i.e. and a *daily water discharge* of 2.000 m³/dayarea of companies in the relevant area: 127.000 m²

degree of purification in area: 100% of companies has settlement tank

assumption that only half of companies emits at same time (correction factor 0.5)

efficiency of removal in STP: R= 0, 25, 50 or 75% depending on the

simple treat calculation for the receiving surface water: Meuse, dilution factor of 100

calculation of initial PEC (t=0) is based on next steps/assumptions:

- a) amount applied in area: 12,7 * D
 b) emission in sewage water: 0,035 * 0,5 * 0,5 * applied amount
 (after settlement and assuming emission by half of the companies at the same time)
 d) concentration in influent STP: emission/daily discharge
 NB this gives the PEC_{eff} for STP organisms
 e) concentration in receiving surface water: influent / (purification efficiency* dilution factor 100)
 NB this gives the PEC_{aq} for short-term/initial exposure for water and sediment organisms as a consequence of effluent discharge from the STP
 f) in short

$$\text{PEC-STP } (\mu\text{g/l}) = \frac{12,7 * 0,035 * 0,5 * 0,5 * D * 10^6}{2000 + Q * 127.000 / 1.000} = 51 * D$$

$$\text{PEC}_{\text{aq}} (\mu\text{g/l}) = \frac{12,7 * 0,035 * 0,5 * 0,5 * D * 10^6 * ((100-R)/100)}{(2000 + 190) * 100} = 51 * D$$

$$\text{PEC}_{\text{aq}} (\mu\text{g/l}) = 0,52 D ((100-R)/100)$$

R = removal by simple treat

FOR MORE DETAILS REFERENCE IS MADE TO APPENDIX 3 OF CHAPTER 7
(ECOTOXICOLOGY; AQUATIC) OF HTB 1.0. (DOCUMENT IS IN DUTCH)

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