Evaluation Manual for the Authorisation of plant protection products 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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ctgb

**Board
for the Authorisation
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

Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 6 Behaviour in surface water, sediment and sewage treatment			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014	-	-
2.1	October 2016	Part I	Addition of the risk assessment framework for protected crops
		Part II	Links to spreadsheets for emission via STP based on USES 2.0, and link to working instructions regarding emission via STP have been added.
2.2	January 2018	Paragraph 1.3.7, page 10	Instructions for modelling the exposure to surface water and sediment of mushroom cultivation have been incorporated in the Evaluation Manual
2.3	February 2019	Paragraph 1.3.2.1 and 1.3.9	New version of the working document included
2.4	January 2020	I.1 and II.1	Sentence included on the administrative EFSA guidance
2.5	September 2023	1.3.4, page 9 and 10	Footnote added concerning the interim approach of selecting the date of application in GEM, for soil-bound and for soilless cultivation

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.

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.

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

1.1. Introduction

This chapter describes the procedure to determine estimated or measured concentrations in surface water and sediment following normal agricultural applications (outdoor and greenhouses). 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 from BBA (2000) (1) are used in EU framework. These tables are included in the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA, 2013).

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

1.2. Data requirements

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

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 7.5 (monitoring data).

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 and sediment).

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

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

1.3. Risk assessment

1.3.1. General

Central question in the *EU approval procedure of active substances* is whether safe scenarios exist in Europe. The answer to this question indicates whether a so-called safe use of a substance exists somewhere in Europe. The question whether a use can be permitted throughout whole Europe is not relevant for the approval of an active substance. For the *zonal applications of plant protection products* a safe use needs to be demonstrated for every use of the product for which the applicant seeks authorisation.

A surface water assessment needs to be performed for all components (active substance, metabolites, breakdown and reaction products) that were identified under point 7.2 (fate and behaviour in water) of part A of Commission Regulation (EU) No 283/2013.

The most important substance-related parameters for model estimation of the PEC in surface water and sediment are:

- $DegT_{50}$ for degradation rate in soil at 20°C (days),
- $DegT_{50}$ for degradation rate in water at 20°C (days),
- $DegT_{50}$ 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).

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

For the application of degradation parameters, in particular standardisation for temperature, we refer to the FOCUS Generic Guidance for estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration (version 1.1, 2014). 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)

- Mitigation measures

The PEC is calculated with the appropriate FOCUS Surface Water model for applications in the form of crop or seed treatment (refer to Generic Guidance for FOCUS surface water scenarios, version 1.4).

For PEC calculations for applications for rice growing, the relevant Guidance document on rice should be used (refer to Guidance Document for Environmental Risk Assessments of Active Substances Used on Rice in the EU for Annex I Inclusion.- Final Report of the Working Group "Med-Rice" prepared for the European Commission in the framework of Council Directive 91/414/EEC, SANCO/1090/2000 - rev.1 June 2003).

No European evaluation methodology has been developed for other applications, such as application on hardened 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.

1.3.2. Estimation exposure concentrations for field uses with FOCUS Surface water

1.3.2.1. 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 with corresponding distances for each crop group to the nearest surface water, as included in the Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA, 2013).

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, when relevant. 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 in SWASH 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, comparable to Step 2. 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. SWASH is linked to SPIN, a pesticide properties tool.
- 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 Guidance document Landscape and Mitigation factors in aquatic ecological risk assessment, EC Document Reference SANCO/10422/2005, version 2.0. This Guidance document should be read and interpreted in context of the Opinion of the Scientific Panel on Plant protection products and their residues regarding the Final Report of the Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment (2007). The relevant model for Step 4 calculations, on top of the available models regarding Step 3, is SWAN.

For zonal fate assessments a working document, taken note in the Central Zone Steering Committee, exists which indicates for which member states which scenarios are considered relevant, and to what extent mitigation using STEP 4 is accepted. A new version 1.1 June 2018 of the working document is available on the public part of the European database CircaBC and has to be used per December 1st 2018.

1.3.2.2. 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.

From the 3.1 model version of Steps 1-2 in FOCUS, metabolites are formed from the active substance that enters the water body from the soil column. Regarding STEP 3, TOXSWA model version 4.4.3 makes it possible to simulation the formation of metabolites in water and sediment. This version (or later versions) should be used for metabolites that require a STEP 3 exposure assessment.

Detailed guidance on how to calculate metabolite concentrations is given in the Generic Guidance for FOCUS surface water scenarios, version 1.4 (applicable from May 2015 onwards).

1.3.3. Estimation exposure concentration with MED-RICE

Exposure calculations for rice growing must be carried out under the Guidance Document for Environmental Risk Assessments of Active Substances Used on Rice in the EU for Annex I Inclusion - Final Report of the Working Group "Med-Rice" prepared for the European Commission in the framework of Council Directive 91/414/EEC, SANCO/1090/2000 - rev.1 June 2003. In the Guidance document, a tiered approach is suggested similar to PEC calculations regarding spray applications and seed treatment (please refer to section 1.3.2). The Guidance document provides information regarding models that may be used for PEC calculations. This may occasionally be relevant for active substance approval dossiers. For zonal dossiers this is not relevant for the central zone.

1.3.4. Estimation exposure concentrations for protected crops

For protected crops the EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments *EFSA Journal,* 2014, **12**, 3 should be followed.

In the guidance document a sub-division between non-permanent covers, walk-in tunnels, greenhouses and closed buildings is made, each with a different (tiered) exposure assessment.

Non-permanent covers
Use under non-permanent covers is assessed as field use. See field uses.

Walk-in tunnels
Walk-in tunnels are to be assessed via the EU field methodology (1.3.2), with the difference that in FOCUS Step 3 only the drainage scenarios are relevant. Please note that FOCUS Step 4 is not applicable.

Greenhouse uses
For the estimation of exposure to surface water resulting from greenhouse uses the model GEM is developed. The GD mentions two example scenarios: “soil bound chrysanthemum in the Netherlands” and “non-soil bound rose in the Netherlands”, both available in GEM .

Soil-bound uses (see also Wipfler et al., WUR-Alterra report 2388, 2014)[1]
The guidance on protected crops states that the models generally used to calculate leaching and drainage from open-field cultivation can equally well be used to calculate leaching and drainage from walk-in tunnels and greenhouses *if appropriate scenarios are available*. […]

Appropriate scenarios are to be established/selected by the notifier and the selection and parameterisation is to be justified, until methodology and scenarios are established and approved by competent bodies. Currently there are no such models available and only example scenarios have been presented in the guidance.

As a first tier the walk-in tunnel assessment can be applied, i.e. up to FOCUS Step 3 Drainage scenarios, as proposed in the EFSA Guidance Document Appendix D. In the second tier the chrysanthemum scenario available in GEM could be used (as indicated in Table 1 of the Guidance Document), using conservative input parameters.

The most important substance-related input parameters of the GEM model are:

- First tier: Longest hydrolysis DT50 for degradation rate in water at 20°C within the greenhouse (days), refinement possible in higher tier (e.g., OECD 309, outdoor mesocosms)
- Geometric mean DT50 for degradation rate in soil at 20°C (days).
- Geometric mean DT50 for degradation rate in surface water at 20°C (days)
- Geometric mean DT50 for degradation rate in sediment at 20°C (days)

[1] It has been established that the PEC values simulated by the GEM scenarios are very sensitive to the application date. On the basis of the outcome of a sensitivity analysis, the following interim approach concerning the selection of the date-of-use is appropriate for the soil-bound surface water scenarios: Include the 30th of May (which is the worst-case date-of-use, based on a number of test calculations with two different substances) in the use schedule and include an additional safety factor of 2 on the resulting PEC value. If the GAP contains multiple applications (for example 4 applications with an interval of 7 days), then May 30 must be set as the last date-of-use. If the 30th of May does not fall within the application period of the GAP, applicants should still use this date. If an acceptable risk cannot be demonstrated based on the outcome with the proposed date of the 30th of May and the safety factor of 2, applicants can refine the assessment by submitting an evaluation for all relevant dates-of-use within the GAP period. In that case, the safety factor of 2 can be omitted.

- Arithmetic mean K_{om} and corresponding arithmetic mean 1/n for suspended organic matter (L/kg) (if not available use K_{om} soil)
- Arithmetic mean K_{om} and corresponding arithmetic mean 1/n for sediment (L/kg) (if not available use K_{om} soil)
- Saturated vapour pressure (Pa) usually available at 20 or 25 °C
- Solubility in water (mg/L) usually available at 20 or 25 °C
- Molecular mass (g/mol)

Non-soil bound uses (see also Van der Linden et al, RIVM report 607407005, 2015)[2]
For soilless cultivation a simple tiered approach is described in the guidance document (Appendix D). For drip irrigation, two simple calculation methods are provided as a conservative approach. For spray applications it is suggested to take into account the amount of condensation water as a total dose per season applied at once (step 1).

The model GEM with the soil-less scenario in rose is given as highest tier in the EFSA Guidance Document. For the Netherlands several non-soil bound scenarios were developed in addition to the rose scenario. As with the example scenarios described in the EFSA Guidance Document, the applicant should justify the representativeness of the scenario for the use applied for in the member states where authorisation is sought

Depending on the applied for use the most appropriate scenario needs to be used.
As various application methods can be used in a greenhouse several substance fate models are available within GEM:
Model A: application by drip irrigation/in nutrient solution.
Model B: spray/fog application to crop grown on shielded slabs (drip irrigation system)
Model C: spray/fog application to crops grown in pots in an ebb/flow system.

The most important substance-related input parameters of the substrate model are:

- The equilibrium sorption coefficient K_{OM} (L kg-1) to substrate (specific for pot plants). In case no specific information is available it is suggested to use the sorption coefficient for soil here.
- Half-life in recirculation water (d) and the temperature at which it was measured. In case no specific information is available it is suggested to use the DegT50 for hydrolysis.
- Molar activation energy (kJ mol-1) for the degradation in recirculation water. It is suggested to use a molar activation energy of 75 kJ mol-1.
- Half-life in the disinfection tank (d) and the temperature at which it was measured. In case no specific information is available it is suggested to use the DegT50 for hydrolysis.
- Half-life on the greenhouse floor (d). In case no specific information is available it is suggested to use 100 d.
- Half-life in substrate (d). In case no specific information is available it is suggested to use the DegT50 for degradation in soil.
- Geometric mean DT50 for degradation rate in surface water at 20°C (days)
- Geometric mean DT50 for degradation rate in sediment at 20°C (days)

[2] It has been established that the PEC values simulated by the GEM scenarios are very sensitive to the application date. On the basis of the outcome of a sensitivity analysis, the following interim approach concerning the selection of the date-of-use is appropriate for the soilless surface water scenarios: Create 12 simulations (or fewer, depending on the application period of use within the GAP) with the date-of-use set to the 15th of each month; Next, two additional simulations should be performed for the month that results in the highest PEC: a simulation with application starting one week before and one week after the 15th of that particular month. The following information should be reported: highest PEC value, to be used for the risk assessment, application dates used in the simulations and application date resulting in the highest PEC value. Note that a different date may apply to metabolites.

- Half-life in greenhouse air (d) and the temperature at which it was measured. It is suggested to use the half-life in air here, when available, otherwise a half-life of 100 d could be used.
- Molar activation energy (kJ mol-1) for the degradation in greenhouse air. It is suggested to use a molar activation energy in air of 45 kJ mol-1.

If water is discharged from the cultivation system via a water purification system (e.g. active carbon filter, UV or ozone treatment system), the user can specify the removal efficiency of the system by pressing the ‘Mitigation’ button and entering the removal fraction. The reduction is applied to both discharge of recirculation water as well as filter cleaning water.

Closed buildings
For applications in closed buildings, emission to surface water is not assessed on an EU level since there is no established methodology. However in the past in several substance dossiers alternative methodologies were used. See 1.3.5-1.3.6. These may also be applicable for zonal dossiers. Please note that when indoor treated crops or seeds are subsequently planted or sown in the field or in protected structures, an exposure assessment relevant for that situation should be performed.

1.3.5. 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 hardened surfaces, application in mushroom growing and other relevant uses will be calculated as described under point 2.3.2.

1.3.6. Estimation exposure concentration resulting from direct exposure through application on hardened 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 hardened surfaces will be calculated as described under point 2.3.2.

1.3.7. PEC calculations in case of indoor mushroom cultivation

Indoor mushroom cultivation can be among the proposed uses of a plant protection product. No EU agreed exposure assessment methodology for indoor uses exists. In Regulation 1107/2009 it is stated: For the purpose of this Regulation, closed places of plant production where the outer shell is not translucent (for example, for production of mushrooms or witloof) are also considered as greenhouses. It cannot be excluded that direct or indirect emissions to various compartments will occur. In the absence of an agreed methodology Ctgb makes use of the following approach.

Surface water
Two scenarios can be distinguished regarding the emission from facilities relevant for mushroom cultivation to surface water and STP:

I) direct emission to large water bodies, and
II) indirect emission via a sewage treatment plant
III) emission after processing waste water in an IBA (Individuele Behandeling van Afvalwater) or IPPC (Integrated Pollution Prevention and Control) installation

The first 2 scenarios are described below; regarding scenario 3, information should be provided with the submission of a dossier.

Elaboration on the calculation method for mushroom growing with examples is presented in the EU part of the Evaluation Manual of the Board for Authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009 by Ctgb, Appendix 2 of Chapter 7 Ecotoxicology; aquatic (version 2.0; January 2014). Please note that additional guidance regarding the risk evaluation of mushroom cultivation is provided in Appendix 3 of Chapter 7 (Aquatic) Ecotoxicology of HTB 1.0 (in Dutch).

I) *Direct emission to large water bodies*
PEC_{sw} (µg/L) = 78 * D (direct emission via settlement tank to surface water)
D = application rate [kg/ha]

The formula is based on the following input parameters and rationale:

input values/parameters:
substance: X
application rate: D kg/ha
application: per event 1 cell of 200 m2
emission percentage: maximum 3,5% per day
sewage water discharge: Q = 1,5 m3/day per facility (1.000 m2)
efficiency settlement tank: 50%
receiving surface water: standard NL ditch
i.e. semi-stagnant
dilution factor 3

calculation of initial PEC (t=0) is based on next steps/assumptions:
a) applied amount per company/cell (200 m2): 0,02*D
b) emission to raw sewage water: 0.035 * amount applied
c) concentration in raw sewage water: emission/daily discharge
d) concentration in sewage water after settlement: 0.5 * concentration in raw sewage water
e) concentration in receiving surface : concentration in sewage water after settlement /dilution factor of 3

in short:

$$PECsw\ (\mu g/L) = \frac{0.02 \times 0.035 \times 0.5 \times D \times 10E06}{1.5 \times 3} = 78\ \times D$$

II) *Indirect emission via a sewage treatment plant*
PEC_{STP} (µg/L) = 51 * D (concentration in influent STP)
PEC_{sw} (µg/L) = 0.51 * D * ((100-R) / 100 (in the receiving waterbody after passing the STP)
D = application rate [kg/ha]
R = removal fraction (concentration in receiving surface water). When there is no data on the removal of the active substance in a STP, this fraction is set to 0.

The formula is based on the following input parameters and rationale:

input values/parameters:
substance: X
application rate: D kg/ha
application: per event 1 cell of 200 m2
emission percentage: maximum 3,5% per day
sewage water discharge: Q = 1,5 m3/day per facility (1.000 m2)

efficiency settlement tank: 50%
standard STP properties ‘Maasdriel’: 13.700 i.e. and a daily water discharge of 2.000 m3/day
area of companies in the relevant area: 127.000 m2
degree of purification in area: 100% of companies has settlement tank
assumption that only half of companies emits at same time (correction factor 0.5)
efficiency of removal in STP: R= 0, 25, 50 or 75% depending on the Simpletreat calculation for the receiving surface water: Meuse, dilution factor of 100

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

a) amount applied in area:12,7 * D
b) emission in sewage water: 0,035 * 0.5 * 0,5 * applied amount
(after settlement and assuming emission by half of the companies at the same time)
c) concentration in influent STP: emission/daily discharge
NB this gives the PECeff for STP organisms
d) concentration in receiving surface water: influent / (purification efficiency* dilution factor 100)
NB this gives the PECsw for short-term/initial exposure for water and sediment organisms as a consequence of effluent discharge from the STP

in short

$$PEC - STP\ (\mu g/L) = \frac{12.7 \times 0.035 \times 0.5 \times 0.5D \times 10E06}{2000 + Q \times 127000/1000} = 51\ \times D$$

$$PECsw\ (\mu g/L) = \frac{12.7 \times 0.035 \times 0.5 \times 0.5D \times 10E6 \times (100 - R/100)}{(2000 + 190) \times 100} = 0.52\ \times D((100 - R)/100$$

III) *emission after processing waste water in an IBA (Individuele Behandeling van Afvalwater) or IPPC (Integrated Pollution Prevention and Control) installation*

Information regarding factors affecting the final PECsw such as removal efficiency, dilution factor and dimensions of the receiving water body to be provided by applicant with the submission of the (zonal) dossier.

Sediment
Calculations of PECsediment (if required) are performed using a ratio derived from TOXSWA for field uses within the same dossier as an approximation (if multiple uses provide different ratio’s then the ratio leading to the highest PECsediment can be chosen). This extrapolation procedure should always be described in the assessment.

1.3.8. 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. 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.

1.3.9. Agreements Central Zone Steering Committee

On the public part of CircaBC agreements of the central zone steering committee are presented. Applicants are advised to check the actual agreements when preparing a zonal dossier.

Currently the following agreements are included:

Meeting CZSC March 2014:
The use of the Q10 value in zonal dossiers of plant protection products was discussed. Conclusion of the discussion was that the Q10 value is regarded as a substance specific parameter (independent whether it is measured or defined by a default value), which is agreed upon in the approval of the active substance. In line with the Guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8), this value should also be used in plant protection dossiers following approval of an active substance. This means that for active substances for which a Q10 value of 2.2 was used in the DAR, the same value must be used in zonal dossiers of plant protection products. Only if the use if a normalisation of the soil degradation endpoints based on the new Q10 value of 2.58 results in a more favourable endpoint and is necessary to demonstrate a safe use, can this new active substance data be accepted in a zonal dossier. If no Q10 value was agreed on during approval of the active substance (e.g. no FOCUS modelling available at that time), the new Q10 value of 2.58 should be used for pragmatic reasons.

Meeting CZSC May 2014:
It was discussed whether kinetic evaluations are product data or active substance data (see bullet points of the meeting on CIRCABC). All Member States agreed that kinetic evaluations concern active substance data since the endpoints from active substance studies (concerning degradation rate) are re-evaluated yielding new active substance endpoints. Therefore kinetic evaluations need to be dealt with according to the Guidance document on the evaluation of new active substance data post approval (SANCO/10328/2004– rev 8). This means that only when a kinetic evaluation results in a more favourable endpoint and is necessary to demonstrate a safe use, this new active substance data be accepted in a zonal dossier.

Meeting CZSC January 2016:
In November 2014 a meeting of FATE-experts from regulatory authorities of the Central Zone was held in Vienna, targeted at harmonisation of the fate assessment of a Central Zone core assessment. After the meeting a working document was prepared describing the procedure for the assessment of environmental fate and behaviour of applications for authorisation and re-authorisation of plant protection products in the Central zone. The final version of the working document was agreed upon by the CZSC with an implementation date of July 1st 2016. The working document has been placed on the public part of CIRCABC and has the full title: Working document of the Central Zone in the Authorisation of Plant Protection Products, Section 5, Environmental Fate and Behaviour.

Meanwhile, the working document has been slightly revised. This new version 1.1 is placed on the public part of CIRCABC and has the full title: Working document of the Central Zone in the Authorisation of Plant Protection Products, Section 8, Environmental Fate and Behaviour . This version should be used from December 2018 onwards.

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.
Point 4 of Annex II of Regulation (EC) No 1107/2009 gives criteria for substitution. In the chapter "Generic aspects" of the Evaluation Manual 2.1, section 4, 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. In the chapter "Generic aspects" of the Evaluation Manual 2.1, section 5, 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 (Uniform Principles) Part I section B. 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 also are presented in Commission Regulation (EU) No 546/2011.

1.4.3. Decision making for plant protection products

The principles for decision making on the authorisation of plant protection products are presented in Commission Regulation (EU) No 546/2011 Part 1 section C. The specific principles Environmental effects, part Behaviour and distribution in the environment as regards behaviour in water also are described in Commission Regulation (EU) No 546/2011.

1.5 Developments

- Emission via dust drift. At the moment EU guidance is being developed with regard to the risk assessment of treated seeds. A new round of commenting by the Member States of the document is expected in 2017 (take note date and entry into force date yet unknown).
- Revision Focus Surface water scenarios (finalisation date unknown)

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.

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

1.1. Introduction

This chapter 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 hardened 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.

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. This chapter only describes the behavioural aspects. The effects on biological methods for sewage treatment have been elaborated in the chapter 7 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 hardened 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
- potato processing industry (no specific scenario available, generic scenario used)
- indoor treatment of cut flowers after cutting

Excel-sheets were developed by Ctgb containing the relevant scenarios from USES (2.0), which could be used for determining PEC calculations in a STP.

Furthermore, several working instructions have been developed for specific applications have that require an STP assessment, but are not included in USES (2.0) with a specific scenario. Both the Excel-sheets and working instructions are available at the Ctgb-website.

1.2. Data requirements

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

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

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

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.

1.3. Risk assessment

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

In EU framework no detailed assessment is made into the potential risk on the basis of research into the effect on an STP and into biodegradation. However, The Netherlands have a specific model (USES 2.0) that will be used when The Netherlands acts as zRMS for a core dossier. Not for all uses with potential emission via an STP application models are available however.

The applicability of the use of the Ctgb Excel-spreadsheets for other Member States should be justified on a case-by-case basis.

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.

Excel-sheets were developed by Ctgb containing the relevant scenarios from USES (2.0), which could be used for determining PEC calculations in a STP (e.g.: indoor application cut flowers after cutting, run-off from hardened surfaces, exposure of PPP by the potato processing industry). The Excel-sheets are available at the Ctgb-website. Furthermore, also at the Ctgb-website, a work instruction is available regarding mushroom cultivation.

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.

Application models (e.g. related to the exposure of PPP by the potato processing industry, see USES for these models) are used to calculate the exposure concentration in the influent of the STP. Excel-sheets have been developed containing the relevant scenarios from USES (2.0) and are available at the Ctgb-website.

A specific methodology regarding exposure related to mushroom cultivation is presented at the CTGB-website.

1.3.3. Calculation acute exposure concentration for emission via use on hardened 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 hardened surfaces is calculated according to the method as included in USES. Any emission reducing technologies (e.g. concerning the run-off percentages) 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.

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. This is not yet elaborated.

2. REFERENCES

1 BBA, 2000: Bekanntmachung über die Abdrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. (8. Mai 2000) in: Bundesanzeiger No.100, amtlicher Teil, vom 25. Mai 2000, S. 9879.