Evaluation Manual for the Authorisation of Plant protection products and Biocides

NL part

Plant protection products

Chapter 7 Ecotoxicology; aquatic

version 1.0; January 2010

Author:
Peter van Vliet, MSc

Coordination:
Werner Pol, MSc, BSc

Lay-out:
Jiske de Wolf

ctgb

Board
for the Authorisation
of Plant protection products and Biocides

Chapter 7 Ecotoxicology; aquatic

Category: Plant protection products

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 NL framework (§2 - §2.5).

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

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for Plant protection products based on existing substances, included in Annex I, and new active substances.
A new substance is a substance not authorised in any of the Member States of the EU on the 25th of July 1993.
The pesticide that contains such substances may be authorised if the criteria laid down in the Wgb (Plant protection products and Biocides Act) 2006 [1] are met. The product is tested against the Plant protection products and Biocides Regulations (Rgb) [2]. The evaluation dossiers must meet Annex II and III of Directive 91/414/EEC (see Application Form and corresponding instructions).

A Member State may deviate from the EU evaluation on the basis of agricultural, phytosanitary and ecological, including climatological, conditions.

The NL framework describes the dossier requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national approval framework or when the national framework has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter is used for evaluation of a substance for inclusion in Annex I in case no European procedure has been described.

2.1. Introduction

This chapter describes the aspects for aquatic and sediment dwelling organisms for which specific rules apply in the national approval framework or when the national framework has been elaborated in more detail than the EU framework.

The MPC (Maximum Permissible Concentration) concept is applied for the aspect aquatic and sediment dwelling organisms as higher tier in the risk assessment to keep in line with the general environmental quality policy and to bring the aquatic risk assessment in line with the Water Framework Directive. In addition, NL-specific drift percentages, deviating from the EU evaluation methodology, are used as input for calculation of the PEC for aquatic and sediment dwelling organisms. There is a national system of drift-reducing measures as well. This serves to meet the specific NL conditions (climatological conditions; specific standard drift-reducing measures packages from the Lozingenbesluit (Discharge Order). This is elaborated in §2.3.

The other points described in this chapter concern further elaborations of the EU procedure.

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

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

2.2. Data requirements

The data requirements for chemical Plant protection products are in compliance with the provisions in EU framework (see §1.2 of this chapter).
The question numbering of the NL Application Form has also been included in § 1.2 of the EU part.
NL-specific data requirements and further elaborations of the EU data requirements are given in the text below.

Experiments carried out after the 25th of July 1993 must have been carried out under GLP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

The studies must be carried out in compliance with the applicable guidelines. An overview of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 7.

For animal welfare reasons it is recommended to limit the vertebrate tests with formulations and also metabolites as much as possible. In some cases it is even not allowed to submit fish studies with formulations, i.e. in the case that already fish studies are available with a comparable formulation. In Appendix D is indicated in which cases it is not necessary to submit fish studies with the formulation or metabolites.

2.3. Risk assessment

The evaluation methodologies for chemical plant crop protection products are in compliance with the provisions in EU framework (see §1.3 of the EU part). For an overview of the risk evaluation method for aquatic and sediment dwelling organisms we refer to the decision tree with explanatory notes included in Appendix 1a and b to this chapter.
NL-specific evaluation methods and further elaborations of the EU methods are given in the text below.

The national first tier evaluation is in line with the risk evaluation methodology for aquatic and sediment dwelling organisms as elaborated in the European Guidance Document on Aquatic Ecotoxicology [3], with the exception of the drift percentages used for the calculation of the concentration in surface water; the used drift percentages are NL-specific, to meet the NL-specific climatological conditions and the specific standard drift-reducing measures packages from the Lozingenbesluit (Discharge Order). For the drift percentages reference is made to chapter 6: Fate and Behaviour in the environment; behaviour in surface water, sediment and sewage treatment plants (STP).

A further adequate risk assessment (second tier) is required in case the first tier criteria of aquatic organisms in the edge-of-field ditch are exceeded. This assessment is carried out for the edge-of-field ditch as well as for WFD (Water Framework Directive) water bodies and the applicable criterion (91/414/EEC criteria in the edge-of-field ditch and the MPC-approach in the WFD water body) should be met in both cases. Assessment against the MPC (as indicated in the Rgb (Regulation holding further Provisions concerning Plant protection products and Biocides) is in this way given a (different) place.

In the case that the bioconcentration trigger (BCF > 100 L/kg) is exceeded in the first tier bioconcentration assessment, regardless of the exceeding of the first tier criteria for aquatic organisms, also an MPC according to INS has to be derived and examined against the predicted environmental concentration in the WFD water body.
Finally, a national method has been elaborated for determination of combination toxicity. Combination toxicity is not relevant in the EU framework because active substances are evaluated instead of products.

Below is outlined how the further adequate risk assessment (second tier) should be carried out, followed by a description of the method for determination of the combined toxicity and risk.

Further adequate risk assessment
Article 2.10 of the *Plant protection products and Biocides Regulations* (Rgb) describes the authorisation criterion aquatic organisms. If for the evaluation of the product a higher tier risk assessment is necessary, a standard is to be set according to the MPC- INS[1] method [4]. For the evaluation of the risk MPC is set as the standard. An acute MPC, called MPCwater (MAC) as well as a chronic MPC, called MPCwater (AA) are derived.
With respect to the higher tier risk assessment there is a differentiation between the edge-of-field ditch and the WFD water body. The higher tier risk assessment in the edge-of-field ditch is performed according to Directive 91/414 and hence the Guidance Document on Aquatic Ecotoxicology [3]. In the WFD-waterbody the MPCwater (MAC) and MPCwater (AA) are applied. The standards in the edge-of-field ditch as well as the WFD-waterbody should be met.

Edge-of-field ditch
The higher tier assessment is carried out according to 91/414 guidance document Aquatic Ecotoxicology [3]. 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 micro-/mesocosm studies reference is made to the Guidance Document on Aquatic Ecotoxicology [3] and the Guidance for summarizing and evaluating aquatic micro- and mesocosm studies [5]. 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 [3]. 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 [6] 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.

[1] INS: international and national quality standards for substances in the Netherlands.

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 [3] 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 [7]) 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 (HCp). The Species Sensitivity Distribution from which the HCp 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 HCp) will be (Figure 1).
The HARAP guidance document [6] mentions HC5 and HC10 values as possible assessment endpoints. However, in the Guidance Document on Aquatic Ecotoxicology [3] currently no established guidance is provided on which HCp is appropriate for assessments under Directive 91/414/EEC.

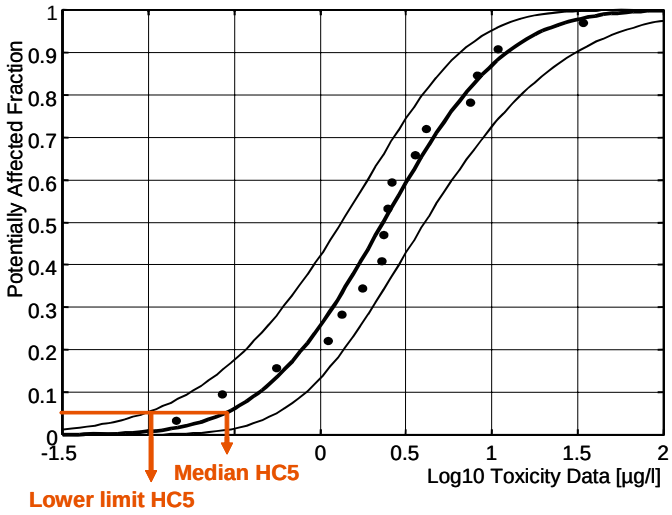


Figure 1: Graphical presentation of the Species Sensitivity Distribution curve, its 95% confidence interval, and the derivation of the lower limit and median Hazardous Concentration to 5% of the species (HC5).

The Species Sensitivity Distribution Approach

As shown in Figure 1, an SSD is a statistical distribution estimated from a sample of toxicity data and visualised as a cumulative distribution function. In the scientific literature dealing with the SSD approach the most frequently calculated Hazardous Concentration from the SSD curve is the HC5 [8,9]. One may question the geographical extrapolation of SSD curves and the derived HC5 values. However, the analyses conducted by [9] suggest that, although the composition of freshwater communities varies across biogeographical regions, climatic zones, and habitat types, the distribution of species sensitivities does not vary markedly. For example, there is no evidence that lotic arthropod assemblages are generally more sensitive than lentic arthropod assemblages to insecticides [9].

Schroer et al. [10] demonstrated that SSDs and HC5 values derived from single species tests with the insecticide lambda-cyhalothrin and freshwater arthropods were very similar between independent studies performed in the Netherlands and the United Kingdom. Recently, calibration of the relationship between HC5 values and results of semi-field experiments for insecticides and herbicides was provided by [9] and [11]. In their evaluations both the median HC5 value and the lower limit HC5 estimate was used. The key point is the focus on a specific taxonomic group where the assessment concerns a PPP with a specific toxic mode-of-action. Maltby et al. [9] demonstrated for insecticides and aquatic arthropods that the lower limit HC5 estimate derived using acute toxicity data provides a conservative estimate of the ecological threshold concentration in micro/mesocosms not only for single, but also for multiple and continuous application of the insecticide. The median HC5 estimate based on acute toxicity for freshwater arthropods is generally protective of single insecticide applications and of continuous and multiple applications when at least a safety factor of 5 is applied [9].
Van den Brink et al. [11] showed that for herbicides and primary producers the lower limit of the acute HC5 and the median value of the chronic HC5 were protective of adverse effects in aquatic micro/mesocosms even under a long-term exposure regime.
The median HC5 estimate based on acute toxicity data of herbicides was protective of adverse effects in aquatic micro/mesocosms when a short-term exposure regime (pulse application in flow-through system; single application of a non-persistent ($DT50_{water}$ < 10 days) herbicide in stagnant test system) was studied [11].

Based on the information presented above the following HC5 values and safety factors will be used in risk assessment:

- In case of a repeated pulse exposure regime: acute HC5 value in combination with a safety factor of 3 or the lower limit of the HC5;
- Single pulse of short duration and DT_{50} in water/sediment study lower than 10 days: acute HC5 value without a safety factor.

These values and safety factors are not applicable on fish, because the available micro-/mesocosm studies used for validation of the HC5 values contained no fish. For fish acute LC_{10} and acute NOEC values are used to construct the SSD and to calculate the acute HC_5, since a higher protection level is desired for vertebrates than for invertebrates and plants. The safety factors which must be applied on the acute HC5 for fish are still under discussion.

There is not much experience with chronic HC5 values. How to use these values into risk assessment is still under discussion.

Micro-mesocosm studies

In the Guidance Document on Aqautic Ecotoxicology [3] 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. For that reason the state of the art in The Netherlands with regard to the acceptability of effects is presented below.

In the Guidance Document on Aquatic Ecotoxicology [3] so called ‘Effect classes’ are mentioned for the interpretation of micro-/mesocoms studies. Brock *et al.* [12] and De Jong *et al.* [5] proposed a refinement of the ‘Effect classes’ used to categorise the results of micro/mesocosm experiments (see below).

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.

Effect class 3B (*Pronounced effects and recovery within 8 weeks post last application*).
Clear response of sensitive endpoints in micro-/mesocosm experiment repeatedly treated with the test substance and that last longer than 8 weeks (responses already start in treatment period), but full recovery of affected endpoints within 8 weeks post last application.

Effect class 4 (*Pronounced effect in short-term study*).
Clear effects (e.g. large reductions in densities of sensitive species) observed, but the study is too short to demonstrate complete recovery within 8 weeks after the (last) application.

Effect class 5A (*Pronounced long-term effect followed by recovery*).
Clear response of sensitive endpoints, effect period longer than 8 weeks and recovery did not yet occur within 8 weeks after the last application, but full recovery is demonstrated to occur in the year of application.

Effect class 5B (*Pronounced long-term effects without recovery*).
Clear response of sensitive endpoints (> 8 weeks post last application) and full recovery cannot be demonstrated before termination of the experiment or before the start of the winter period.

In The Netherlands there is a consensus now about the Effect classes which are relevant for the derivation of the different endpoints. Effect class 1 is considered as relevant for the NOEC. When recovery is taken into account effect class 3a is normally considered as the relevant effect level for derivation of the NOEAEC (No Observed Ecologically Adverse Effect Concentration).

The results of several model ecosystem experiments performed with the same insecticide have revealed that the threshold level for no (Effect class 1) or slight (Effect class 2) effects are remarkably consistent – at least for short-term (single or repeated pulses) exposure regimes (see data on chlorpyrifos and lambda-cyhalothrin [12]). Whether this is also the case for compounds with other modes of action and for long-term exposure regimes needs to be investigated. Data available for the herbicide atrazine [12] suggest a larger variability in Effect classes 1–2 between experiments under long-term exposure regimes. Brock et al. [12] reported that threshold levels for effects (Effect classes 1–2) can be predicted with lower uncertainty than, for example, Effect classes 3–5. One explanation is that factors such as indirect effects and recovery of affected endpoints are influenced by spatio-temporal variation in species composition and by the ecological infrastructure (for example, connectivity between water bodies) of the surroundings.

The studies presented in [12] for chlorpyrifos and lambda-cyhalothrin indicate that for short-term exposure regimes (single or repeated short-term pulses) and in the case of only a single high quality micro- and mesocosm study being available, an assessment factor of 3 may be necessary for the spatio-temporal extrapolation of Effect class 3a NOEAEC to ensure that at this short-term concentration level no class 4–5 effects will occur in various field situations. Effect class 1 concentrations may be used without the application of an additional assessment factor and effect class 2 concentrations should have a factor of 2.
In case of the data presented for atrazine in [12] an assessment factor of 3 may be necessary for the spatio-temporal extrapolation of Effect class 2 NOEAEC in order to assure that at this chronic concentration level no class 3–5 effects will occur.
It should be noted, however, that the above-mentioned assessment factors are based on a limited number of compounds, all of which are insecticides and herbicides. Other assessment factors may be required for other compounds, such as fungicides, that may have a less specific mode of action.

Exposure
The PECmax in the edge-of-field ditch will be used normally, as in the first tier.
The underlying assumption (also in GD Aquatic Ecotoxicology [3]) is that initial/short-term exposure may cause acute as well as chronic effects.

WFD (Water Framework Directive) water bodies
By decree of the Ministry of Agriculture, Nature and Food Quality, the Ministry of Housing, Spatial Planning and the Environment and the Ministry of Transport, Public Works and Water Management, Ctgb has to assess from September 2009 onwards – based on an interim assessment methodology, see C-212.6 – whether an ecotoxicological risk in the WFD water bodies might occur. This is implemented by examining the MPCwater (MAC) and MPCwater (AA)[2] against a calculated exposure concentration in the WFD water body.
This interim assessment methodology is valid till the implementation of the definitive assessment methodology for the aquatic environment, expected in 2011.

Exposure
A simple method for calculating the (time-weighted) average of the concentration in the WFD water bodies is at the moment not available. Experts expect that the concentration course at this distance from the source (the application) will be fairly even (and the maximum or time-weighted concentration, depending on the time span, will not be very different). Calculation of this effect (e.g. by means of breakthrough curves) is impossible at this term. For that reason the MPCwater (MAC) as well as the MPCwater (AA) will be assessed against the PECmax in the WFD water bodies in the interim assessment methodology.[3]
For more details regarding the exposure reference is made to chapter 6: Fate and Behaviour in the environment; behaviour in surface water, sediment and sewage treatment plants (STP).

Further refinement options
In case application of the higher tier described above for the edge-of-field ditch and/or WFD water body still yields a criterion exceedance, the applicant must **firstly propose drift-reduction measures**.

[2] Only in exceptional cases, e.g. substances for which an MPCwater (AA) has no meaningful significance (e.g. rapidly degrading substances with acute effects only), assessment may be restricted to MPCwater (MAC).

[3] This means that the MPCwater (AA) will in the interim period always be determinative of risk/criterion exceedance (MPCwater (AA) is more stringent than MPCwater (MAC)).

If this does not yield the desired result, the following further refinement possibilities are applicable (N.B. the proposed drift reduction measures will be maintained after potential refinements!):

Edge-of-field ditch:
No further refinement is possible, except further emission restriction by amendment of label/instructions for use (e.g. dose or frequency).

WFD water bodies
- For multiple applications for which it can be demonstrated that 2 or more applications have no ecotoxicological relevant coherence, e.g. in case the interval is longer than the life cycle of relevant organisms – further case-to-case elaboration required (expert judgement) – a dilution factor of, e.g., 5 can be chosen instead of 3. NB. Such application schemes are not common.
- For applications of substances for which sorption is a relevant factor in the disappearance, adequate use of the second option under 'disappearance resulting from transport/residence time' by dissipation (DT50 water) is a possibility, provided that the criterion for sediment organisms in the edge-of-field ditch is met separately.
- The relevant application period and application frequency should be taken into account in a further substantiation – if any – of the estimation of the annual average exposure concentration in the water body.
- In case the criterion exceedance is small (maximum factor 5, in line with drinking water decision tree) a temporary authorisation could be granted under certain conditions (only for new substances on the Dutch market for which (adequate) monitoring data are not yet available) under condition of post-registration monitoring. Some examples of such conditions:
  - it is meaningful to start a monitoring programme (the substance can be detected above the limit of detection, i.e., not very rapidly disappearing from the water phase). NB. Starting up such a monitoring programme only seems meaningful in case the MPRwater (chronic) is exceeded because if the MPRwater (acute) is exceeded, the maximum exposure concentration must be measured directly in the WFD water bodies; this will be very difficult in practice.
  - the field of use covers a restricted acreage.

Combination toxicity
Combination products are formulated Plant protection products that contain more than one active substance. Combinations of Plant protection products of which, in accordance with the recommendations in the directions for use, the user prepares a combination in a tank (tank mix) are also considered as combination products.
When evaluating the side effects of combination products on non-target organisms the question arises whether the risk must be estimated on the basis of a toxicity test with the combination product or whether a reasonable risk estimate can be made on the basis of the toxicity data of the separate active substances.
There is no European guidance as regards combination toxicology.

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

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

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

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

2.4. Approval

Risk assessment for aquatic and sediment dwelling organisms has been laid down in regulations. The Wgb (Plant protection products and Biocides Act) 2006 [1] stipulates in Art. 28 (1) (b4 and b5): "a pesticide may only be authorised where this has no unacceptable effect on the environment".

The evaluation of products on the basis of existing active substances already included in Annex I or new substances has been laid down in the Plant protection products and Biocides Regulations (Rgb) [2] where it is elaborated that these products are evaluated according to the national specific criteria.

2.4.1. Criteria and trigger values

For the criteria and trigger values for aquatic and sediment dwelling organisms for the national authorisation reference is made to the EU part (§ 1.4.2).

For the Dutch specific criteria and trigger values as applied in the evaluation of surface water reference is made to the Plant protection products and Biocides Regulations (Rgb).
Article 2.10 (new and existing substances) and Article 10.3 (existing substances not including in Annex I) of the Plant protection products and Biocides Regulations (Rgb) describes the authorisation criterion surface water.

The texts specifically referring to aquatic and sediment dwelling organisms are given below (in Dutch):

§ 4. Bepalingen inzake het milieutoxicologische risico van chemische gewasbeschermingsmiddelen

Artikel 2.10. Waterorganismen

1. Een effect op waterorganismen van een gewasbeschermingsmiddel is geen onaanvaardbaar effect als bedoeld in bijlage VI, deel I, onderdeel C, punt 2.5.2.2, bij richtlijn 91/414/EEG, indien bij de uitvoering van een adequate risicobeoordeling als bedoeld in dit beginsel wordt aangetoond dat er geen overschrijding van het MTR voor waterorganismen is.
2. Het college berekent het MTR, bedoeld in het eerste lid aan de hand van de methode INS.

Artikel 10.3. Beoordeling van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet

Het college geeft in de beoordeling van een aanvraag omtrent toelating van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet, ongeacht voor welke vorm van toelating als bedoeld in hoofdstuk 9 van de wet een aanvraag is ingediend, een oordeel over elk onderdeel van bijlage VI bij richtlijn 91/414/EEG onderscheidenlijk bijlage VI bij richtlijn 98/8/EG met inachtneming van de specifieke bepalingen die voor elke vorm van toelating bij wet of bij besluit zijn gegeven.

2.4.2. Decision making

The risk to aquatic and sediment dwelling organisms is determined as follows:
Where the criteria mentioned in the UP are not exceeded, the product is permissible.
Where one of the mentioned criteria is exceeded, the product cannot be authorised unless an (adequate) risk evaluation clearly demonstrates that under field conditions no unacceptable effects occur after application of the plant protection product in accordance with the directions for use. If relevant monitoring data, carried out in surface water and/or sediment, show that the criterion for aquatic and/or sediment dwelling organisms is exceeded, the product cannot be authorised.
Criteria to be met by monitoring data are given in Chapter 6 Fate and Behaviour in the environment; behaviour in surface water, sediment and sewage treatment plant (STP).

2.5. 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 Annex II and III data requirements regarding endocrine disruption will be taken into account by setting several data requirements.
- Macrophytes
  In the process of revision of Annex II and III 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 Annex II and III a test with a second invertebrate species will be required as a standard requirement.
- Amphibians
  In the process of revision of Annex II and III 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 [13, 14]. 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 [3].
- Working Group decision scheme Water
  The Working Group decision scheme Water is working on developing a decision scheme for the assessment of the risk of Plant protection products for the aquatic environment. According to the expectations the decision scheme will be finished somewhere in 2011.

II EFFECTS ON A SEWAGE TREATMENT PLANT (STP)

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for Plant protection products based on existing substances, included in Annex I, and new active substances. A new substance is a substance not authorised in any of the Member States of the EU on the 25th of July 1993.
The pesticide that contains such substances may be authorised if the criteria laid down in the Wgb (Plant protection products and Biocides Act) 2006 [1] are met. The product is tested against the Plant protection products and Biocides Regulations (Rgb) [2]. The evaluation dossiers must meet Annex II and III to Directive 91/414/EEC (see Application Form and corresponding instructions).

A Member State may deviate from the EU evaluation methodology on the basis of agricultural, phytosanitary and ecological, including climatological, conditions.

The NL framework describes the dossier requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national decision scheme or when the national decision scheme has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter is used for evaluation of a substance for inclusion in Annex I in case no European procedure has been described.

2.1. Introduction

This chapter describes the data for effects on an STP for which specific rules apply in the national decision scheme or when the national decision scheme has been elaborated in more detail than the EU framework.

Methods for exposure estimation for an STP have not been laid down in EU framework. Criteria for this aspect have neither been described. This aspect has therefore been elaborated nationally (see §2.3. and 2.4.1). For the methods for exposure estimation of an STP we refer to Chapter 6 Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plant (STP). The national elaboration of criteria setting is described in §2.4.1.

This chapter deals with substances which, in view of the nature of their use, may reach a sewage or waste water treatment plant. This category includes plant protection products that are used in mushroom growing (see Appendix 2), chicory forcing, greenhouse cultures, and for pre-treatment of cut flowers. Use on hard surfaces (pavements) by municipalities, private organisations, companies and households may also contribute to Plant protection products reaching STPs via runoff [15].

2.2. Data requirements

The data requirements for chemical Plant protection products are in compliance with the provisions in EU framework (see §1.2 of the EU part). The question numbering of the NL Application Form has also been included in § 1.2 of the EU part.

Experiments carried out after the 25th of July 1993 must have been carried out under GLP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

The studies must be carried out in compliance with the applicable guidelines. A review of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 7.

The data requirements for the NL evaluation are identical to the data requirements for the EU; reference is therefore made to the EU part §1.2, where the NL question codes are given as well.

2.3. Risk assessment

Methods for exposure estimation of an STP are given in Chapter 6, Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plant (STP). The exposure is compared with a criterion derived on the basis of the toxicity to micro-organisms in an STP.

2.4. Approval

Risk assessment of effects on an STP has been laid down in regulations. The Wgb (Plant protection products and Biocides Act) 2006 [1] stipulates in Art. 28 (1) (b4 and b5):
“a pesticide may only be authorised where this has no unacceptable effect on the environment”.

The evaluation of products on the basis of existing active substances already included in Annex I or new substances has been laid down in the Plant protection products and Biocides Regulations (Rgb) [2] where it is elaborated that these products are evaluated according to the national specific criteria.

2.4.1. Criteria and trigger values

For the criteria and trigger values as applied in the risk assessment for biological methods of waste water treatment reference is made to the Plant protection products and Biocides Regulations (Rgb).
Article 2.10 a (new and existing substances) and Article 10.3 (existing substances not including in Annex I) of the Plant protection products and Biocides Regulations (Rgb) describes the authorisation criterion for biological methods of waste water treatment.

The texts specifically referring to the aspect regarding the effects on an STP are given below (in Dutch):

§ 4. Bepalingen inzake het milieutoxicologische risico van chemische gewasbeschermingsmiddelen

Artikel 2.10a. Rioolwaterzuiveringsinstallatie [Treedt in werking per 01-01-2010]
Het college verleent geen toelating voor een gewasbeschermingsmiddel indien verwacht mag worden dat een zuiveringstechnisch werk als bedoeld in artikel 1.1 van de Waterwet zal worden blootgesteld aan dit gewasbeschermingsmiddel en de concentratie van de werkzame stof of het reactie- of afbraakproduct ervan in het influent meer zal zijn dan 0,1 van de EC50 van het zuiveringstechnisch werk, tenzij met een adequate risicobeoordeling is vastgesteld dat geen onaanvaardbare effecten zullen optreden op de doelmatige werking van voormeld werk.

Artikel 10.3. Beoordeling van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet

Het college geeft in de beoordeling van een aanvraag omtrent toelating van een gewasbeschermingsmiddel of biocide als bedoeld in artikel 121 van de wet, ongeacht voor welke vorm van toelating als bedoeld in hoofdstuk 9 van de wet een aanvraag is ingediend, een oordeel over elk onderdeel van bijlage VI bij richtlijn 91/414/EEG onderscheidenlijk bijlage VI bij richtlijn 98/8/EG met inachtneming van de specifieke bepalingen die voor elke vorm van toelating bij wet of bij besluit zijn gegeven.

2.4.2. Decision making

Decisions making on approval proceeds as follows:
The product is permissible in case the criteria mentioned under 2.4.1 are not exceeded.

Where the criteria mentioned under 2.4.1 is not met, the product is not permissible unless it is demonstrated that there are no unacceptable effects on the processes in an STP.

2.5. Developments

None

3. APPENDICES

Appendix 1A Explanatory notes decision tree Risk to aquatic and sediment dwelling organisms based on 91/414/EC: First tier

1) For each active substance, information concerning toxicity to aquatic organisms (P10.2a/A8.2a) 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 (question P10.2a).

2) The acute toxicity research (A8.2.1a/A8.2.4a/A8.2.6a) 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 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 [3].

3) In case of chronic or repeated exposure (more than 1 application according to WG/GA), chronic toxicity data (question A8.2.2a/A8.2.5a) 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 (A7.2.1.3.2a).

4) Chronic toxicity studies (question A8.2.2a/A8.2.5a) should in any case be submitted for the active substance. This concerns chronic tests with fish and daphnia. If the 48 h EC50 for *Chironomus* sp is at least ten times lower than the Daphnia 48 h EC50 (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, ánd
   - $DT_{50} \geq 2$ 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 (A7.2.1.3.2a) after 14 days (A8.2.7a) $\geq$ 10% of the active substance and/or metabolite is found in the sediment, a chronic toxicity test with sediment dwelling organisms (*Chironomus sp*.) (A8.2.7a) 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) $\geq$ 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 EC50 for algae
   - 0.1 of the EC50 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). This means that a differentiation is made between an edge-of-field ditch assessment and the Water Framework Directive (WFD) waterbody assessment. The higher tier risk assessment in the edge-of-field ditch is performed according to Directive 91/414 and hence the Guidance Document on Aquatic Ecotoxicology [3]. In the WFD-waterbody the MPCwater (MAC) and MPCwater (AA) are applied. The standards in the edge-of-field ditch as well as the WFD-waterbody should be met. For further information reference is made to the decision tree on the higher tier risk assessment for aquatic and sediment organisms (Appendix 2).
If monitoring data determined in surface water and/or sediment show that the criteria for aquatic and/or sediment dwelling organisms is exceeded, the risk is high and the authorisation is terminated. Information on the criteria to be met by monitoring data is given in Chapter 6 Behaviour and fate in the environment; behaviour in surface water, sediment and sewage treatment plant (STP).

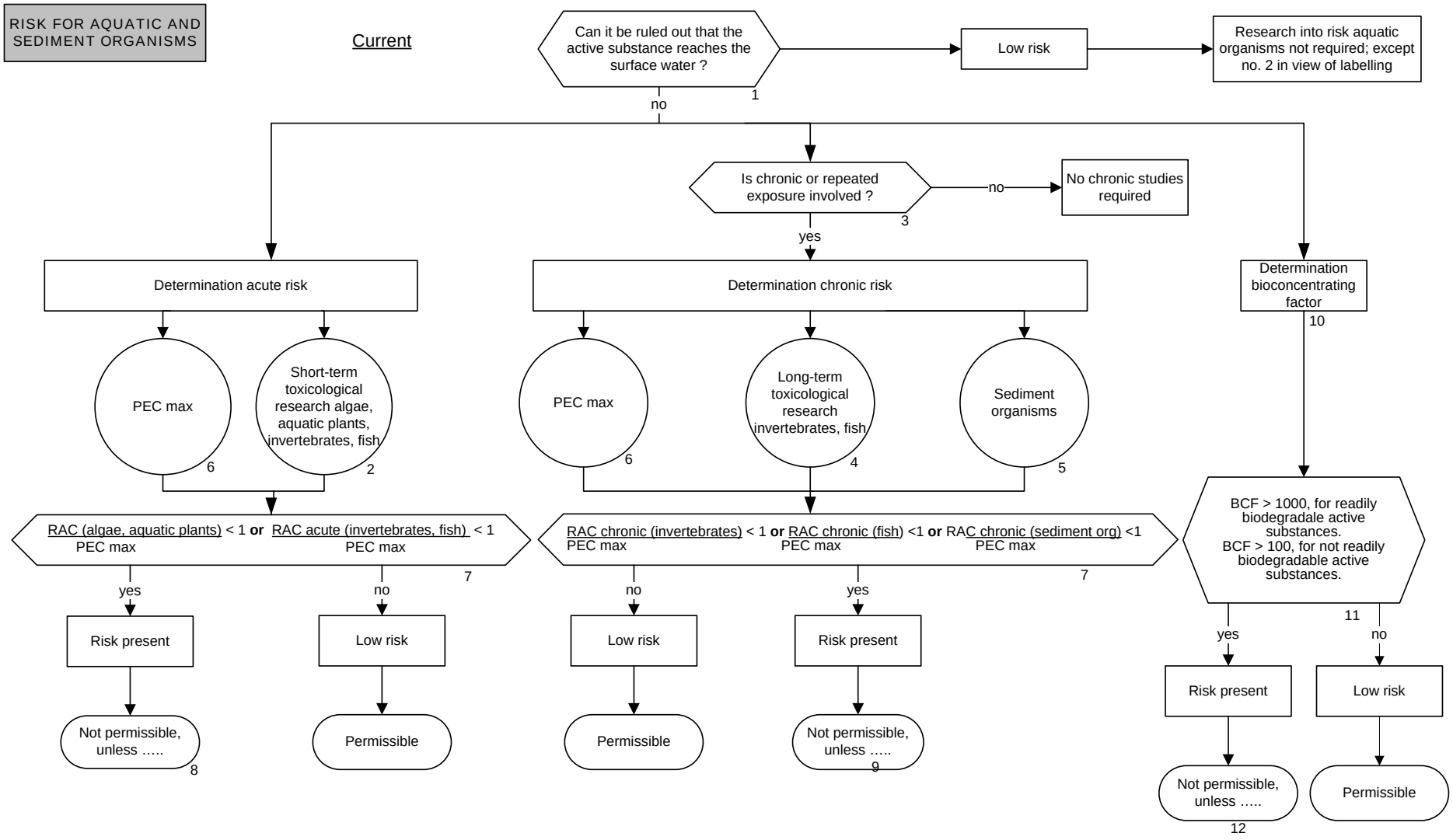
10) Research is requested to determine species accumulation and elimination, i.e., the extent to which the substances in question are directly absorbed from the water, retained (bioconcentration factor BCF), and excreted by the organism.
The octanol/water partition coefficient (Kow) (question A2.08a and b) 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) (A2.08a and b), for which the following formula (Veith et al., 1979 [4]) is used:

logBCF = 0.85*logKow - 0.70 (L/kg)

Experimental research with fish is required for substances with a logKow > 3 (A8.2.3a), 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). This means that a differentiation is made between an edge-of-field ditch assessment and the Water Framework Directive (WFD) waterbody assessment. The higher tier risk assessment in the edge-of-field ditch is performed according to Directive 91/414 and hence the Guidance Document on Aquatic Ecotoxicology [3]. In the WFD-waterbody the MPCwater (MAC) and MPCwater (AA) are applied. The standards in the edge-of-field ditch as well as the WFD-waterbody should be met. For further information reference is made to the decision tree on the higher tier risk assessment for aquatic and sediment organisms (Appendix 2).


RISK FOR AQUATIC AND SEDIMENT ORGANISMS
Current
Can it be ruled out that the active substance reaches the surface water ?
1
Low risk
Research into risk aquatic organisms not required; except no. 2 in view of labelling
no
Is chronic or repeated exposure involved ?
3
no
No chronic studies required
yes
Determination acute risk
Determination chronic risk
Determination bioconcentrating factor
10
PEC max
6
Short-term toxicological research algae, aquatic plants, invertebrates, fish
2
PEC max
6
Long-term toxicological research invertebrates, fish
4
Sediment organisms
5
RAC (algae, aquatic plants) < 1 or RAC acute (invertebrates, fish) < 1
PEC max PEC max
7
RAC chronic (invertebrates) < 1 or RAC chronic (fish) <1 or RAC chronic (sediment org) <1
PEC max PEC max PEC max
7
BCF > 1000, for readily biodegradale active substances.
BCF > 100, for not readily biodegradable active substances.
11
yes
Risk present
Not permissible, unless …..
8
no
Low risk
Permissible
no
Low risk
Permissible
yes
Risk present
Not permissible, unless …..
9
yes
Risk present
Not permissible, unless …..
12
no
Low risk
Permissible

Appendix 1B Explanatory notes decision tree Risk to aquatic and sediment dwelling organisms: Higher tier

1) With respect to the higher tier risk assessment there is a differentiation between the edge-of-field ditch and the Water Framework Directive (WFD) waterbody. The higher tier risk assessment in the edge-of-field ditch is performed according to Directive 91/414 and hence the Guidance Document on Aquatic Ecotoxicology [3]. In the WFD-waterbody the MPCwater (MAC) and MPCwater (AA) are applied. The standards in the edge-of-field ditch as well as the WFD-waterbody should be met.

2) The higher tier risk assessment can be triggered by exceeding of the first tier bioaccumulation criteria or by exceeding of the first tier TER values for the different standard test species. In the edge-of-field ditch the higher tier risk assessments are performed according to Directive 91/414.

3) 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;
   - 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 [3].

4) For the higher tier risk assessment triggered by exceeding of the first tier TER values several possibilities exist, e.g.:
   - modified exposure studies;
   - SSD approach;
   - micro-/mesocosm studies.
   For more information about these studies and approaches reference is made to the Guidance Document on Aquatic Ecotoxicology [3], the Guidance for summarizing and evaluating aquatic micro- and mesocosm studies [5] and paragraph 2.3. In this paragraph also information is presented with regard to the acceptability of effects.

5) 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.

6) A TER is calculated based on the relevant higher tier 91/414 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, a lower limit HC5, or an HC5 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.

7) 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.

8) In the WFD water body the MPC-approach is applied. The MPC (MAC) as well as the MPC (AA) is derived together with a PECmax WFD waterbody. A simple method for calculating the (time-weighted) average of the concentration in the WFD water bodies is at the moment not available. Experts expect that the concentration course at this distance from the source (the application) will be fairly even (and the maximum or time-weighted concentration, depending on the time span, will not be very different). Calculation of this effect (e.g. by means of breakthrough curves) is impossible at this term.

9) The MPCwater (MAC) as well as the MPCwater (AA) will be assessed against the PECmax in the WFD water bodies in the interim assessment methodology. This means that in the interim period the MPCwater (chronic) will always be determinative of risk/criterion exceedance (MPCwater (chronic) is more stringent than MPCwater (acute)). Only in exceptional cases, e.g. substances for which an MPCwater (AA) has no meaningful significance (e.g. rapidly degrading substances with acute effects only), assessment may be restricted to MPCwater (MAC).

   If the TER < 1, there is a risk present; drift reduction measures must be applied. If these are sufficient the risk in the WFD-water body is acceptable. If not, further refinements are possible. For information about the possible refinements, see paragraph 2.3. It is emphasized that the proposed drift reduction measures will be maintained after potential refinements.

10) In case the criterion exceedance is small (maximum factor 5, in line with drinking water decision tree) a temporary authorisation could be granted under certain conditions. It is only possible for new substances on the Dutch market for which (adequate) monitoring data are not yet available under condition of post-registration monitoring.
    Some examples of such conditions:
    - it is meaningful to start a monitoring programme (the substance can be detected above the limit of detection, i.e., not very rapidly disappearing from the water phase). NB. Starting up such a monitoring programme only seems meaningful in case the MPCwater (AA) is exceeded because if the MPCwater (MAC) is exceeded, the maximum exposure concentration must be measured directly in the WFD water bodies; this will be very difficult in practice.
    - the field of use covers a restricted acreage.

11) If the risk is acceptable in the edge-of-field ditch as well as the WFD water body the product is permissible regarding the risk to aquatic and sediment dwelling organisms.

Appendix 2 Risk evaluation crop protection products in mushroom culture

English translation to follow.

4. REFERENCES

1 Regeling voor de toelating, het op de markt brengen en het gebruik van gewasbeschermingsmiddelen en biociden (Wet gewasbeschermingsmiddelen en biociden) (Plant protection products and Biocides Act, Wgb 2006);
NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/;

2 Regeling van de Minister van Landbouw, Natuur en Voedselkwaliteit van 26 september 2007, nr. TRCJZ/2007/3100, houdende nadere regels omtrent gewasbeschermingsmiddelen en biociden (Plant protection products and Biocides Regulations (Rgb), published in the Government Gazette (Staatscourant) 188 of 28 September 2007 came into effect on 17 Oktober 2007;
including
Regeling van 20 oktober 2009 tot wijziging van de Regeling gewasbeschermingsmiddelen en biociden in verband met de aanwijzing van beoordelingsmethoden), published in the Government Gazette (Staatscourant) 16032 of 26 Oktober 2009 came into effect on 1 January 2010;
NL acts, decisions, orders, etc. can be obtained via http://wetten.overheid.nl/

3 European Commission (2002). Guidance Document on Aquatic Ecotoxicology in the context of Directive 91/414/EEC (SANCO/3268/2001 rev 4 final, 17 October 2002).

4 Vlaardingen, P.L.A. van & E.M.J. Verbruggen. Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007. RIVM Report 601782001/2007

5 F.M.W. de Jong, T.C.M. Brock, E.M. Foekema, P. Leeuwangh. 2008, Guidance for summarizing and evaluating aquatic micro- and mesocosm studies. RIVM Report 601506009/2008.

6 Campbell PJ, Arnold DJS, Brock TCM, Grandy NJ, Heger W, Heimbach F, Maund SJ, Streloke M. 1999. Guidance document on higher-tier aquatic risk assessment for pesticides (HARAP). SETAC-Europe Publication 179 p.

7 Aldenberg T, Jaworska, JS. 2000. Uncertainty of hazardous concentrations and fraction affected for normal species sensitivity distributions. Ecotoxicol Environ Saf 46: 1 – 18.

8 Posthuma L, Suter GW, Traas TP (Eds). 2002. The Use of Species Sensitivity Distributions in Ecotoxicology. Lewis Publishers, Boca Raton, 587 pp.

9 Maltby L, Blake N, Brock TCM, Van den Brink PJ. 2005. Insecticide species sensitivity distributions: the importance of test species selection and relevance to aquatic ecosystems. Environ Toxicol Chem 24: 379-388.

10 Schroer AFW, Belgers JDM, Brock TCM, Matser AM, Maund SJ, Van den Brink PJ. 2004. Comparison of laboratory single species and field population-level effects of the pyrethroid insecticide lambda-cyhalothrin on freshwater invertebrates. Arch Environ Contam Toxicol 46: 324-335.

11 Van den Brink PJ, Blake N, Brock, TCM, Maltby L. 2006. Predictive value of species sensitivity distributions for effects of herbicides in freshwater ecosystems. Human and Ecological Risk Assessment, 12:645-674.

12 Brock, T.C.M., Arts, G.H.P., Maltby, L. and Van den Brink, P.J. 2006. Aquatic risks of pesticides, ecological protection goals and common claims in EU legislation. Integrated Environmental Assessment and Management 2, E20-E46.

13 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.

14. 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.
15. FRAUNHOFER-INSTITUT FÜR UMWELTCHEMIE UND ÖKOTOXIKOLOGIE (2001). Ökotoxikologische Prüfung von Pflanzenschutzmitteln hinsichtlich ihres Potentials zur Grundwassergefährdung - Ecotoxicological testing of pesticides with respect to their potential of endangering groundwater communities, UBA-Text 76/01.
16. Stowa, 1997, Bestrijdingsmiddelen in communaal afvalwater (Pesticides in community waste water), ISBN 90.74476.80.5.