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

EU part

Plant protection products

Chapter 7 Ecotoxicology; aquatic

version 2.3; Juli 2020

ctgb

Board for the Authorisation of plant protection products and biocides

Chapter 7 Ecotoxicology; aquatic

Category: Plant Protection Products

Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 7 Aquatic			
Version	**Date**	**Paragraph**	**Changes**
2.1	October 2016	1.2	Text from data requirements deleted from the Manual, replaced with reference/links to Regulations (EU) No 283/2013 and 284/2013. Short list of data requirements included in the text.
		1.2.3	Criteria for relevant metabolites are adjusted
		1.3	Further elaboration or clarification on risk assessment issues that are used by Ctgb included in the text of 1.3: - Points of attention regarding the use of NOEC or NOEAEC from micro-/mesocosmstudies - Expression of the endpoints from aquatic studies - Algae (Methodology for calculating the section-by-section coefficient of variation in algal studies (OECD 201) - PECsw-twa - Further elaborations of the criteria reported in the EFSA guidance document on aquatic risk assessment - With respect to SSD and micro-/mesocosm studies reference is made now to EFSA aquatic GD
2.2	January 2020	1.3	Conclusions regarding the aquatic risk assessment of the EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, July 2019, are included in the text: - Additional information on relevant endpoint for algae and macrophytes (A.1); - Additional information regarding the geomean approach (A.2); - General recommendations on mesocosm experiments (representativeness and vulnerability of the communities tested, experimental design of mesocosm experiments, effect classes, consideration of indirect effects, representative ness of mesocosm studies when the risk assessment at lower tiers is triggered by a non-freshwater species) (B.1); - Extrapolation of studies between different agroclimatic conditions (B.2) - Use of refined exposure studies as Tier

			2C (B.4.3) - Alternative test design in Myriophyllum studies (B.4.4) - Minimum detectable difference (B.4.5) - How to express the endpoint for sediment-dwelling organisms when tested in the presence of sediment (B.4.6)
		I.1 and II.1	Sentence included on the administrative EFSA guidance
2.3	Juli 2020	Chapter 1.3	Bullet points from the final agreements from the 4th CZHW in Ecotoxicology, Dessau, Sept 20-21 2018 on ‘Risk mitigation measures’, ‘Refined exposure studies’ and ‘Derivation of endpoints for aquatic tests with instable substances’ included.

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.

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.

Notifiers preparing an assessment report for active substances need to comply with the relevant guidance, instructions and format laid down in the EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances.

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). That chapter describes the determination of estimated or measured concentrations in the sediment.

Guidelines for the risk assessment for aquatic organisms are described in the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290).

For sediment organisms these guidelines can be found in Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001).

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

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.

1.2.1. Data requirements for the active substance

The date 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).

Point 8.2 consists of the following data requirements:

8.2.1:	Acute toxicity to fish
8.2.2:	Long-term and chronic toxicity to fish
8.2.2.1:	Fish early life stage test
8.2.2.2:	Fish full life cycle test
8.2.2.3:	Bioconcentration in fish
8.2.3:	Endocrine disrupting properties
8.2.4:	Acute toxicity to aquatic invertebrates
8.2.4.1:	Acute toxicity to *Daphnia magna*
8.2.4.2:	Acute toxicity to additional aquatic invertebrate species
8.2.5:	Long-term and chronic toxicity to aquatic invertebrates
8.2.5.1:	Reproductive and developmental toxicity to *Daphnia magna*
8.2.5.2:	Reproductive and developmental toxicity to an additional aquatic invertebrate species
8.2.5.3:	Development and emergence in *Chironomus riparius*
8.2.5.4:	Sediment dwelling organisms
8.2.6:	Effects on algal growth
8.2.6.1:	Effects on growth of green algae
8.2.6.2:	Effects on growth of an additional algal species
8.2.7:	Effects on aquatic macrophytes
8.2.8:	Further testing on aquatic organisms

1.2.2. Data requirements for the product

The date requirements regarding the risk of the plant protection product for aquatic and sediment dwelling organisms are described in Commission Regulation (EU) No 283/2013, point 10.2 (effects on aquatic organisms).

Point 10.2 consists of the following data requirements:

10.2.1:	Acute toxicity to fish, aquatic invertebrates or effects on algal growth and macrophytes
10.2.2:	Additional long-term and chronic toxicity on fish, aquatic invertebrates and sediment dwelling organisms
10.2.3:	Further testing on aquatic organisms

1.2.3. Data requirements for metabolites

Metabolites in the water phase

For metabolites that are formed at more than 10 % at any timepoint or between 5 and 10 % at two or more occasions or at more than 5 % at the end of the study, a risk assessment (RA) is needed. In general, RA for metabolites formed below 5 % or below 10 % (observed at a single occasion) is not considered necessary. However, if there is reason to believe that a metabolite formed at < 5 % has intrinsic properties comparable to the parent substance in terms of its biological target activity, or that it has certain structural properties indicating high reactivity (i.e. mutagenicity) or endocrine disrupting properties or that it has unacceptable

toxicological properties, then that metabolite may be ecotoxicologically relevant and a RA is needed. Data on transformation rate, bioconcentration and acute toxicity to algae, invertebrates and fish are required for such metabolites.

Metabolites in the sediment phase
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, because they may well be ecotoxicologically relevant. Hence, all available information and expert judgement should be used to assess if metabolites <10% give rise to particular concern..

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 on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290) with respect to the water phase and in the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001) regarding the sediment phase.

1.3. Risk assessment

Aquatic organisms
The risk assessment methodology for aquatic organisms has in EU context been elaborated in the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290). Each study is analysed and evaluated separately. The final conclusion and the endpoint per aspect (such as LC_{50} fish and NOECecosystem) are presented in a list of endpoints.

Risk assessment is based on comparison with endpoints. The risk evaluation for aquatic 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 organisms.

Sediment dwelling organisms
The risk assessment methodology for sediment dwelling organisms has in EU context been elaborated in the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001).

What is written above for aquatic organisms about endpoints, risk assessment, higher tier and exposure concentrations also applies to sediment dwelling organisms.

In addition, further elaboration or clarification on risk assessment issues that are used by Ctgb are included in the text below:

A. Issues EFSA aquatic guidance document
Certain parts of the aquatic guidance document Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290) are still under discussion, e.g. the relevant endpoints for algae and aquatic plants and the geomean approach. Many Member States commented on these parts and expressed their concerns. The actual situation is that there is no agreement between the Member States about the approach to follow on these points. Member States asked for an update of the Guidance Document to deal with the concerns. It is decided by EFSA that a corrigendum of the aquatic GD is necessary on these issues; as long as such a corrigendum is not performed, Member States follow their own approach.

A.1 Relevant endpoints for algae and macrophytes
In the EFSA aquatic guidance document (Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290)) it is strongly recommended to use the ErC50 value as the endpoint for algae/macrophytes in risk assessment. In the former guidance (SANCO) the lowest endpoint (EbC50, EyC50, ErC50) had to be selected for the risk assessment. Because the ErC50 value is in most cases higher than the EC50 based on biomass or yield the protection level for algae and macrophytes will be lower when following the recommendation of the new guidance document. In the peer review meeting on recurring issues on ecotoxicology of October 2018 (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, June 2019) Germany presented a meta-analysis of Tier 1 and higher tier data. It was shown that Tier 1 endpoints expressed in terms of growth rate (i.e. ErC50 values) for algae and *Lemna* are respectively 6.9- and 3.5-fold higher than the Eb/yC50 values. Furthermore, comparison of Tier 1 data with endpoints from mesocosm studies indicated that the Tier 1 RAC calculated using ErC50 values is only protective in 42% of cases; while the same comparison based on EbR50 indicated a sufficient level of protection in 75% of the cases.
The experts acknowledged this concern. However, considering the available scientific knowledge, it was suggested that EFSA further considers this issue in the context of the revision of the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290) by taking into consideration all the available scientific knowledge on this aspect (e.g. van Wijngaarden and Arts, 2018).

For EU-dossiers it was decided to use the ErC50 in the risk assessment and to mention all endpoints (ErC50, EbC50 and EyC50) in the LoEP (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, December 2015), so that for the product assessment MSs can choose the endpoints they consider most appropriate. For the zonal assessments there is no decision yet taken by the Central Zone Steering Committee (CZSC).

The standard test duration of algae tests is 72 hours, according to the relevant OECD guideline. However, also tests with a duration of 96 hours and 120 hours are available. According to the new aquatic GD of EFSA (2013), algae tests with a test duration of 72-h and 96-h are

acceptable. If endpoints are available at 72-h as well as 96-h the lowest of the two should be used for risk assessment.

With respect to the endpoints from 120-h tests the endpoints at 72-h and 96-h should be determined, if possible. The lowest of the two should be used for risk assessment. If it is not possible to determine the endpoints at 72-h and/or 96-h, the 120-h endpoint is used for risk assessment.

The standard test duration of *Lemna* tests is 7 days, according to the relevant guideline. However, also 14-day endpoints are sometimes available. If the last endpoint is lower than the 7-d endpoint, the 14-d endpoint should be used for risk assessment, because there is no reason to assume that the endpoint at 14 days is less reliable (in consultation with Gertie Arts from WUR Environmental Research).

A.2 Geomean approach

For using the geometric mean in risk assessment additional data than the ones defined in the data requirements are needed. However, in some cases, two endpoints are sufficient for carrying out the geomean approach.

For using the geomean approach, the endpoints should be derived by highly comparable tests (including duration of the tests and how these tests cover the life cycle of the tested species).

At the zonal harmonisation workshop in Vienna (2015) it was decided that the geomean is only accepted for the acute risk assessment. The geomean is accepted for the chronic risk assessment of algae and *Lemna* (not *Myriophyllum*) but not for fish and invertebrates. However, there is a concern that the level of protection is not sufficient for each single active substance and PPP. Germany has made a proposal for a decision scheme in which it is decided whether the lowest endpoint or a geomean should be used.
In the peer review meeting on recurring issues on ecotoxicology of October 2018 (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, June 2019) the following was decided for the assessment of active substances at EU level: in cases where the RACgeomean is greater than the lowest endpoint, the lowest endpoint should be used to calculate the RAClowest. The minimum modified AF for deriving the RAClowest should be 20 for invertebrates and 30 for fish. The experts suggested that the approach should be further considered with the revision of the EFSA PPR Panel (2013).
There was no agreement for using a geometric mean for chronic data. This should be further considered together with the entire approach when the aquatic guidance (Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290)) is revised.

B. Other issues

B.1 General recommendations on mesocosm experiments

In the peer review meeting on recurring issues on ecotoxicology of October 2018 (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, June 2019) several general recommendations on mesocosm experiments were expressed (see below).

B.1.1 Representativeness and vulnerability of the communities tested.

The AF applied to the NOEC or NOAEC (for deriving the ETO- or ERO-RAC) is used for spatio-temporal extrapolations (for values of the AF, see Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface

waters (EFSA Journal 2013; 11(7):3290) p. 127; tables 34 and 35); it does not cover other elements (e.g. low representation of some vulnerable taxa).

It should be considered that the community represented is usually dominated by R-strategists, with high reproductive potential, and which are therefore of low vulnerability. This concern is particularly relevant for ERO derivation.

For invertebrates, this concern can be addressed by ensuring a sufficient number of EPT (Ephemeroptera, Plecoptera, Trichoptera) species. These taxa are generally quite vulnerable due to their reproductive cycles and to their high sensitivity to some substances. It is noted that EPT are also an important component of a functioning ecosystem. It was, however, noted that these taxa are generally not particularly abundant in mesocosms, and that most of them prefer cold fast-running water, while most mesocosm experiments are carried out in pond-like structures. Some experts also suggested that it may be appropriate to build up a list of the species/taxa which should be present in the mesocosms.

It was agreed that the absence or low abundance of vulnerable groups, i.e. EPT, should not necessarily result in the invalidation of the experiment. However, their absence should trigger the need for further considerations, e.g. the selection of a higher AF and/or request for further testing to confirm that EPT are not among the most sensitive species. In such assessment, particular consideration should be paid to the mode of action of the active substance.

B.1.2 Experimental design of mesocosm experiments

Recommendations were made on establishment time, recolonization, emergence, insect instars, replicates, number of samples and sampling times. For these issues reference is made to the report of the meeting (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, June 2019), section 4.3.

B.1.3 Effect classes

The terminology for effect classes currently included in the (Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290)) is based on the definitions by Brock et al. (2006) and De Jong et al. (2008) and modified to add the information about the minimum detectable difference (MDD).

Effect class 2 (slight effects) is defined as ‘Effects concern short-term and quantitatively restricted responses usually observed at individual samplings only’.

MDD classes do not propose a quantification for ‘slight effects’, but they do set to 50 % the limit for MDD able to detect ‘small effects’ (MDD class IV).

Brock et al. (2015) suggested that a class 2 effect can be set if the MDD is < 70 % on the sampling after the effect, or < 90 % on the two samplings after the effect. The paper also added that class 2 effects can be set when, on the sampling after the effect, the percentage deviation from controls is less than 20 %.

It must be noted that the decision scheme in the (Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290)) for the setting of the NOEC on the basis of effect class 2 concentration does not specify an MDD trigger nor a proper percentage effect for the sampling times following the one indicating an effect. This indeed opens up possible interpretation on the criteria to be used for setting class 2 effect concentrations. This should be further clarified in the revision of the guidance document.

B.1.4 Consideration of indirect effects

Community interactions (indirect effects; food chain effects) are to be appropriately considered when assessing effects of PPPs. For example, if the recovery option is

selected for algae in a study with a herbicidal mode of action, the study should be critically evaluated for potential effects on higher trophic levels (e.g. zooplankton).

B.1.5 Representativeness of mesocosm studies when the risk assessment at lower tiers is triggered by a non-freshwater species

The current aquatic guidance (Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290)) was developed to perform risk assessments for freshwater environments, in accordance with the data requirements specified in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013. The same AGD, however, does not exclude the opportunity of using data from non-freshwater (marine or brackish) species in the risk assessment scheme. On the contrary, endpoints for these species are regularly used in the evaluations of active substances and PPPs.

Data from ecotoxicological tests on non-freshwater species can refer to species at all trophic levels (e.g. *Skeletonema costatum* for primary producers, *Americamysis bahia* for aquatic invertebrates and *Cyprinodon variegatus* for fish). It is not unusual that the lower tier risk assessment is driven by non-freshwater species. When the evaluation at these lower tiers highlights a potentially high risk, an option to refine the assessment is to conduct mesocosm studies on freshwater communities. Non-freshwater species are hardly represented in such mesocosms, and therefore it is questionable whether these studies are adequate to derive an endpoint able to cover the organisms represented at lower tiers by non-freshwater species.

Usually, the presence of other organisms considered taxonomically similar to the most sensitive non-freshwater species is taken into account to solve the issue. However, the concept of 'taxonomically similar' is open to many interpretations: the term 'taxon' indicates a group of organisms with similar characteristics that can be applied to all the hierarchical levels of biological classification.

The role of phylogeny was discussed at the meeting and some experts disagreed about the use of this approach. It was highlighted that phylogeny is very fluid and hence difficult to be relied upon.

The proposal of setting a 'fixed' taxonomic hierarchical limit is problematic, as for some groups it is possible to get a better picture (more sub-group represented) than for others. However, a minimum level to be addressed was proposed on the basis of the comparison between *A. bahia* and the more closely related taxa that are often tested in mesocosms (Gammarids and Isopods). On this basis the minimum level to be matched should be the superorder. However, a general rule should be to consider which is the closest taxon that can reasonably be tested in a mesocosm, considering its autecology.

Overall, a stepwise procedure was proposed and agreed upon:

Step 1: check whether in the mesocosm the taxa closely related to *A. bahia* are included as the minimum representativeness requirement.

- If the mesocosm does not meet the minimum representativeness requirement, it cannot be considered to cover the risk for the most sensitive taxonomic group.
- If the mesocosm covers the minimum representativeness requirement, go to step 2.

Step 2: check that the 'representative surrogate taxa' (those taxonomically similar to the marine species driving the risk assessment at Tier 1) respond to the treatment, showing clear effects.

- If the 'representative surrogate taxa' respond to the treatment, the mesocosm is considered representative and can be used to address the risk assessment.
- If the 'representative surrogate taxa' do not respond to the treatment, go to step 3.

Step 3: perform further analysis and additional laboratory experiments might be requested

with the ‘representative surrogate taxa’. This would allow a better interpretation of the mesocosm by verifying whether the sensitivity of the ‘representative surrogate taxa’ is similar to that of the marine species untested in the mesocosm.

B. 2 Points of attention regarding the use of NOEC or NOEAEC from micro-/mesocosmstudies

B.2.1 Total period of effects

When extrapolating the results from a mesocosm study to a proposed application regime for a product, it has to be kept in mind that the total period of effects in the whole season may not be longer than 8 weeks, if the NOEAEC (based on recovery) is used for risk assessment. It must also be kept in mind that for certain compounds like Insect Growth Regulators the effects can appear later in the study. The period before the appearance of the effects is in that case not taken into account.

In certain cases it is not clear from the GAP how many crop-cycles are possible in a growing season (GAP only presents the uses for one crop-cycle). It is important to have the right information in order to be able to apply the right endpoint from the micro-/mesocosm study. In cases that the NOEAEC value cannot be used because the total period of effects is greater than 8 weeks, the NOEC (based on class 1 effects) from the micro-/mesocosm study may be used for risk assessment, if there is no accumulation of the substance in the water-phase. If there is a build-up of the active substance in the water, the mesocosm study is in principle not appropriate to use in the risk assessment, because the number of applications and therefore the maximum concentration in practice is higher than in the mesocosm study.

B.2.2 Product with two or more active substances

Another issue is the question which endpoint to use from a micro-/mesocosm study if it concerns a product with two or more active substances and a mesocosm study is only available for one or more of the active substances separately, but not for the product. In that case the recovery endpoint (NOEAEC) cannot be used for risk assessment, because the presence of the other active substance(s) in the product can hamper the recovery of the affected species. Hence, in these cases the NOEC (based on class 1 effects) should be used for risk assessment.

B.2.3 ERO-RAC or ETO-RAC

With regard to core assessments, it was agreed during the harmonization meeting in Vienna (2015) to use the ETO-RAC, if available. The Central Zone Steering Committee decided that the ERO-option should be applied in case no ETO (NOEC) is reported in the LoEP (Warsaw, May 2015). However, meanwhile DE started a discussion on a third option on CIRCABC. This point therefore remains open.

B.2.4 Extrapolation of studies between different agroclimatic conditions

In the peer review meeting on recurring issues on ecotoxicology of October 2018 ((EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, June 2019), the issue about extrapolation between different agroclimatic conditions was discussed. In the case of mesocosms, the majority of the experts at the meeting agreed that the no observable effect concentration (NOEC) and the ecological threshold option (ETO) regulatory acceptable concentration (RAC) can be used in the risk assessment with the assessment factor (AF) recommended by aquatic guidance (EFSA PPR Panel, 2013), and this can be considered as independent of the experimental conditions (e.g. the climatic zone). However, when an ecological recovery option (ERO) RAC is derived, the extrapolation between zones should be considered carefully taking into account the fact that the ability for recovery may vary pending on the agroclimatic conditions.

A case-by-case evaluation should be carried out, based on the information available.

B.3 Expression of the endpoints from Tier 1 test and formulation tests (with one or more active substances) for unstable substances

At Tier 1, laboratory standard tests must be performed under standard (i.e. mostly worst case) exposure. Therefore, OECD guidelines recommend that the concentrations should be maintained and must be > 80 % and < 120 % of nominal at the end of the exposure period (or at the end of the renewal period for semi-static design).
If the concentration cannot be maintained (i.e. if the substance is dissipating 'fast'), the validity of the study should be questioned and the test may be rejected as highlighted during the EFSA peer review meeting on general recurring issues in ecotoxicology (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, December 2015).

During this EFSA peer review meeting, Member States agreed that in principle:
1) **Nominal concentrations** can be used to express the toxicity from any kind of test if the test concentrations were maintained at ± 20 % of the nominal at all times throughout the test including the study end sampling. Mean measured is also an option for this situation.
2) **Initial measured concentrations** can be used to express the toxicity from any kind of test if the initial test concentrations were below 80 % of the nominal and this concentration was maintained throughout the test (within ± 20 % of the initial) including the final sampling. Mean measured is also an option for this situation.
3) **Mean measured concentrations** must be used to express the toxicity from any kind of test when the test concentrations were not maintained within the range of ± 20 % of the nominal or initial measured, but significant concentrations of the test item were still present at the end of the exposure period (or at the end of the renewal period for semi-static design).
4) When the test concentrations were not maintained and significant residues were not present at the end of the exposure period (or at the end of the renewal period for semi-static design), the **validity of the study should be questioned**.

It was also pointed out that further clarifications should be provided in the AGD.
In practice (and not due to a causal relation), however, semi-static and/or flow-through design is rarely used for tests with:
- algae for which semi-static tests are very uncommon and flow-through tests not established in the regulatory context, due to the technical complexity when conducting the test;
- formulated products with one or more active substance, especially for tests with algae.
This proposal addresses these issues. It especially considers the cases where the recovery of an active substance at the end of a test is < 80 % (i.e. the test substance is dissipating fast) and where requesting a new semi-static or flow-through test (as required by EFSA, 2015) may not be feasible or desirable (i.e. algae tests and vertebrate tests).

An adequate expression of the endpoint from formulated product tests is needed:
- for the purposes of classification and labelling, and
- as the basis for mixture toxicity assessment since it should enable an assessment of potential synergism or additive toxicity due to one or more co-formulants or additional active substances.

The described approach aims to serve both purposes.
Until a revision of the 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 position paper is intended to fill the gap as an interim solution, i.e. for such cases where above-cited requirements 3 and 4 cannot be easily fulfilled and performing tests under semi-static or flow-through conditions are an issue.

A paper regarding this issue has been discussed during the Central Zone Harmonisation Workshop in Dessau, 20-21 September 2018 and later agreed on by the MS of the Central Zone ("Expressing endpoints from Tier 1 tests and formulation tests (with one or more active substances) for unstable substances").The approach is included as Appendix J in the EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, June 2019. Reference is made to this document.

B.4 Other issues discussed between Member States

The following issues from the EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, December 2015 and EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, June 2019 are also relevant:

B.4.1 Algae (Methodology for calculating the section-by-section coefficient of variation in algal studies (OECD 201) (from EFSA, 2015).

Based on the clarification provided at the meeting, it was clear that the methodology to be used for calculating the CV for section-by-section specific growth rates is the following: calculate specific growth rates for first control replicate for day 0-1, 1-2 and 2-3 and then calculate CV for first control replicate. Use the same approach to calculate CV values also for 2nd and 3rd control replicates. Then calculate the mean CV.

B.4.2 PECsw-twa – Further elaborations of the criteria reported in the EFSA guidance document on aquatic risk assessment (from EFSA, 2015)

The experts at the meeting considered there is a need to have further clarifications and corrections on the EFSA aquatic guidance document regarding the application of the PECsw;twa. The main issues identified were 1) identification of organisms for which the reciprocity appraoch is applicable (e.g. fish, *Lemna, Daphnia,* all); 2) indication of the duration over which linear reciprocity needs to be determined (e.g. entire study, part of the study); 3) recommendation on how to express the endpoint (all study or just the linear part?) in case reciprocity is only determined for a part of the study; 4) clarification regarding the criteria to assess linearity (e.g. R^2 value, p-value of the regression, etc.); 5) clarification on the assessment of the latency.

It was agreed that until further guidance on reciprocity and latency of effects is available, then the use of TWA approaches are unlikely to be sufficiently robust to be used in regulatory risk assessment.

B.4.3 Use of refined exposure studies as Tier 2C (from EFSA, 2019)

At the meeting, Germany presented an update on the Central Zone Harmonisation Meeting in Dessau, 20-21 September 2018, regarding the use of refined exposure studies. A position paper was also made available before the meeting. Nevertheless, it was pointed out that a complete agreement could not be reached at the central zone level regarding these kinds of experiments. The MSs of the central zone agreed on the following two pre-requisites:
- the GAP must be covered in terms of exposure pattern, and
- if a refined exposure toxicity is delivered by the applicant, all information must be provided in order to facilitate its evaluation and potential implementation in the RA.

Although no final agreement was reached, most MS consider:

 that the Tier 2C approach should generally not be supported at zonal level, considering that implementation in ERA is complex and linked to high uncertainties

 if a conclusion of low risk based on a lower tier approach with RMM is possible this should be favoured over a conclusion based on a Tier 2C approach, considering the uncertainties related to such a Tier 2C approach

 if applicants still decide to deliver a refined exposure toxicity test (Tier2C option), a lower tier (e.g. Tier 1) risk assessment should always be also presented up to FOCUS step 4 with an agreed level of Risk Mitigation Measures (RMM).
Representatives from the northern zone reported that this kind of refinement is not considered acceptable for their zonal assessments. It was explained that this is mainly due to doubts that the FOCUS profiles can accurately reflect exposure in the field (particularly as they are currently based on limited time simulations). It was, however, noted that the same doubt should also apply to the use of mesocosms, for which exposure profiles are also compared to the FOCUS predictions. Other concerns were related to the uncertainties in the extrapolation of the results to the field, e.g. the uncertainties on the life stage of the tested species which are exposed in this kind of test. It was indeed highlighted that it is very difficult to have a match of the pulsed exposure with the most sensitive life stage, particularly when knowledge is lacking about which is the most sensitive stage.
It was also noted that the use of the Tier 2C refinement may be problematic for populations of short-lived species (e.g. algae, aquatic plants, daphnids). Indeed, some potential recovery may take place in these tests, while ERO is not an option at Tier 2, as recovery in the field would be influenced by the relationship with other species. For primary producers, it was suggested that an EC10 be used instead of an EC50, in order to reduce the possibility of an effect that it is 'absorbed' by a subsequent recovery (it should be noted that this approach is already included in the position paper presented by Germany). In addition, repeated measurements over time of the relevant endpoint(s) help to detect whether a possible recovery takes place. For daphnids and other short-lived invertebrates, testing at the individual level (i.e. not using populations) should exclude any concern about recovery at the population level, since only repair mechanisms at the level of the individual occur.
In the approach (still not agreed) initially suggested for the central zone, a prerequisite for carrying out refined exposure tests is to provide a risk assessment using endpoint(s) from experiments carried out under constant exposure and that includes mitigation measures. Everyone agreed that providing a lower tier risk assessment with mitigation measures is a reasonable approach for all kinds of refinement. However, it was also highlighted that this does not relate specifically to Tier 2C in any way. It was also agreed that showing a low risk with mitigation measures at lower tiers should not be considered as a reason to avoid an assessment of the available higher tier studies.
It was agreed that the scheme for assessing Tier 2C should be reconsidered and possibly further developed in the revision of the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290).

B.4.4 Alternative test design in Myriophyllum studies (from EFSA, 2019)
It was agreed that Myriophyllum studies performed to OECD TG 239 but with an alternative test design (i.e. one shoot per pot per test vessel) should be considered acceptable.

B.4.5 Minimum detectable difference (from EFSA, 2019)
The MDD, presented in the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290). and the paper by Brock et al. (2015), is considered to be a valid tool to help with the evaluation of the biological results to assess the statistical power – or the absence of power – of a study to detect treatment-related direct effects. It should preferably be reported on non-aggregated data for the relevant taxon and time points. An issue linked to the unclear beta-error associated with the MDD in the available documents mentioned above was raised by Germany.
It was concluded that the use of the MDD is supported and that further considerations and clarifications will be addressed in the revision of the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290).

B.4.6 How to express the endpoint for sediment-dwelling organisms when tested in the presence of sediment (from EFSA, 2019)

During the Pesticide Peer Review Meeting 133 (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, December 2015) it was discussed how the endpoints for aquatic Tier 1 studies should be expressed. It was agreed that 'the toxicity endpoint for Tier 1 studies (i.e. mean measured, nominal or initial measured), should not depend on the study design, on the physical chemical or environmental fate parameters, on technical difficulties when testing, or on how the endpoint would be used in the first-tier risk assessment. The choice must depend on the actual exposure throughout the whole exposure period of that particular test. Where a suitable exposure throughout the whole period was not demonstrated, none of the endpoints should be used in first-tier risk assessments.' This discussion did not specifically cover the case of the toxicity tests on sediment-dwellers when tested in the presence of sediment.

The studies more frequently available for addressing the effects on sediment dwellers are performed on *Chironomus riparius* (OECD 218 and OECD 219).

In the context of the peer review of the active substance risk assessment, the issue of how the concentrations should be expressed in the case of sediment-dweller toxicity testing was often raised. In particular, there have been instances in which it was questionable to express the endpoints as measured concentrations at the beginning of the test, i.e. in the cases where the concentrations were not maintained in the whole system.

EFSA recommended that the decision on how to express the endpoint for the sediment-dwellers is based on the assessment of the mass balance calculation in order to determine the repartition of the substance in the various compartments. In this view the submission of mass balance calculations as part of the dataset for the sediment-dwellers is highly recommended, particularly in the case of the substances that are difficult to test (concentrations poorly maintained in the test system). In the latter cases, it is also relevant that intermediate measurements in the various compartments are performed (see also Commission Regulation (EU) No 283/2013, Section 8.2.5.3). When a mass balance is available, it is possible to consider the recommendations of the Pesticide Peer Review Meeting 133 (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, December 2015). It is additionally recommended that the key endpoints from the sediment-dweller studies are always presented in terms of mg substance/kg dry sediment and mg substance/L water. This would ensure that both exposure via water and sediment are covered for sediment-dwellers.

Where the concentrations in the test system are not maintained, the recommendations of the Pesticide Peer Review Meeting 133 (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, December 2015) should be considered, i.e. express the endpoint as the mean measured concentration using mg substance/kg dry sediment and/or mg substance/L water, accordingly, if significant levels are detected in the sediment or in the water or in both. The calculations should be based on geometric mean concentrations. It is proposed to further discuss whether, in such cases, the use of these studies in a Tier 2C approach, similar to the proposal in the EFSA aquatic guidance document (Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290)) for the refined exposure studies, would be suitable. This means that it should be demonstrated that the exposure in the study simulates a realistic worst-case exposure relative to the predicted exposure. In this view, a comparison between the exposure in the test system and the expected exposure (FOCUS profiles) should be performed. In order to follow this approach, intermediate analytical measurements should be performed in the course of the study.

It is acknowledged that issues similar to those for the sediment-dwellers could also occur for toxicity tests with the rooted macrophyte *Myriophyllum spicatum* (OECD TG 239). In those cases it is suggested that the same approach as above is applied. It is noted that OECD TG 239 already highlights that 'if there is evidence that the concentration has declined (i.e. is not maintained within 20 % of the nominal or measured initial concentration in the treated compartment) throughout the test, then analysis of the results should be based on the

geometric mean concentration during exposure or models describing the decline of the concentration of the test chemical in the treated compartment'.
Overall, the experts agreed with the proposal to use the mass balance for checking whether the concentrations were adequately maintained. Practical examples of the needed calculations are included in Appendices G and J of EFSA, 2019 (EFSA technical report: Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology, June 2019).

B.4.7 Risk mitigation measures (RMM) (from CZHW 2018, Dessau)
In the Central Zone Harmonisation Workshop in Dessau, 20-21 September 2018, the following was agreed (bullet point):
- The MS agreed that RMM up to 90% drift reduction and 30 m buffer zone should be presented in the core assessment.

Decision-scheme
A decision scheme 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
Annex II of Regulation (EC) No 1107/2009 provides the procedure and criteria for the approval of an active substances, safeners and synergists.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance.

1.4.2. Evaluation of plant protection products
The principles for the evaluation regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles).

The specific principles for decision making for aquatic organisms are included in Part B Evaluation, point 2.5.2.2.

1.4.3. Decision making for plant protection products
The principles for the decision-making regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles).

The specific principles for decision making for aquatic organisms are included in Part C Decision making, point 2.5.2.2.

1.5. Developments
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.

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 [1,2]. 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.

Ecological modelling
Reference is made to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290).
Section 11.3 of this document gives information about the state-of-the-art of the use of mechanistic effect models in regulatory environmental risk assessment.

In the near future, the PPR Panel will elaborate scientific opinions on good modelling practice and more specifically on modelling within the aquatic RA. Since there is a lack of experience and guidance for these approaches in RA, the use of mechanistic modelling within the authorisation of PPPs has to be evaluated carefully and case-by-case until special guidance becomes available.

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)[3] 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 semi-field studies specifically studied structural endpoints of fungi. Maltby *et al* (2009)[3] 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)[4, 5] and CBS (2009)[6]. Their data indicate that HC_5 concentrations derived by Maltby *et al*. (2009)[3] 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).

Sediment organisms
Regarding sediment organisms the following EFSA Opinion was published:
EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2015. Scientific Opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water. EFSA Journal 2015;13(7):4176, 145pp. doi:10.2903/j.efsa.2015.4176.
This opinion is assumed to be input for future guidance.

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. EFSA is planning to 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.

Notifiers preparing an assessment report for active substances need to comply with the relevant guidance, instructions and format laid down in the EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances.

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 Commission Implementing Regulation (EU) No 540/2011.

1.2. Data requirements

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

Generally, EU and OECD guidelines for the protocol of experiments are mentioned in Commission Communication 2013/C 95/01 and Commission Communication 2013/C 95/02.

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.

1.2.1. Data requirements for the active substance

The date requirements regarding the effects of the active substance on sewage treatment plants (STPs) are described in Commission Regulation (EU) No 283/2013, point 8.8 (effects on biological methods for sewage treatment).

Point 8.8 consists of the following data requirements:
8.8: Effects on biological methods for sewage treatment

1.2.2. Data requirements for the product

According to Commission Regulation (EU) No 284/2013, 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

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

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance.

1.4.2 Evaluation of plant protection products

Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles), 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 (i.e. the Uniform Principles), 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

None.

2. APPENDICES

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) 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, aquatic invertebrates 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, aquatic invertebrates and fish.
For fish acute toxicity data are always required for rainbow trout (*Oncorhynchus mykiss*). Seven fish should be used, also in a limit test.
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.
For pesticides with an insecticidal mode of action data are required for *Daphnia* sp. (*D. magna* preferred) and an additional arthropod (preferably a *Chironomus* test, if data on *Americamysis bahia* are not already available).
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. For metabolites that are formed at more than 10 % or between 5 and 10 % at two or more occasions or at more than 5 % at the end of the study, data is needed. In general, data for metabolites formed below 5 % or below 10 % (observed at a single occasion) is not considered necessary. However, if there is reason to believe that a metabolite formed at < 5 % has intrinsic properties comparable to the parent substance in terms of its biological target activity, or that it has certain structural properties indicating high reactivity (i.e. mutagenicity) or endocrine disrupting properties or that it has unacceptable toxicological properties, then that metabolite may be ecotoxicologically relevant and data is needed.Data on transformation rate, bioconcentration and acute toxicity to algae, aquatic invertebrates 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 on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290).

3) Also chronic toxicity data (283/2013 point 8.2.2/8.2.5) must be submitted , unless there is 90% or more loss of the original substances over 24 hours via hydrolysis.

4) A chronic study with fish and *Daphnia* sp. is required. For fish this should be a Early life-stage test, unless a fish full life-cycle (FFLC) test is provided. An FFLC may be required depending on the persistence and bioaccumulative potential of the substance; the following critera applies: BCF > 1000 ánd the elimination during the 14 day depuration phase in the bioconcentration study <95% ánd the substance is stable in water or sediment ($DegT_{90}$ > 100 days).
For pesticides with an insecticidal mode of action preferably the most sensitive standard test arthropods (*Daphnia, Chironomus, Americamysis*) from the acute Tier 1 data set should be selected as test species in the chronic effect assessment. If in the acute assessment a certain standard test arthropod is a factor of 10 more sensitive a chronic test with this arthropod should be performed.

5) Where in a water/sediment study (283/2013 point 7.2.2.3.) at or after 14 days (283/2013 point 8.2.7) ≥ 10% of the active substance and/or metabolite is found in the sediment or when the substance interferes with moulting hormones (e.g. insect growth regulators), a chronic toxicity test with sediment dwelling organisms (*Chironomus sp*.) (283/2013 point 8.2.7) must be provided unless the EC10/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 aquatic invertebrates
- 0.1 of the EC50 for algae
- 0.1 of the EC50 for aquatic plants

- 0.1 of the NOEC for long-term toxicity to fish and aquatic invertebrates
- 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 6) 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 on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290).

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., 1979[1]) is used:

logBCF = 0.85*logKow - 0.70 (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. , more than 90% loss of the original substance over 24 h via hydrolysis. BCF_k (kinetic bioconcentration factor) values should be reported as growth-corrected and as lipid-normalised values (default 5% lipid content).

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 on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290).

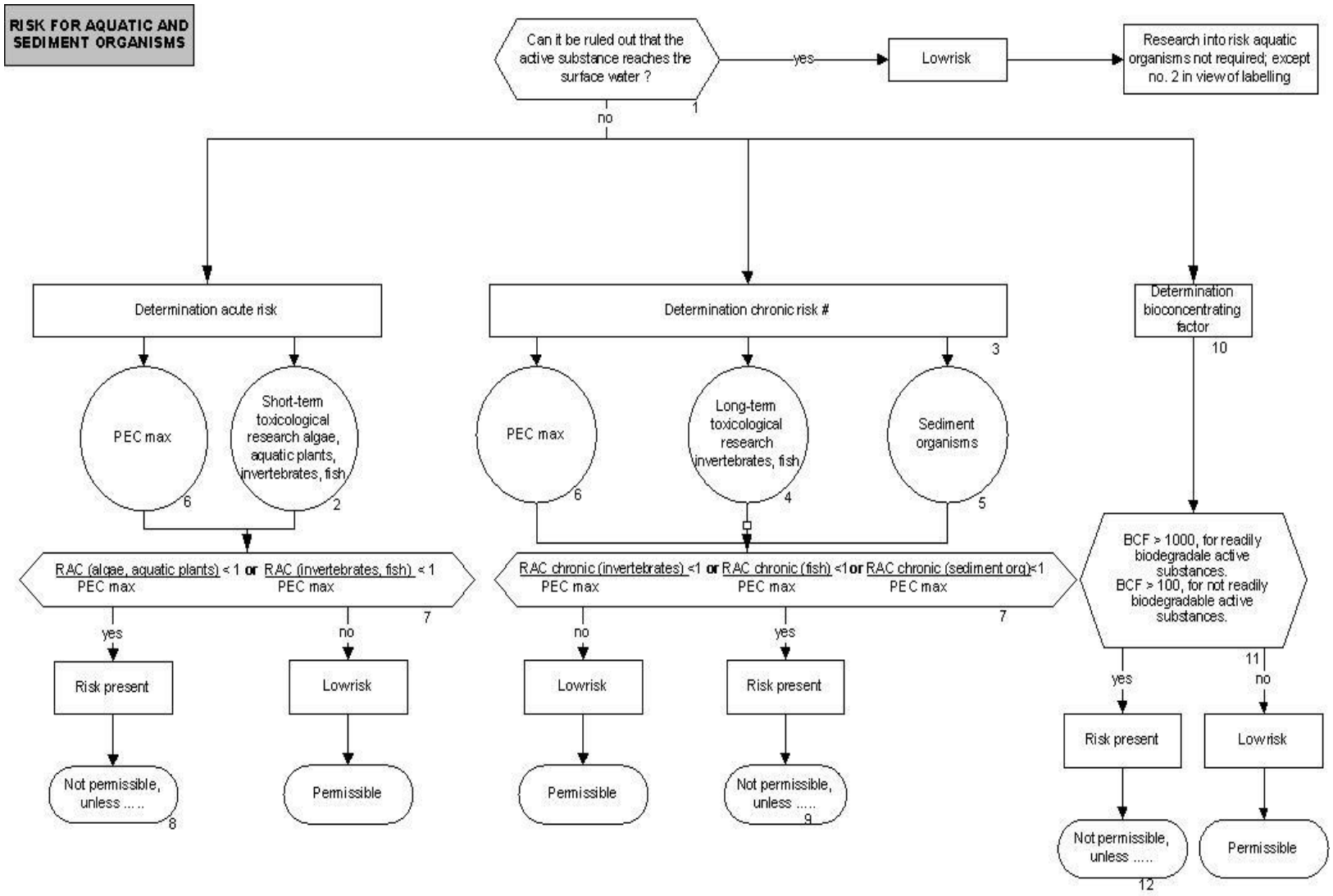
For the higher tier risk assessment triggered by exceeding of the first tier TER values several possibilities exist, e.g.:
- geomean approach;
- SSD approach;
- modified exposure tests;

[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.

- micro-/mesocosm studies.

For more information about these studies and approaches reference is made to the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013; 11(7):3290).

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 is the mean HC5 value with a certain safety factor. More information can be found in the EFSA aquatic guidance.
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 the EFSA aquatic guidance.
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.



Unless there is 90% or more loss of the original substance over 24 hours via hydrolysis

3. REFERENCES

1 Lepper, P. 2004. Manual of the methodological framework used to derive quality standards for priority substances of the Water Framework Directive. Fraunhofer Institute, Molecular Biology and Applied Ecology. Updated summary of B4-3040/2000/30637/MAR/E1.

2 HEALTH COUNCIL OF THE NETHERLANDS: COMMITTEE ON PESTICIDES AND GROUNDWATER (1996). Risks of pesticides to groundwater ecosystems. Rijswijk: Health Council of the Netherlands, 1996; publication no. 1996/11E. ISBN:90-5549-135-7.

3 Maltby L, Brock TCM, Van den Brink PJ. 2009. Fungicide risk assessment for aquatic ecosystems: importance of interspecific variation, toxic mode of action and exposure regime. *Environ Sci Technol* 43:7556-7563.

4 Dijksterhuis J, Van Doorn T, Postma J. 2009. De gevoeligheid van oppervlaktewaterschimmels blootgesteld aan azolen en strobilurines die worden toegepast in de landbouw. Centraal Bureau voor Schimmelcultures / Ecofide, Utrecht, Weesp, 32 pp.

5 Dijksterhuis J, Van Doorn T, Postma J. 2011. Effects of seven fungicides on non-target aquatic fungi. *Wat Air Soil Pollut* DOI 10.1007/s11270-011-0836-3.

6 CBS 2009. De gevoeligheid van schimmels in het oppervlaktewater voor fungiciden die worden toegepast in de landbouw. Centraal Bureau voor Schimmelcultures, Utrecht, Weesp, 22 pp.