

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

EU part

Plant protection products

**Chapter 6 Fate and behaviour in the environment:
behaviour in surface water, sediment and sewage
treatment plants (STP)**

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of plant protection products and biocides**

Chapter 6 Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plants (STP)

Category: Plant Protection Products

General introduction	3
I Behaviour in surface water and sediment	3
1. EU framework	3
1.1. Introduction	3
1.2. Data requirements	4
1.2.1. Data requirements for the active substance	4
1.2.2. Data requirements for the product	9
1.3. Risk assessment	13
1.3.1. Estimation exposure concentrations with FOCUS Surface water	15
1.3.2. Estimation exposure concentration with MED-RICE	16
1.3.3. Estimation exposure concentration resulting from indirect exposure through discharge via sewage treatment plants (STP)	16
1.3.4. Estimation exposure concentration resulting from direct exposure through application on hard surfaces (pavements)	17
1.3.5. Estimation exposure concentration for products containing more than one active substance or tank mixes	17
1.3.6. Use of monitoring data	17
1.4. Approval	17
1.4.1. Evaluation	18
1.4.2. Decision making	19
1.5. Developments	19
II behaviour in a sewage treatment plant (STP)	20
1. EU-framework	20
1.1. Introduction	20
1.2. Data requirements	20
1.2.1. Data requirements for the active substance	21
1.2.2. Data requirements for the product	26
1.3. Risk assessment	26
1.3.2. Calculation exposure concentrations for discharge via a sewage treatment plant (STP)	26
1.3.3. Calculation acute exposure concentration for emission via use on hard surfaces	28
1.4. Approval	28
1.4.1. Evaluation	29
1.4.2. Decision making	29
1.5. Developments	29
2. Appendices	30
3. References	31

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the persistence in the soil of a plant protection product and its active substance and how reference values are derived in the EU framework (§1 - §1.5) under Regulation (EC) No 1107/2009 [1]. The described risk assessment in this chapter can be used for both the approval procedure for active substances as well as for zonal applications for the authorization of plant protection products (i.e. core registration reports).

Substances that are approved under Regulation (EC) No 1107/2009 and were approved under Directive 91/414/EEC [2] are included in Commission Implementing Regulation (EU) No 540/2011 [3].

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

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

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

This chapter consists of two parts, one part about behaviour in surface water and sediment (I) and a second part about behaviour in sewage treatment plants (STP) (II).

I BEHAVIOUR IN SURFACE WATER AND SEDIMENT

1. EU FRAMEWORK

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

1.1. Introduction

This chapter describes the procedure to determine estimated or measured concentrations in surface water and sediment following normal agricultural applications (outdoor and glasshouses). For the assessment of applications to hardened surfaces and special indoor cultivations and storage treatments see Part II (STP). Estimated or measured concentrations in surface water are used for the risk assessment for organisms that depend on surface water (aquatic organisms and birds and mammals). The above implies a relationship with chapter 7 Ecotoxicology; aquatic, and Ecotoxicology; terrestrial; birds and mammals.

The concentration in surface water depends on factors such as the extent to which a

substance leaches through and reaches the water via drainage pipes. Another important entry route for surface water and sediment is the fraction of a pesticide blown away during application (spray drift). Drift tables developed by Rautmann are used in EU framework. These tables are included in the first revision of the Guidance Document on Aquatic Ecotoxicology [4].

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

1.2. Data requirements

In order to qualify for inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [6] must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the performance of experiments are mentioned in Commission Communication 2013/C 95/01 [7].

Experiments carried out after 25 July 1993 should have been carried out under GLP.

The data requirements, and the fact whether or not they are required for certain fields of use, and the corresponding guidelines are summarised in the overview table; see Appendix A to Chapter 6.

1.2.1. Data requirements for the active substance

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

The data requirements regarding the behaviour of the active substance in surface water and sediment are described in part A of Commission Regulation (EU) No 283/2013, point 7.2 (fate and behaviour in water and sediment) and 7.4 (monitoring data).

Fate and behaviour in water and sediment
(283/2013; 7.2)

7.2. Fate and behaviour in water and air

The information provided, taken together with that provided for one or more plant protection products containing the active substance, and other relevant information, shall be sufficient to establish or permit estimation of:

(a) persistence in water systems (bottom sediment and water, including suspended particles);

- (b) the extent to which water and sediment organisms are at risk;
- (c) potential for contamination of surface water and groundwater.

Route and rate of degradation in aquatic systems (chemical and photochemical degradation)

7.2.1. Route and rate of degradation in aquatic systems (chemical and photochemical degradation)

The data and information provided, together with other relevant data and information, shall be sufficient to:

- (a) identify the relative importance of the types of processes involved (balance between chemical and biological degradation);
- (b) where possible, identify the individual components present;
- (c) establish the relative proportions of the components present and their distribution as between water, including suspended particles, and sediment; and
- (d) permit the residue of concern to which non-target species are or may be exposed, to be defined.

Hydrolytic degradation
(283/2013; 7.2.1.1.)

7.2.1.1. Hydrolytic degradation

Circumstances in which required

The hydrolysis rate of purified active substances shall be determined and reported at 20 °C or 25 °C. Studies on hydrolytic degradation shall also be performed for degradation and reaction products which account at any time for more than 10 % of the amount of active substance added in the hydrolysis study, unless sufficient information on their degradation is available from the test performed with the active substance. No additional hydrolysis information on degradates shall be required if they are considered to be stable in water.

Test conditions

The hydrolysis rate for pH 4, 7 and 9 under sterile conditions in the absence of light shall be determined and reported at 20 °C or 25 °C. For active substances that are stable or have a low rate of hydrolysis at 20-25 °C, the rate shall be determined at 50 °C, or another temperature above 50 °C. If degradation is observed at 50 °C or above, the degradation rate at at least three other temperatures shall be determined and an Arrhenius plot shall be constructed to permit an estimate to be made of hydrolysis rate at 20 °C and 25 °C. The identity of hydrolysis products formed and the rate constants observed, shall be reported. The estimated DegT50 values shall be reported for 20 °C or 25 °C.

Result

→ DT50-hydrolysis transformation product

Direct photochemical degradation

(283/2013; 7.2.1.2)

7.2.1.2. Direct photochemical degradation

Circumstances in which required

For compounds with a molar (decadic) absorption coefficient (ϵ) $> 10 \text{ L} \times \text{mol}^{-1} \times \text{cm}^{-1}$ at a wavelength (λ) $\geq 295 \text{ nm}$ direct phototransformation of purified active substances shall be determined and reported unless the applicant shows that contamination of surface water will not occur.

Studies on direct photochemical degradation shall also be performed for metabolites, breakdown and reaction products which account at any time for more than 10 % of the amount of active substance added in the photolysis study, unless sufficient information on their degradation is available from the test performed with the active substance.

No additional photolysis information on degradates shall be required if they are considered to be stable under photolytic conditions.

Test conditions

The direct phototransformation in purified, (for example distilled) buffered water using artificial light under sterile conditions, if necessary using a solubiliser, shall be determined and reported. In the first theoretical step a maximum possible photolysis rate shall be estimated based on the molar extinction coefficient of the active substance. If photolysis is considered to be a potentially significant degradation pathway, photolysis experiments for range finding shall be carried out (tier 2). Determination of quantum yield and direct photolysis route/rate (tiers 3 and 4) shall be carried out for active substances where tier 2 indicates significant photolysis. The identity of breakdown products formed which exceed 10 % of the applied test substance at any time during the study, a mass balance to account for at least 90 % of the applied radioactivity, as well as photochemical half-life (DT50) shall be reported.

Result

→ DT50-photolysis transformation product

Indirect photochemical degradation

(283/2013; 7.2.1.3)

7.2.1.3. Indirect photochemical degradation

Circumstances in which required

Studies on indirect photochemical degradation may be submitted where there are indications from other available data that route and rate of degradation in the water phase can be significantly influenced by indirect photodegradation.

Test conditions

Studies shall be performed in an aqueous system containing organic (humic substances) and inorganic (salts) compounds in a composition that is typical for natural surface waters.

Route and rate of biological degradation in aquatic systems

(283/2013; 7.2.2)

“Ready biodegradability”

(283/2013; 7.2.2.1.)

7.2.2. Route and rate of biological degradation in aquatic systems

7.2.2.1. "Ready biodegradability"

Circumstances in which required

The 'ready biodegradability' test shall be performed. If no such test is provided, the active substance shall by default be considered not 'readily biodegradable'.

Result

→ substance is "ready biodegradable" or "not ready biodegradable"

Aerobic mineralisation in surface water

(283/2013; 7.2.2.2.)

7.2.2.2. Aerobic mineralisation in surface water

The data and information provided, together with other relevant data and information, shall be sufficient to:

- (a) identify individual components present, which at any time account for more than 10 % of the amount of active substance added, including, where possible, non-extractable residues;
- (b) identify individual components present, which account for more than 5 % of the amount of active substance added in at least two sequential measurements, where possible;
- (c) identify individual components (> 5 %) for which at the end of the study the maximum of formation is not yet reached, where possible;
- (d) identify or characterise, where possible, other individual components;
- (e) establish, where relevant, the relative proportions of the components (mass balance);
and
- (f) permit, where relevant, the sediment residue of concern and to which non-target species are or may be exposed, to be defined.

Circumstances in which required

Studies on aerobic mineralisation in surface water shall be provided unless the applicant shows that contamination of open water (freshwater, estuarine and marine) will not occur.

Test conditions

The rate of degradation and the pathway or pathways shall be reported either for a 'pelagic' test system or for a 'suspended sediment' system. Where relevant, additional test systems, which differ with respect to organic carbon content, texture or pH shall be used.

Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and, where relevant, sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂ ;
- (c) volatile compounds other than CO₂ ; and

(d) individual identified transformation products.

The duration of the study shall not exceed 60 days unless the semi-continuous procedure with periodical renewal of the test suspension is applied. However, the period for the batch test may be extended to a maximum of 90 days, if the degradation of the test substance has started within the first 60 days.

Water/sediment study
(283/2013;.7.2.2.3)

7.2.2.3. Water/sediment study

The information provided, together with other relevant information, shall be sufficient to:

- (a) identify individual components present which at any time account for more than 10 % of the amount of active substance added, including, where possible, non-extractable residues;
- (b) identify individual components present which account for more than 5 % of the amount of active substance added in at least two sequential measurements, where possible;
- (c) identify individual components (> 5 %) for which at the end of the study the maximum of formation is not yet reached, where possible;
- (d) identify or characterise, where possible, also other individual components present;
- (e) establish the relative proportions of the components (mass balance); and
- (f) define the sediment residue of concern, to which non-target species are or may be exposed.

Where a reference is made to non-extractable residues these shall be defined as chemical species originating from active substances used in accordance with good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues or the nature of the sediment matrix. These non-extractable residues are not considered to include fragments through metabolic pathways leading to natural products.

Circumstances in which required

The water/sediment study shall be reported unless the applicant shows that contamination of surface water will not occur.

Test conditions

The degradation pathway or pathways shall be reported for two water/sediment systems. The two sediments selected shall differ with respect to organic carbon content and texture, and where relevant, with respect to pH.

Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂ ;
- (c) volatile compounds other than CO₂ ;
- (d) individual identified transformation products;

- (e) extractable substances not identified; and
- (f) non-extractable residues in sediment.

The duration of the study shall be at least 100 days. It shall be longer where this is necessary to establish the degradation pathway and water/sediment distribution pattern of the active substance and its metabolites, breakdown and reaction products. If more than 90 % of the active substance is degraded before the period of 100 days expires, the test duration may be shorter.

The degradation pattern of potentially relevant metabolites occurring within the water/sediment study shall be established either by extension of the study for the active substance, or by conducting a separate study for potentially relevant metabolites.

Result

→ DT50 active substance and/or transformation product (water/sediment system)

Irradiated water/sediment study
(283/2013; 7.2.2.4)

7.2.2.4. Irradiated water/sediment study

The same general provisions as provided under point 7.2.2.3 apply.

Circumstances in which required

If photochemical degradation is of importance a water/sediment study under influence of a light/dark regime may additionally be provided.

Test conditions

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

Degradation in the saturated zone
(283/2013; 7.2.3.)

7.2.2.4. Irradiated water/sediment study

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

Monitoring data
(283/2013; 7.5.)

7.5. Monitoring data

Available monitoring data concerning fate and behaviour of the active substance and relevant metabolites, breakdown and reaction products in soil, groundwater, surface water, sediment and air shall be reported.

1.2.2. Data requirements for the product

The text below in grey frames has been taken from Commission Regulation (EU) No 545/2011. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the

grey frames. Question numbers (NL as well as EU) are given below the headings. The endpoints of the study are given as well, if relevant.

The data requirements regarding the behaviour of the plant protection product in surface water and sediment are described in part A of Commission Regulation (EU) No 284/2013 under point 9.2 (fate and behaviour in water).

Generally, EU and OECD guidelines for the performance of experiments are mentioned in Commission Communication 2013/C 95/02 [8].

Introduction

1. Predicted environmental concentrations (PEC).

1.1. A realistic worst-case estimation shall be made of the expected concentrations of the active substance and metabolites, breakdown and reaction products:

- which account for more than 10 % of the amount of active substance added,
- which account for more than 5 % of the amount of active substance added, in at least two sequential measurements,
- for whose individual components (> 5 %) the maximum of formation is not yet reached at the end of the study, in soil, surface in soil, groundwater, surface water, sediment and air, following use as proposed or already occurring.

1.2. For the purposes of the estimation of such concentrations the following definitions apply:

(a) Predicted environmental concentration in soil (PEC S): the level of residues in the top layer of the soil and to which non-target soil organisms may be exposed (acute and chronic exposure).

(b) Predicted environmental concentration in surface water (PEC SW): the level of residues, in surface water to which non-target organisms may be exposed (acute and chronic exposure).

(c) Predicted environmental concentration in sediment (PEC SED): the level of residues, in sediment to which non-target benthic organisms may be exposed (acute and chronic exposure).

(d) Predicted environmental concentration in groundwater (PEC GW): the level of residues in groundwater.

(e) Predicted environmental concentration in air (PEC A): the level of residues in air, to which man, animals and other non-target organisms may be exposed (acute and chronic exposure).

1.3. For the estimation of these concentrations all relevant information on the plant protection product and on the active substance shall be taken into account. Where relevant the parameters set out in Section 7 of Part A of the Annex to Regulation (EU) No 283/2013

shall be used.

1.4. When models are used for estimation of predicted environmental concentrations they shall:

- make a best-possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,
- where possible be reliably validated with measurements carried out under circumstances relevant for the use of the model,
- be relevant to the conditions in the area of use.

1.5. The information provided shall, where relevant, include that referred to in Section 7 of Part A of the Annex to Regulation (EU) No 283/2013.

2. For solid plant protection products, treated and coated seeds there shall be an assessment of the risk from dust drift on to non-target species during application or sowing. Until agreed dust dissipation rates are available, then likely exposure levels shall be determined using a range of application techniques, suitable dust measurement methodology and, where appropriate, mitigation measures.

Fate and behaviour in water and sediment
(284/2013; 9.2)

Aerobic mineralisation in surface water
(284/2013; 9.2.1)

9.2. Fate and behaviour in water and sediment

9.2.2. Impact on water treatment procedures

Circumstances in which required

The persistence and behaviour of plant protection products in open water (freshwater, estuarine and marine) shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.2.2.2 of Part A of the Annex to Regulation (EU) No 283/2013.

The test shall be reported unless the applicant shows that contamination of open water will not occur.

Test conditions

The rate of degradation and the pathway or pathways shall be reported either for a 'pelagic' test system or for a 'suspended sediment' system. Where relevant, additional test systems, which differ with respect to organic carbon content, texture or pH shall be used.

Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and, where relevant, sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂ ;
- (c) volatile compounds other than CO₂ ;
- (d) individual identified transformation products;
- (e) extractable substances not identified; and
- (f) non-extractable residues in sediment.

The duration of the study shall not exceed 60 days unless the semi-continuous procedure with periodical renewal of the test suspension is applied. However, the period for the batch test may be extended to a maximum of 90 days, if the degradation of the test substance has started within the first 60 days.

Water/sediment study
(545/20119.2.2)

9.2.2. Water/sediment study

Circumstances in which required

The persistence and behaviour of plant protection products in aquatic systems shall be investigated unless it is possible to extrapolate from data obtained on the active substance and metabolites, breakdown and reaction products in accordance with the requirements set out in point 7.2.2.3 of Part A of the Annex to Regulation (EU) No 283/2013.

The test shall be reported unless the applicant shows that contamination of surface water will not occur.

Test conditions

The degradation pathway or pathways shall be reported for two water/sediment systems. The two sediments selected shall differ with respect to organic carbon content and texture, and where relevant, with respect to pH.

Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂ ;
- (c) volatile compounds other than CO₂ ;
- (d) individual identified transformation products;
- (e) extractable substances not identified; and
- (f) non-extractable residues in sediment.

The duration of the study shall be at least 100 days. It shall be longer where this is necessary to establish the degradation pathway and water/sediment distribution pattern of the active substance and its metabolites, breakdown and reaction products. If more than 90% of the active substance is degraded before the period of 100 days expires, the test duration may be shorter.

The degradation pattern of potentially relevant metabolites occurring within the water/sediment study shall be established by extension of the study for the active substance, when it is not possible to extrapolate from point 7.2.2.3 of Part A of the Annex to Regulation (EU) No 283/2013.

Irradiated water/sediment study
(284/2013; 9.2.3)

9.2.3. Irradiated water/sediment study

If photochemical degradation is of importance, a water/sediment study under influence of a light/dark regime may additionally be reported.

Test conditions

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

Estimation of concentrations in surface water and sediment
(284/2013; 9.2.5)

9.2.5. Estimation of concentrations in surface water and sediment

The surface water and sediment contamination routes shall be defined taking into account relevant agricultural, plant health, and environmental (including climatic) conditions.

Suitable estimations (calculations) of predicted environmental concentration in surface water PEC_{sw} and sediment PEC_{sed} of active substance shall be submitted, unless the applicant shows that contamination will not occur. PEC_{sw} and PEC_{sed} estimations shall relate to the maximum number and highest rates of application, at the shortest interval, for which authorisation is sought, and be relevant to ditches, ponds, and streams.

Relevant EU surface water modelling tools shall be run. The factors which shall be considered in making PEC_{sw} and PEC_{sed} estimations relate to direct application to water, drift, run-off, discharge via drains and atmospheric deposition, and include processes such as volatilisation, adsorption, advection, hydrolysis, photolysis, biodegradation, sedimentation and re-suspension, and transfer between water and sediment. Initial maximum concentration following an application (global maximum), short-term and long-term PEC_{sw} calculations for relevant water bodies (time weighted averages) shall be provided. Corresponding initial maximum concentration following an application (global maximum), short-term and long-term PEC_{sed} calculations for relevant water bodies (time weighted averages) shall also be provided. These PEC values shall be provided for the active substance and all metabolites, breakdown and reaction products identified as a part of the residue definition for the risk assessment with respect to surface water and sediment. They shall be used to complete risk assessments, through a comparison with the endpoints derived from data from ecotoxicological studies.

Short-term and long-term PEC SW and corresponding short-term and long-term PEC_{sed} calculations for relevant static water bodies (ponds; time weighted averages) and for relevant slow moving water bodies (ditches and streams; time weighted averages), shall be calculated with the aid of a moving time-window. Appropriate time windows with respect to data from ecotoxicological studies shall be applied.

The need to perform additional higher tier tests and the type and conditions of the tests to be performed shall be discussed with the national competent authorities.

1.3. Risk assessment

Studies into the behaviour of an active substance in water and sediment are required for a

correct estimation of the concentration of this active substance in surface water and sediment. These estimated concentrations, the PEC (Predicted Environmental Concentration), are important parameters in the risk assessment for water and sediment organisms.

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as DT_{50} for degradation rate in water and K_{OM}) are presented in a list of endpoints.

Risk is assessed on the basis of the endpoints.

The most important substance-related parameters for model estimation of the PEC are:

- DegT₅₀ for degradation rate in soil at 20°C (days),
- DegT₅₀ for degradation rate in water at 20°C (days),
- DegT₅₀ for degradation rate in sediment at 20°C (days),
- K_{om} and corresponding 1/n for soil (L/kg),
- K_{om} and corresponding 1/n for suspended organic matter (L/kg),
- K_{om} and corresponding 1/n for sediment (L/kg),
- Saturated vapour pressure (Pa),
- Solubility in water (mg/L),
- Molecular mass (g/mol).

For the application of degradation parameters, in particular standardisation for temperature, we refer to the FOCUS Degradation Kinetics [9]. This guidance also describes that if degradation parameters for the separate compartments cannot be derived, the DT_{50,system} value from a water-sediment study can be used in one compartment and a default value of 1000 days in the other compartment.

Besides the substance properties above, the level of the PEC depends on the following factors:

- Dose rate (kg/ha)
- Application frequency
- Period between consecutive applications (days)
- Exposure routes (spray drift, drainage and run-off)
- Spray drift-mitigation measures

Please note that for non-professional use the dose rate in kg/ha is corrected to match a maximum acreage of 500 m².

The PEC is calculated with the FOCUS Surface Water model (FOCUS SW) [10] for applications in the form of crop or seed treatment. Guidance under MED-RICE [11] is used for PEC calculations for rice growing.

No European evaluation methodology has been developed for other applications, such as application on hard surfaces, in mushroom growing, and in potato stores. Until these sections have been elaborated in the EU, the PEC as result of the exposure through these applications will be calculated as described under point 2.3.

1.3.1. Estimation exposure concentrations with FOCUS Surface water

1.3.1.1. Active substance

FOCUS SW provides simulations for three different water types, ditch, stream and pond and several exposure routes.

These exposure routes are drift, run-off and drainage. Surface water loading via drift is based on the BBA drift figures (Rautmann table) with corresponding distances for each crop group to the nearest surface water, as included in the first revision of the Guidance Document on Aquatic Ecotoxicology [4].

The PEC estimation follows 4 steps.

- Step 1 assumes a single loading corresponding with the maximum annual (where applicable aggregated) dose rate in the particular use without further specific characteristics. Exposure is calculated on the basis of the BBA drift figures, while using the calculated 90-percentile value and assuming a contribution of 10% of the dose

reaching the water through run-off or drainage. The distance between crop and surface water is fixed.

- In Step 2 a more realistic loading based on the dose rate, actual application scheme and crop interception is considered. Degradation of the substance during the periods between the different applications is taken into account. Spray drift is taken into account for each application while adjusting the percentile of the separate inputs; this results in the total drift figure being based on the 90-percentile again. The contribution of the dose reaching the water through run-off or drainage ranges from 0 to 5%, depending on region, soil type, and season.
- Step 3 contains 6 drainage and 4 run-off scenarios. Each scenario contains soil/climate combinations of regions in the EU, which are vulnerable to drainage and run-off. One or two of the water types mentioned above can be chosen for each scenario. Each water type has its own set of environmental parameters and cultures. The contribution by drift in each scenario is determined on the basis of the Rautmann table. The contribution by drainage is (where applicable) modelled with the FOCUS SW module MACRO and the contribution via run-off is (where applicable) modelled with PRZM. Finally, the behaviour of the substance, which reaches surface water and sediment via the various routes, is modelled with FOCUS-TOXSWA.

Finally, step 4 offers the option to calculate PECs with more specific local conditions where it is also possible to apply loading-mitigation measures. This step is envisaged for calculating scenarios in which step 3 gives no 'safe use'. Within the TOXSWA model it is feasible to define buffer zones with regard to drift and run-off. Further guidelines are given in FOCUS Landscape and mitigation [12, 13]. On this report the PPR has commented in their opinion of March 2007 [14]. Among others, remarks were made regarding the maximum percentage reduction to be achieved. This opinion should be followed when applying the FOCUS L&M guidance.

1.3.1.2. Metabolites

Metabolites may be emitted to surface water and sediment via the following routes:

1. An active substance reaches surface water and sediment where it degrades. Degradation route and rate are estimated in the water/sediment study.
2. An active substance degrades in the soil to metabolites which may reach the surface water via run-off or drainage. The formation of such metabolites is assessed in soil transformation studies in laboratory or field.
3. Metabolites that have been formed in the soil reach surface water via groundwater. The formation of such metabolites is shown in lysimeter studies.

FOCUS SW contains a specific module to calculate metabolite concentrations.

The required data are:

The formation fraction in soil or water/sediment studies, the K_{om} and the DT_{50} of the metabolite.

Detailed guidance on how to calculate metabolite concentrations is given in the FOCUS surface water guidance document [11].

1.3.2. Estimation exposure concentration with MED-RICE

Exposure calculations for rice growing must be carried out under the guidance in the context of MED-RICE [11].

1.3.3. Estimation exposure concentration resulting from indirect exposure through discharge via sewage treatment plants (STP)

This form of exposure has not been elaborated in the EU. Until this point has been

elaborated in the EU, the PEC as result of indirect exposure following application on hard surfaces, application in mushroom growing and other relevant uses will be calculated as described under point 2.3.2.

1.3.4. Estimation exposure concentration resulting from direct exposure through application on hard surfaces (pavements)

This form of exposure has not been elaborated in the EU. Until this point has been elaborated in the EU, the PEC as result of direct exposure following application on hard surfaces will be calculated as described under point 2.3.2.

1.3.5. Estimation exposure concentration for products containing more than one active substance or tank mixes

For tank mixes or combination products, the exposure concentrations of each relevant a.s. are calculated separately. In the subsequent aquatic risk assessment (Chapter 7) combination toxicology is taken into account.

1.3.6. Use of monitoring data

There is no consensus in the EU about the evaluation methodology for the use of monitoring data to arrive at approval of an active substance in Commission Implementing Regulation (EU) No 540/2011 [3]. The evaluation of monitoring data is usually based on expert judgement. Member states may have their own procedure to assess monitoring data in their National Addenda.

1.4. Approval

This section describes the approval criteria for active substances (section 1.4.1) and plant protection products (section 1.4.2 and 1.4.3). For the EU approval procedure of active substances a representative formulation has to be included in the dossier. Therefore section 1.4.1 to 1.4.3 apply. For the zonal applications of plant protection products only section 1.4.2 and 1.4.3 apply.

1.4.1. Approval of the active substance

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

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

3. Criteria for the approval of an active substance

3.1. Dossier

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

Point 4 of Annex II of Regulation (EC) No 1107/2009 gives criteria for substitution. The texts specifically applicable to the aspect behaviour in surface water and sediment are

presented below. In the chapter “Generic aspects” of the Evaluation Manual 2.0, more information is provided on criteria for substitution.

Point 5 of Annex II of Regulation (EC) No 1107/2009 gives information on low risk substances. The texts specifically applicable to the aspect behaviour in surface water and sediment are presented below. In the chapter “Generic aspects” of the Evaluation Manual 2.0, more information is provided on low risk substances.

1.4.2. Evaluation of plant protection products

The principles for the evaluation of the effects on the environment are presented in Commission Regulation (EU) No 546/2011 [14]. These concern the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects.

The specific principles Environmental effects, part Behaviour and distribution in the environment regarding behaviour in water are in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.1.3. Member States shall evaluate the possibility of the plant protection product reaching surface water under the proposed conditions of use; if this possibility exists they shall estimate, using a suitable calculation model validated at EU level, the short-term and long-term predicted concentration of the active substance and of metabolites, degradation and reaction products that could be expected in the surface water in the area of envisaged use after use of the plant protection product according to the proposed conditions of use. If there is no validated EU calculation model, Member States shall base their evaluation especially on the results of mobility and persistence in soil studies and the information on run-off and drift as provided for in the Annex to Regulation (EU) No 544/2011 and to Regulation (EU) No 545/2011.

This evaluation will also take into consideration the following information:

- (i) the specific information on fate and behaviour in soil and water as provided for in the Annex to Regulation (EU) No 544/2011 and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - molecular weight,
 - solubility in water,
 - octanol/water partition coefficient,
 - vapour pressure,
 - volatilization rate,
 - hydrolysis rate in relation to pH and identity of breakdown products,
 - dissociation constant;
- (iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 545/2011, including the information on distribution and dissipation in soil and water;
- (iv) possible routes of exposure:
 - drift,
 - run-off,
 - overspray,
 - discharge via drains,
 - leaching,
 - deposit in the atmosphere;
- (v) where relevant, other authorized uses of plant protection products in the area of

envisaged use containing the same active substance or which give rise to the same residues;

- (vi) where relevant, data on the procedures for drinking water abstraction and treatment in the area of envisaged use.

1.4.3. Decision making for plant protection products

The principles for decision making regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 [14]. These concern the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects.

The specific principles Environmental effects, part Behaviour and distribution in the environment as regards behaviour in water are in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.1.3. No authorization shall be granted if the concentration of the active substance or of relevant metabolites, breakdown or reaction products to be expected after use of the plant protection product under the proposed conditions of use in surface water:

- exceeds, where the surface water in or from the area of envisaged use is intended for the abstraction of drinking water, concentrations above which compliance with drinking water quality established in accordance with Directive 2000/60/EC of the European Parliament and of the Council¹ is compromised, or
- has an impact deemed unacceptable on non-target species, including animals, according to the relevant requirements provided for in point 2.5.2.

The proposed instructions for use of the plant protection product, including procedures for cleaning application equipment, must be such that the likelihood of accidental contamination of surface water is reduced to a minimum.

1.5 Developments

Emission via dust drift. At the moment EU guidance is being developed with regard to the risk assessment of treated seeds. The draft guidance document on the authorisation of plant protection products for seed treatment will be taken into account by The Netherlands to keep up with the latest developments when dealing with a seed treatment product.

¹ OJ L 327, 22.12.2000, p. 1.

II BEHAVIOUR IN A SEWAGE TREATMENT PLANT (STP)

1. EU-FRAMEWORK

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

1.1. Introduction

This chapter 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, chicory forcing and greenhouse cultures. Use on hard surfaces (pavements) by municipalities, private organisations, companies and households may also be a cause of plant protection products reaching sewage treatment plants via run-off (Stowa, 1997).

The loading of surface water and sediment must be calculated for the evaluation of the risk to aquatic and sediment organisms in the context of the evaluation of the permissibility of plant protection products. Different emission routes are possible. One is the discharge onto a sewage treatment plant (STP). **Behavioural** aspects of products in an STP and **effects** of the products on the purification of waste water must be taken into account when calculating the loading of surface water and sediment. This chapter only describes the behavioural aspects. The effects have been elaborated in the chapter Ecotoxicology; aquatic organisms.

The programme USES (version 2.0) is used to calculate the concentration for emission routes associated with other uses (such as discharge via an STP or emission via hard surfaces/amenity areas).

This programme contains several modules for calculating the concentration in surface water and sediment for emission routes associated with different uses.

Currently the STP assessment applies to application of PPP to

- hardened surfaces
- indoor cultivations of e.g. mushrooms (not glasshouses)
- potato processing industry (no specific scenario available, generic scenario used)

1.2. Data requirements

In order to qualify for inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [6] must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the performance of experiments are mentioned in Commission Communication 2013/C 95/01 [7].

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

Experiments carried out after 25 July 1993 should have been carried out under GLP.

The data requirements, and the fact whether or not they are required for certain fields of use, and the corresponding guidelines are summarised in the overview table; see Appendix A to Chapter 6.

1.2.1. Data requirements for the active substance

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

The data requirements regarding the behaviour of an active substance in a sewage treatment plant are described in Commission Regulation (EU) No 283/2013, point 7.1 (fate and behaviour in the soil) and 7.2 (fate and behaviour in water and air).

Adsorption and desorption in soil
(283/2013; 7.1.3)

Adsorption and desorption
(283/2013; 7.1.3)

7.1.3.1 Adsorption and desorption

The information provided, together with other relevant data, shall be sufficient to establish the adsorption coefficient of the active substance and of its metabolites, breakdown and reaction products.

Adsorption and desorption of the active substance
(283/2013; 7.1.2.1.1)

7.1.3.1.1 Adsorption and desorption in soil

Circumstances in which required

Studies on adsorption and desorption of the active substance shall be provided, except where the nature and manner of use of plant protection products containing the active substance preclude soil contamination such as indoor uses on stored products or brush applied wound healing treatments for trees.

Test conditions

Studies on the active substance shall be reported for at least four soils.

Where the batch equilibrium method cannot be applied due to fast degradation, methods such as studies with short equilibration times, QSPR (Quantitative Structure Property Relationship) or the HPLC (High-Performance Liquid Chromatography) method shall be considered as possible alternatives. Where the batch equilibrium method cannot be applied

due to weak adsorption, column leaching studies (see point 7.1.4.1) shall be considered as an alternative.

7.1.3.1.2 Adsorption and desorption of metabolites, breakdown and reaction products

Circumstances in which required

Studies on adsorption and desorption shall be provided for all metabolites, breakdown and reaction products, for which in soil degradation studies one of the following conditions is fulfilled:

- (a) they account for more than 10 % of the amount of active substance added, at any time during the studies;
- (b) they account for more than 5 % of the amount of active substance added in at least two sequential measurements;
- (c) the maximum of formation is not reached at the end of the study but accounts for at least 5 % of the active substance at the final measurement;
- (d) all metabolites found in lysimeter studies at annual average concentrations exceeding 0,1 µg/L in the leachate.

Test conditions

Studies on metabolites, breakdown and reaction products shall be provided for at least three soils.

Where the batch equilibrium method cannot be applied due to fast degradation, methods such as studies with short equilibration times, QSPR or the HPLC method shall be considered as an alternative. Where the batch equilibrium method cannot be applied due to weak adsorption, column leaching studies (see point 7.1.4.1) shall be considered as an alternative.

Aged sorption

(283/2013; 7.1.3.2)

7.1.3.2 Aged sorption

As a higher tier option, information on aged sorption may be provided.

Circumstances in which required

The need to carry out a study on aged sorption shall be discussed with the national competent authorities.

Test conditions

In absence of guidance being included in the list referred to under point 6 of the introduction, the type and conditions of the study to be performed shall be discussed with the national competent authorities. The influence on the rate of degradation shall also be considered. Aged sorption data shall be compatible with the model in which those values will be used.

Result:

→ $K_{OM}(K_{oc}/1.724)$

A conversion factor of 1.724 is used to translate K_{oc} into K_{om} .

For substances that are (almost) only discharged to surface water via biological treatment

plants, the extent of adsorption to activated sludge can be determined as refinement of the risk assessment. This K_p value (partition coefficient solid matter - water) can then be entered in the model that is used to calculate the exposure concentration as result of discharge via an STP.

Test guideline

ISO 18749 Water quality – Adsorption of substances in activated sludge – Batch test using specific analytical methods [15].

Result:

→ partition coefficient (K_p) STP

Route and rate of biological degradation in aquatic systems

"Ready biodegradability"

(283/2013; 7.2.2.1.)

7.2.2. Route and rate of biological degradation in aquatic systems

7.2.2.1. "Ready biodegradability"

Circumstances in which required

The 'ready biodegradability' test shall be performed. If no such test is provided, the active substance shall by default be considered not 'readily biodegradable'.

Result

→ substance is "ready biodegradable" or "not ready biodegradable"

This information originates from ready or inherent biodegradability tests. The result of the study (ready biodegradable/not ready biodegradable) is converted to a certain rate constant in the model which serve to calculate the concentration in surface water and sediment. This value can be adjusted, e.g., by making a more precise estimate of the degradation rate from the water/sediment study. A problem with ready biodegradability tests is that the degradation rate depends on the exposure concentration. This applies to all substances, not only to plant protection products. It happens that a ready test cannot be carried out with plant protection products because the product is too toxic to the micro-organisms.

Aerobic mineralisation in surface water

(283/2013; 7.2.2.2.)

7.2.2.2. Aerobic mineralisation in surface water

The data and information provided, together with other relevant data and information, shall be sufficient to:

- (a) identify individual components present, which at any time account for more than 10 % of the amount of active substance added, including, where possible, non-extractable residues;
- (b) identify individual components present, which account for more than 5 % of the amount of active substance added in at least two sequential measurements, where possible;
- (c) identify individual components (> 5 %) for which at the end of the study the maximum of formation is not yet reached, where possible;

(d) identify or characterise, where possible, other individual components;

(e) establish, where relevant, the relative proportions of the components (mass balance);
and

(f) permit, where relevant, the sediment residue of concern and to which non-target species are or may be exposed, to be defined.

Circumstances in which required

Studies on aerobic mineralisation in surface water shall be provided unless the applicant shows that contamination of open water (freshwater, estuarine and marine) will not occur.

Test conditions

The rate of degradation and the pathway or pathways shall be reported either for a 'pelagic' test system or for a 'suspended sediment' system. Where relevant, additional test systems, which differ with respect to organic carbon content, texture or pH shall be used.

Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and, where relevant, sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂ ;
- (c) volatile compounds other than CO₂ ; and
- (d) individual identified transformation products.

The duration of the study shall not exceed 60 days unless the semi-continuous procedure with periodical renewal of the test suspension is applied. However, the period for the batch test may be extended to a maximum of 90 days, if the degradation of the test substance has started within the first 60 days.

Water/sediment study

(283/2013.2.2.3)

7.2.2.3. Water/sediment study

The information provided, together with other relevant information, shall be sufficient to:

- (a) identify individual components present which at any time account for more than 10 % of the amount of active substance added, including, where possible, non-extractable residues;
- (b) identify individual components present which account for more than 5 % of the amount of active substance added in at least two sequential measurements, where possible;
- (c) identify individual components (> 5 %) for which at the end of the study the maximum of formation is not yet reached, where possible;
- (d) identify or characterise, where possible, also other individual components present;
- (e) establish the relative proportions of the components (mass balance); and
- (f) define the sediment residue of concern, to which non-target species are or may be

exposed.

Where a reference is made to non-extractable residues these shall be defined as chemical species originating from active substances used in accordance with good agricultural practice that cannot be extracted by methods which do not significantly change the chemical nature of these residues or the nature of the sediment matrix. These non-extractable residues are not considered to include fragments through metabolic pathways leading to natural products.

Circumstances in which required

The water/sediment study shall be reported unless the applicant shows that contamination of surface water will not occur.

Test conditions

The degradation pathway or pathways shall be reported for two water/sediment systems. The two sediments selected shall differ with respect to organic carbon content and texture, and where relevant, with respect to pH.

Results obtained shall be presented in the form of schematic drawings showing the pathways involved, and in the form of balance sheets which show the distribution of radio-label in water and sediment as a function of time, as between:

- (a) active substance;
- (b) CO₂ ;
- (c) volatile compounds other than CO₂ ;
- (d) individual identified transformation products;
- (e) extractable substances not identified; and
- (f) non-extractable residues in sediment.

The duration of the study shall be at least 100 days. It shall be longer where this is necessary to establish the degradation pathway and water/sediment distribution pattern of the active substance and its metabolites, breakdown and reaction products. If more than 90 % of the active substance is degraded before the period of 100 days expires, the test duration may be shorter.

The degradation pattern of potentially relevant metabolites occurring within the water/sediment study shall be established either by extension of the study for the active substance, or by conducting a separate study for potentially relevant metabolites.

Result

→ DT₅₀ active substance and/or transformation product (water/sediment system)

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as DT₅₀ STP) are presented in a list of endpoints (see Appendix B to Chapter 6).

Irradiated water/sediment study
(283/2013; 7.2.2.4)

7.2.2.4. Irradiated water/sediment study

The same general provisions as provided under point 7.2.2.3 apply.

Circumstances in which required

If photochemical degradation is of importance a water/sediment study under influence of a light/dark regime may additionally be provided.

Test conditions

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

Degradation in the saturated zone

(283/2013; 7.2.3.)

7.2.2.4. Irradiated water/sediment study

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

1.2.2 Data requirements for the product

Commission Regulation (EU) No 284/2013 mentions no data requirements for evaluation of the behaviour in sewage treatment plants.

1.3. Risk assessment

There is no international consensus on the available models within the EU.

In EU framework a broad judgement is made about the potential risk on the basis of research into the effect on an STP and into biodegradation. A detailed risk assessment, in which exposure is tested against toxicity, is not carried out.

However, The Netherlands have a specific model (USES 2.0) that will be used when The Netherlands acts as zRMS for a core dossier.

Please note that for non-professional use the dose rate in kg/ha is corrected to match a maximum acreage of 500 m².

1.3.1. Surface water and sediment

For substances that are discharged onto an STP, the removal of the substance in a sewage treatment plant is calculated by using the STP model Simpletreat in USES 2.0. The concentration in the effluent followed by a dilution factor gives the concentration in the surface water (output provided directly by USES). For calculation of concentration in the effluent see next paragraph.

For mushroom cultivation, an example calculation is presented in Appendix 3 of Chapter 7 Ecotoxicology; aquatic (in Dutch).

The calculated predicted environmental concentration (PEC) in surface water and sediment is used in the risk assessment for aquatic and sediment organisms.

1.3.2. Calculation exposure concentrations for discharge via a sewage treatment plant (STP)

For substances that are discharged to an STP, the removal of the substance in such an STP is calculated with the sewage treatment model Simpletreat in USES 2.0.

The concentration in the effluent is calculated on the basis of degradation data and

physical-chemical parameters. The disappearance of an (active) substance from the aqueous phase depends on its substance properties.

A specific model scenario in Simpletreat is used for mushroom growing, which also determines the concentration of a Plant Protection Product in the effluent. The calculation method for mushroom growing with examples is presented in Appendix 3 of Chapter 7 Ecotoxicology; aquatic.

Application models (e.g. for mushroom growing; see USES for these models) are used to calculate the exposure concentration in the influent of the STP. A risk estimate for the effects of Plant protection products on an STP is made with data about the effect on waste water treatment.

N.B. An application model for calculation of the concentrations in the influent of an STP is not available for all uses with potential emission via an STP. Currently, only the models for mushroom growing and for use on hard surfaces (pavements) and in amenity areas (public parks/gardens) are used. Dilution takes place because several companies/individuals are discharging waste water from other sources onto the same STP. This is at the moment not yet adequately incorporated into a model for the different relevant types of applications. Furthermore, other input parameters are not available or they are insufficiently reliable. It is therefore currently not possible to estimate the concentration in the effluent of an STP for all types of applications.

1.3.3. Calculation acute exposure concentration for emission via use on hard surfaces

This is a specific case with emission to STP instead of direct emission to an arable edge-of-field ditch. For the applications on hardened surfaces the concentrations for the diverse scenarios are calculated using the amenity use scenarios of USES 2.0. There are four scenarios available:

1. direct run-off to surface water
2. discharge through rain water flow (separate sewage system)
3. discharge through pour over (overflow of mixed sewage system)
4. discharge through STP (sewage treatment plant connected to a mixed sewage system).

The exposure concentration in surface water and sediment through Plant protection products on hard surfaces is calculated according to the method as included in USES. Any (obligatory) emission reducing technologies on the label (e.g., application according to the DOB² methodology) can be taken into account for the assessment.

1.4. Approval of the active substance

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

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

3. Criteria for the approval of an active substance

3.1. Dossier

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

² DOB: duurzaam onkruidbeheer (in english known as SWEEP - sustainable weed control on pavements). Defined run-off factors are 3.5 % for applications under DOB (this value is the 90-th percentile determined from field experiments with glyphosate). Default run-off factors for professional use without dob and non-professional use on hardened surfaces are set by Ctgb to a value of 10 %, based on consultation with experts from RIVM, Alterra and PRI. Run-off values are substance specific. however, in the absence of such data, these default values are used for all substances.

- (10) Substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment. In order to achieve the same level of protection in all Member States, the decision on acceptability or non-acceptability of such substances should be taken at Community level on the basis of harmonised criteria. These criteria should be applied for the first approval of an active substance under this Regulation. For active substances already approved, the criteria should be applied at the time of renewal or review of their approval.

1.4.1. Evaluation

No evaluation criteria have been laid down for the parameters that determine the concentration in the influent of an STP. The evaluation criteria for the effects in an STP have been laid down in the chapter Ecotoxicology; aquatic organisms.

1.4.2. Decision making

The decision making criteria for the effects in an STP and effects on aquatic organisms have been elaborated in chapter 7 Ecotoxicology; aquatic organisms.

1.5. Developments

The currently applied methodology for mushroom growing can probably also be applied for other cultures such as chicory forcing and pre-treatment of cut flowers. This is not yet elaborated.

2. APPENDICES

None

3. REFERENCES

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Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment
(The EFSA Journal (2006) 437, 1-30)

- 13 ISO 18749 Water quality – Adsorption of substances in activated sludge –
Batch test using specific analytical methods