

Technical Agreements for Biocides Environment (ENV)

October 2022

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Preface

The Technical Agreements for Biocides (TAB) collects the general agreements of the Working Groups (WG) that are not yet included in any other BPR related guidance. These WG agreements are not the official view of ECHA, nor are they legally binding.

The TAB can be found in the public S-CIRCABC Interest Group¹ but is also accessible to public via a link on the ECHA website.

Starting from October 2020, version numbers will be assigned to single TAB entries and no longer to the TAB document as a whole. Starting point (i.e. "version 1") are entries as noted in the latest TAB document, published in December 2019. Changes to these entries made after December 2019 will be implemented in the form of a new entry with the same reference number but a higher version number. Where - due to different timelines for applicability of entries for active substances and products - more than one version of the same entry is applicable, all applicable versions will be displayed. Expired entries are moved to the section "Expired TAB entries" at the end of the document.

In addition, the applicability of TAB entries will be shown per entry, which depends on the type of entry. Publication (i.e. reference) date and applicability dates are given as presented in Table 1 below. For more information on rules regarding applicability of guidance and TAB entries see BPC-31 document "Applicability time of new guidance and guidance-related documents in active substance approval", CG document Doc. no. CG-33-2019-07 and CA document CA-July12-Doc.6.2d (see footnotes 2, 3, and 4).

¹ <u>https://webgate.ec.europa.eu/s-circabc/w/browse/65ed457b-535f-41e5-a559-aa8b168d1558</u>

Applicability of the TAB entry		f the TAB entry
Type of entry in the TAB	(A) for active substance approval	(B) for product authorisation
a) Editorial changes of the existing guidance	As of the reference date	As of the reference date ²
b) Clarification/interpretation of the existing guidance (clarification /explanation)	As of the reference date	As of the reference date ²
c) New guidance as new technical scientific advice is given which triggers new data requirements	six months after the reference date ³	2 years after the reference date ⁴
d) New guidance as new or updated technical scientific advice is given in order to have a harmonised approach on how the assessment should be done (without new data requirements)	six months after the reference date ³	2 years after the reference date ⁴
 e) New guidance not triggering new data requirements where: no guidance was available at all for a certain issue new guidance is correcting major mistakes of former guidance new guidance is considerably more reliable than former guidance. 	As of the reference date ³	Not defined by any CG/CA/BPC document, therefore same deadline as for d)

Table 1 Type of TAB entries and applicability dates

² CG document Doc. no. CG-33-2019-07, Date of applicability of: A) Technical Agreements of Biocides (TAB) entries and B) Conclusions of the Working Groups on the technical questions referred from CG https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/00cafca0-81f6-44c2-8aaf-05cb1cbcff93/CG-33-2019-07%20AP%2014.3%20Date%20of%20applicability TAB%20entries CG%20quest rev1.pdf

³ Applicability time of new guidance and guidance-related documents in active substance approval, BPC-31, <u>https://echa.europa.eu/documents/10162/4221979/applicability_guidance_jan_16_en.pdf/0b9c0634-eb54-4805-8b5e-b95f09a05632</u>

⁴ CA document CA-July12-Doc.6.2d, Relevance of new guidance becoming available during the process of authorisation and mutual recognition of authorisations of biocidal products, <u>https://echa.europa.eu/documents/10162/23036409/ca-july12-doc 6 2d final en.pdf</u>

Procedure

TAB is a living document that will be updated over time. Any suggestions on the need to change the content can be sent at any time to <u>BPC-WGs@echa.europa.eu</u>.

Proposals to include, revise or delete entries will be open for commenting by the WG members in the frame of the commenting of general minutes of each WG meeting, to which TAB entries are added in an Annex. After the commenting period, ECHA will revise the TAB if necessary, and publish it on the ECHA website.

The procedure does not involve re-discussions at the WG. However, the TAB entry may be discussed at the WG if necessary.

1 Effect and Hazard Assessment

ENV 1 Are additional studies with plants required for the evaluation of the active substance if the information available from the DAR submitted under the pesticides EU framework (Directive 91/414/EEC/Regulation EC 1107/2009) indicates that plants are not the most sensitive taxonomic group?

Version 1 (TM IV 2007)

If information submitted under the pesticides EU framework indicates that plants are not the most sensitive taxonomic group, there is no need to require a new study with plants for the evaluation of the active substance.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV 2 Should both the experimentally derived and estimated BCF value be included in the CAR?

Version 1 (TM IV 2008)

Both, the estimated (applying QSARs recommended in the TGD) and the experimental results for the BCF values should be presented in the CAR.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV 3 How to perform effects assessment and PNEC derivation for metabolites when no experimental data is available on the ecotoxicity of the metabolite, and instead, the toxicity is estimated by using QSAR or read-across?

Version 1 (WG-I-2016, WG-II-2016)

In the absence of experimental data, the ecotoxicity of relevant metabolite could possibly be estimated with QSAR analysis and/or read-across. Only QSARs valid for the molecular structure of the metabolite should be used. Based on the results of the QSAR estimation or read-across, the following could be concluded:

- The available QSAR and/or data for read across do not allow for reliable determination of ecotoxicity endpoints for the metabolite. Experimental data on ecotoxicity should be generated for the metabolite(s) under investigation
- The ecotoxicity of the metabolite is equal to the ecotoxicity of the parent compound and the PNEC of the parent substance can be used as an estimate for the PNEC of the metabolite.
- The metabolite is more toxic than the parent compound by a factor of x (eg. 5 or 10). The PNEC of the metabolite can be derived from the available data on the parent substance by applying the corresponding factor to the PNEC of the parent.
- The metabolite is less toxic than the parent compound, and it can be assumed that the PNEC for metabolites is covered by the PNEC of the parent substance.

Based on the substance properties, the different options for the evaluation should be considered according to the guidance provided in BPR IV B v.1.0 Section 3.10 (Effect assessment for rapidly degrading substances). For further guidance on the use of QSARs and read-across consult REACH Guidance R.6: QSARs and grouping of chemicals

(https://echa.europa.eu/documents/10162/13632/information_requirements _r6_en.pdf/77f49f81-b76d-40ab-8513-4f3a533b6ac9).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV 4 Which active substance constituents should be considered in the PBT assessment and risk assessment (including constituents of plant extract material or other UVCB substance)?

Version 1 (WG-IV-2016)

A PBT assessment should be conducted for each constituent occurring in the active substance in a concentration $\geq 0.1\%$ (w/w), in accordance with REACH R.11 guidance.

A risk assessment should be conducted for each constituent occurring in the active substance in a concentration $\geq 5\%$ (w/w). This trigger is based on the lower trigger value for relevant metabolites.

A risk assessment should be performed for each constituent occurring in the active substance in a concentration <5% (w/w), when the PBT assessment at screening level following the R.11 guidance, shows that this constituent fulfils at least two of the three PBT criteria.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Setting PNECs when experimental data is available

242 New!

Version 1 (WG-II-2022)

During the active substance (AS) evaluation, effect endpoints of experimental ecotoxicological data are assessed. It should be determined whether these endpoints refer to pure AS concentrations or to concentrations of AS as manufactured. When during the conduct of such studies the AS is measured in the respective media (e.g. water or soil), the pure AS is identified and quantified. Consequently, the effect endpoints and the PNECs should be expressed in pure AS concentrations.

The Assessment Report should specify for the PNECs whether they are based on pure AS or based on AS as manufactured.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENV Warning sentence for bees

Νοωι

244

Version 1 (WG-II-2022)

A warning sentence should be applied for all biocidal products used outdoor under PT18, PT19 and PT08 containing an active substance used as an insecticide, acaricide or product to control other arthropods which is found to be below the toxicity threshold. In the case of PT8 products the warning sentence will only be used for products applied in-situ outdoor and not to treated wood.

The warning sentence should apply regardless of the concentration of the active substance in the product.

The already agreed upon warning sentence is:

"This biocidal product contains (active substance name) which is dangerous to bees".

An active substance would be found to be below the toxicity threshold if a standard contact or oral acute LD50 datapoint on adult honeybees, bumble bees or solitary bees exists for that substance and is below 11 ug/bee (OECD 213 and 214, for instance). In case there are more than one datapoints available, the one showing the lowest LD50 should be considered. Information that has been submitted for the same substance for other regulatory frameworks (e.g. PPP) can also be used.

Literature data on acute endpoints can also be used to compare with the threshold if the studies are reliable and relevant.

It is stated in the CA document that "In order to avoid applying a disproportionate measure, the warning sentence should only be required for products containing active substances for which scientific evidence exists in regards to their hazard (intrinsic) properties to bees", therefore in the absence of studies performed according to standard guidelines and/or reliable and relevant literature data demonstrating that the substance is below the toxicity threshold, no scientific evidence exists which could enable an assessment of hazard properties to bees.

In this respect the WG would like to note that current guidance (Guidance on BPR, volume IV part A) notes the following: "test on bees and/or other beneficial arthropods may be required for insecticides, acaricides and substances in products to control other arthropods which are used outdoors". Therefore, as depicted in Table 5 data is missing for many active substances used in PT 8, 18 and 19 which may be currently authorised and used outdoors. Until further data becomes available, the hazard properties for bees of these substances cannot be assessed.

This proposal applies in the absence of the Biocides Pollinator Guideline and shall be revised accordingly once the guideline becomes available.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

2 Exposure assessment

2.1 Exposure assessment - general items

ENV 5 Can the persistence categories in soil from the PPP be used in the CAR?

Version 1 (TM III 2005)

The PPP categories on the categorisation of persistence in soil shall not be used in the CAR, neither other categories, for example on mobility.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV 6 Calculation of PEC in sediment – consideration of suspended matter

Version 1 (WG-IV-2015)

It was agreed at WG-IV-2015 that the adsorption to suspended matter should be considered when calculating the PEC value for sediment based on the PEC_{surface-water} also for strong adsorbing substances and metals.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV 7 Aggregated exposure assessment

Version 1 (WG-III-2014, WG-III-2016)

A quantitative aggregated exposure assessment should be performed covering all relevant PTs with identical emission routes at the approval stage of the active substance. The focus should be on uses with release via the STP. Both a tonnage and consumption-based approach should be performed. The most critical one is leading the conclusions.

At WG-III-2016 it was further specified that always as a first step, an evaluation on the need to conduct an aggregated exposure assessment should be performed (and reflected in the CAR), based on the decision tree available in the CAR template.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV 8 Can a PEC/PNEC>1 be accepted as long as the corresponding PEC value is within the natural background concentration for a specific substance?

Version 1 (WG-V-2016)

The WG agreed that the decision should be made case by case as it depends on the type of substance and the type of use. In general, the decision should be well explained, and the recommendation provided in the CAR should be followed for the product authorisation.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV 9 Use of the model SimpleTreat 4.0 for biocides

Version 1 (WG-I-2016, AHEE-1, WG-I-2017)

Which version of SimpleTreat should be used to calculate the fate of a chemical in the STP?

For active substance CARs submitted to ECHA (and consecutive product authorisation after approval of the active substance), SimpleTreat 4.0 shall be

applied at the latest six months after the decision at WG-I-2017 (25-07-2017). For product authorisation SimpleTreat 4.0 shall be applied 2 years after the WG-conclusion (25-01-2019).

Should degradation rates be temperature corrected?

When using the default values for degradation rates for the STP (guidance BPR IV B v.1.0, Table 6) depending on biodegradability (outcomes of ready and inherent biodegradability tests), no temperature correction should be performed. However if results from other degradation tests are used as input parameter (e.g. OECD 303 or OECD 314), the degradation rate should be corrected to the environmental standard temperature (288.15K) of the STP by Simple Treat.

What are the default operational parameters for SimpleTreat 4.0?

For the environmental risk assessment of biocides the operational mode of the STP has to be set to "municipal". The default operational parameters are a BOD-load per person of 60 g/person/d in raw sewage, a sludge loading rate (SLR) of 0.1 kg BOD/kg MLSS/d and a concentration of suspended solids (Css) in the effluent of 30 mg/L. The values for BOD and SLR are integrated as default values in SimpleTreat 4.0. The value for Css needs to be changed manually by the user to 30 mg/L in the "Mode of operation"-tab of SimpleTreat 4.0. The other default operational parameters for a municipal STP should not be changed.

How to transfer SimpleTreat 4.0 output to EUSES?

Until SimpleTreat 4.0 will be integrated in EUSES, a workaround is required in order to transfer the results of SimpleTreat 4.0 to EUSES. Details are provided in the background document to this TAB entry, in which section 1.3 describes the steps to be followed for the transfer.

The background document is provided in the CIRCABC TAB repository (entry "ENV009..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVExposure assessment for metabolites in the terrestrial compartment –10indirect exposure via sewage sludge and exposure via manure/slurry

Version 2 (AHEE-2)

The document on the exposure assessment for metabolites in the terrestrial compartment was extended by including next to the indirect release via sewage sludge also the release path via manure/slurry application.

The background document is provided in the CIRCABC TAB repository (entry "ENV010v2..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	02/08/2019
Date of applicability for active substances:	02/08/2019
Date of applicability for products:	02/08/2021

ENVExposure assessment of metabolites in the terrestrial compartment –10indirect exposure via sewage sludge

Version 1 (AHEE-1, WG-V-2016, WG-III-2017)

According to the BPR guidance on Volume IV. Part A - Information Requirements (v 1.1, Chapter 1.6) in general, an environmental risk assessment for the relevant compartments needs to be performed for all major metabolites. A quantitative assessment should be performed on a case-by-case basis. In the background document to this entry the quantitative risk assessment of relevant metabolites in the terrestrial compartments for indirect exposure via sewage sludge application is harmonizing, including groundwater refinement with FOCUS PEARL.

The background document is provided in the CIRCABC TAB repository (entry "ENV010..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

e) New guidance, immediately applicable

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVSURPLUSsludge considering concentration of suspended solids in239effluent of 30 mg L-1 in SimpleTreat 4.0

New!

Version 1 (WG-IV-2021)

The default value for SURPLUSsludge of 0.019 (kg eq-1 d-1) as given in Biocides Guidance Volume IV Part B+C, 2017 (Table 7) is outdated. It refers to SimpleTreat 3.1 with the corresponding parameter settings for BOD, sludge loading rate (k_{SLR}) and suspended solids concentration in the effluent (C_{SO, SLS}) and other parameters that are dependent on these three, that are used to calculate SURPLUSsludge. However, the use of SimpleTreat 4.0 has been agreed by the WG ENV and this version is integrated in EUSES 2.2.0. SimpleTreat 4.0 has different values for BOD and k_{SLR} by default (compared to SimpleTreat 3.1) while after WG ENV agreement the former default value for $C_{SO, SLS}$ is kept at 30 mg L-1 (ref. TAB ENV 9). The corresponding value for SURPLUSsludge is now 0.0212 (kg eq-1 d-1). Assessors should take care to use the SURPLUSsludge value of 0.0212 (kg eq-1 d-1) when estimating the concentration in dry sewage sludge (Csludge) outside of SimpleTreat 4 or EUSES 2.2.2. Csludge is required to calculate PECsoil via STP sludge application on soil. Both SimpleTreat 4 and EUSES 2.2.0 calculate the value for SURPLUSsludge automatically when the concentration of suspended solids in the effluent is set to 30 mg L-1.

Using the agreed settings and SimpleTreat 4.0, the SLUDGERATE value changes to 813 kg/d (instead of the previous value of 790 kg/d).

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENVPEC and PNEC calculations – considerations to be included in the240CAR/PAR

New!

Version 1 (AHEE-6)

The derivation of the PEC and the PNEC should be clearly explained in the CAR/PAR in what regards the assumptions made when degradation is considered in the derivation of endpoints from ecotoxicological studies.

The time window for deriving an ecotoxicological endpoint based on TWAconcentrations depends on the relevant exposure duration in the study. Once used for PNEC-derivation, the resulting PNEC for the ecosystem is no longer related to a specific test duration, but represents a value that is protective for chronic exposure of the ecosystem as a whole. The time window for the PEC, for aquatic and terrestrial assessment, is fixed and is based on a reasonable time for the chronic exposure of the ecosystem. For PT 8 the PEC Time 1 is based on 30 days in order to be coherent with a typical life cycle period of soil and water organisms (OECD, 2003).

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENV Calculation of PEC values – Consistency with PNECs

243 New!

Version 1 (WG-II-2022)

For risk assessment purposes, when PNEC values are based on pure active subsatnce (AS), PEC values should be derived based on pure AS content. Only if PNEC values are based on the content of AS as manufactured, PEC values should be derived based on the content of AS as manufactured.

In case the endpoint was not clearly stated as pure in the approval documents, the risk assessment must be done with concentrations as manufactured until the endpoint is clarified at the renewal of the approval.

The AS content in a biocidal product is expressed in the SPC as the content of the AS as manufactured. In addition, in the PAR, the AS content should also be expressed as pure AS (as the pure AS content could be the point of reference in the AS approval). Therefore, depending on the PNEC values available for the substance, the appropriate PEC values can be calculated so that a meaningful PEC/PNEC ratio is derived.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

2.2 Degradation

ENV When should indirect photolysis be considered?12

Version 1 (TM I 2005, WG-I-2015)

Indirect photolysis is generally not included in the risk assessment due to lack of harmonised guidelines, but direct photolysis is used to identify relevant metabolites and to judge whether the rate of direct photochemical transformation may contribute to the overall decline of a chemical.

Please refer also to Vol. IV Part A (Guidance on information requirements), chapter 10.1.1.1.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which DT₅₀ value is to be used when multiple study results are available? (worst case value vs. geometric mean)

Version 1 (TM IV 2007, TM IV 2012)

If up to three DT_{50} -values from different water-sediment or soil systems are available, the worst-case value will be used whereas when more than three DT_{50} -values for the respective compartment are available then the geometric mean will be used.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Can a water-sediment simulation study be considered instead of a STP 14 simulation test, for the refinement of exposure of non-biodegradable substances?

Version 1 (TM I 2008)

A water-sediment simulation study can be considered as an alternative to a STP simulation test. The resulting DT_{50} value (biodegradation in water phase,

not dissipation) from this test can be used as a worst-case value for degradation in the STP.

The opposite is not acceptable, i.e. using the DT_{50} value from a STP simulation test as a substitute for degradation in a water- sediment system.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Is the request of simulation studies for not readily biodegradable substances necessary for exposed environmental compartments in order to check inclusion criteria for Union listing and detect relevant metabolites, or shall studies only be requested if a risk is identified?

Version 1 (TM II 2008, WG-I-2015)

The need for simulation studies with respect to the inclusion in the Union list of approved active substances is in principle exposure driven.

However, with regard to assessment of the exclusion- and substitution criteria (Art. 5 and Art. 10 of the BPR), simulation tests may be required. It is further stated in Vol. IV Part A (Information requirements, chapter 4.2.5: "...If a substance is not readily biodegradable and either not vB or not classified as B or T, it may not be necessary to conduct simulation studies for the indirectly exposed environmental compartments [.....]. As soon as there is new information and this result in the substance being considered as B or T [...], it may become necessary to perform a P assessment. For the environmental risk assessment in the indirectly exposed compartments, the first tier assessment can be performed without the need for simulation studies [....] Additional simulation studies in indirectly exposed compartments may be useful to refine the first tier risk assessment."

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVMay different soil DT50 values for substances where degradation is pH16dependent be used for PECsoil and PECgw assessment?

Version 1 (WG-III-2017)

It is acceptable to use different soil DT50 values for PECsoil and PECgw assessment, taking into account the pH dependant degradation as outlined in FOCUS guidance

(https://esdac.jrc.ec.europa.eu/public_path/projects_data/focus/gw/NewDoc s/GenericGuidance2_2.pdf): the worst case (highest) DT50 is used to calculate the 1st tier PECsoil. Whereas the geometric mean DT50 values, calculated for acidic and alkaline soils respectively, is used for higher tier groundwater modelling.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Should photolysis metabolites be identified in case the activesubstance under evaluation is readily biodegradable?

Version 1 (TM IV 2008)

The identification of photolysis metabolites can be waived when the biodegradation rate is faster than the photodegradation rate. However, it must be checked that:

- 1. The biodegradation rates are actually faster than the photodegradation rate.
- 2. That both rates are expressed using a comparable endpoint (mineralization or primary degradation).
- 3. That the metabolites formed during photolysis tests remained below 50% and were not persistent.

Other information such as exposure of the water compartment, or adsorption might be considered.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV How shall the results of an STP simulation study in the environmentalexposure assessment be used?

Version 1 (TM IV 2010)

The level of elimination in the STP simulation test can be directly used quantitatively in the exposure assessment and there is no need to revert to the use of the default rate constants from the TGD e.g. for substances that are inherently biodegradable.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVRevised molar activation energy of 65400 J/mol use in temperature182correction of biodegradation processes

Version 1 (AHEE-3, WG-III-2020)

The current ECHA guidance on biocides for environmental risk assessment, Vol IV, Part B&C (2017) provides an equation for temperature correction (equation nr. 28):

DT50 (X°C)=DT50 (T)e^((0.08(T-X)))

With T being the experimental temperature and X the compartment temperature (e.g. 12°C).

It is to be noted that the Equation 28 (Vol IV, part B&C) is a variation of the Q10 approach. Since Q10 is derived for a temperature difference of 10°C and temperatures of 10°C and 20°C, equation 28 is applicable to the same restrictions.

Equation 28 has been used outside of its original applicability domain in allowing temperature corrections other than from 20 to 10°C. A wider applicability is however incorrect, since equation 28 effectively entails multiplication by Q10. Moreover, the equation is inaccurate due to rounding of the value contained in the exponent.

It was agreed to use the Arrhenius equation in the form below to correct biodegradation rates in the temperature range of 0 to 30°C:

$$\boldsymbol{k}_{T_1} = \boldsymbol{k}_{T_2} \boldsymbol{e}^{\left(\frac{E_a}{R} \left[\frac{1}{T_2} - \frac{1}{T_1}\right]\right)}$$

or

 $\boldsymbol{DT50}_{T_1} = \boldsymbol{DT50}_{T_2} \boldsymbol{e}^{\left(\frac{E_a}{R} \left[\frac{1}{T_1} - \frac{1}{T_2}\right]\right)}$

Note that temperatures in the equations should be entered in degrees Kelvin.

Parameter	Description	Unit	Value
DT50	half-life value for biodegradation	[d]	
k	rate constant for biodegradation	[d ⁻¹]	
Т	temperature	[K]	
Ea	activation energy	[J mol ⁻¹]	65400
R	gas constant	[J mol ⁻¹ K ⁻¹]	8.314472

The background document including further information is provided in the CIRCABC TAB repository (entry "ENV182..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	08/02/2021
Date of applicability for active substances:	08/02/2021
Date of applicability for products:	08/02/2021

ENV Rate constant for volatilisation in soil 185

Version 1 (WG-VII-2018)

The WG agreed that the correct equation to calculate kvolat is equation 54 provided in the BPR guidance Volume IV. Part B + C v.2.0, which reflects a correction of the previous guidance version back to the calculation as originally provided in the TGD of 2003 (including a temperature correction in 2017). However, the following correction should be performed when using the equations of Volume IV. Part B + C v.2.0: The unit of Kaslair should be provided in m/d instead of m/s using the default value of 90.72 (as provided in the TGD of 2003).

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENVConsideration of OECD 314 B studies within the environmental risk213assessment under the BPR

Version 1 (AHEE-3, AHEE-4)

The OECD 314 series of simulation tests are designed to provide the extent and kinetics of degradation (primary and ultimate) for five potential situations related to discharge of chemicals into sewer system and subsequently to sewage treatment plant and to the receiving water, respectively. The OECD 314 B specifically focus on the primary and ultimate degradation under realistic conditions in activated sludge and can be used estimating final effluent concentrations. During the development of the test guideline (TG) in frame of the OECD Working Group of National Co-ordinators of the TGs programme (WNT) it was concluded that specific rules for the use of the data of OECD 314 B studies in risk assessment would have to be established by each regulatory authority itself. Thus, the document published on the public CIRCA side linked below on 14 July 2020 will give background information on the lacks identified in the test guideline and shall provide information on how to proceed when OECD 314 B are submitted in frame of a.s. approval / b.p. authorisation under BPR.

The background document including further information is provided in the CIRCABC TAB repository (entry "ENV213..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	14/07/2020
Date of applicability for active substances:	14/07/2020
Date of applicability for products:	14/07/2022

2.3 Groundwater

ENV What groundwater concentration limits should be applied to single 19 biocide active substance, metabolites and mixtures (e.g. when the active substance is defined as a mixture block)?

Version 1 (TM IV 2011, TM IV 2012, TM I 2013)

For single biocidal active substances the limit of 0.1 μ g/l¹ should always be applied in groundwater. This is an absolute trigger, and no risk assessment or relevance assessment of active substance concentrations above this limit is ever possible. The 0.1 μ g/l should also be applied to all metabolites in a tiered assessment scheme. Any metabolites predicted to occur above the 0.1 μ g/l should be assessed with regards to their relevance according to Vol. IV Part A (Information Requirements), Section 1.6. Where a metabolite is determined to be relevant according to this guidance, the 0.1 μ g/l or a lower concentration due to its toxicological properties, must be strictly applied just as it is for a biocide active substance (i.e. no risk assessment of a relevant metabolite above 0.1 μ g/l is ever possible). For metabolites shown to be non-relevant, a final drinking water risk assessment may be required to demonstrate the acceptability of non-relevant metabolite concentrations above the 0.1 μ g/l².

The 0.1 μ g/l limit should also apply to all individual fractions of a biocidal active substance mixture or mixture block, when these individual fractions are separately quantified with regard to groundwater contamination potential. Additionally, for a mixture or block group of biocide active substances, the higher 0.5 μ g/l limit should apply to the total mixture concentration predicted in groundwater. For mixtures of metabolites formed from active substance mixture or mixture blocks, the same approach as applied to individual metabolites should apply. The 0.1 μ g/l limit (for individual metabolites) and the 0.5 μ g/l (for total metabolite mixture concentrations) should both be applied at the first tier. Where either of these limits is exceeded, the guidance provided in Vol. IV Part A, Section 1.6 on relevance of metabolites should be applied.

¹ Note that for some substances a lower limit than $0.1\mu g/l$ may be set on the basis of, for example, toxicological data. In these situations, the $0.1\mu g/l$ limit should be replaced with the lower toxicological limit when applying the guidance above.

² According to the TM I 2013 discussion, DE and DK express some reservations, regarding the final drinking water risk assessment for metabolites.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Cut off criteria for groundwater assessment of biocides 20

Version 1 (WG-II-2014)

The document providing cut off criteria for the assessment of the groundwater compartment was developed by UK and was endorsed at WG-II-2014.

The document is provided in the CIRCABC TAB repository (entry "ENV020..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Threshold values for groundwater assessment 21

Version 1 (WG-IV-2016)

For the groundwater assessment, the threshold concentrations as referred to in Annex VI of the BPR (point 68) for parent and metabolites apply.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Freundlich adsorption coefficient to be used in FOCUS models 22

Version 2 (WG-IV-2017)

The FOCUS models require the Freundlich adsorption isotherm (K_F andn) in order to determine sorption to soil of the active substance. For the selection of the non-linearity constant (n), the following three scenarios should be considered:

1. The Applicant performs a full OECD 106 batch sorption study (Determination of Freundlich adsorption isotherms (Tier 3)) at five

concentrations covering preferably two orders of magnitude and derives reliable^{1/n} values. Here, the arithmetic mean of the empiric 1/n values should be used in the FOCUS model.

- 2. The Applicant performs only the screening stage experiment of OECD 106, investigating sorption at a single concentration. Here, a default 1/n of 1 is to be used in any FOCUS modelling. This more conservative value is needed because of the lack of data on the relationship between the substance's sorption and concentration.
- 3. The Applicant attempts to perform a full OECD 106 batch sorption study at multiple concentrations but it proves impossible to derive reliable n values. Here, a default 1/n of 0.9 is to be used in any FOCUS modelling. This value takes account of the Applicant's effort to derive empiric data for the relationship between the substance's sorption and concentration.

This is in line with the approach applied for plant protection products (PPP). If the PPP guidance changes in the future, resulting in a change of the default value for the Freundlich adsorption coefficient, this TAB entry will be changed accordingly.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Freundlich adsorption coefficient to be used in FOCUS models 22

Version 1 (WG-V-2016)

The FOCUS models require the Freundlich adsorption isotherm (KFand n) in order to determine sorption to soil of the active substance. For the selection of the non-linearity constant (n), the following three scenarios should be considered:

1) The Applicant performs a full OECD 106 batch sorption study at multiple concentrations and derives reliable 1/n values. Here, the arithmetic mean of the empiric 1/n values should be used in the FOCUS model.

2) The Applicant performs only the screening stage experiment of OECD 106, investigating sorption at a single concentration. Here, a default 1/n of 1 is to be used in any FOCUS modelling. This more conservative value is needed because of the lack of data on the relationship between the substance's sorption and concentration.

3) The Applicant attempts to perform a full OECD 106 batch sorption study at multiple concentrations, but it proves impossible to derive reliable n values. Here, a default 1/n of 0.9 is to be used in any FOCUS modelling. This value takes account of the Applicant's effort to derive empiric data for the relationship between the substance's sorption and concentration.

This is in line with the approach applied for plant protection products (PPP). If the PPP guidance changes in the future, resulting in a change of the default value for the Freundlich adsorption coefficient, this TAB entry will be changed accordingly.

Type of entry:	b) Clarifications/existing guidance
Publication date:	01/08/2017
Date of applicability for active substances:	01/08/2017
Date of applicability for products:	01/08/2017

ENV What parameter setting should be applied to FOCUS groundwater 23 scenarios (PEARL) when they are used in biocide exposure assessments

Version 2 (AHEE-3, WG-II-2021)

Molar activation energy:

In case of using FOCUS PEARL version 4.4.4 the value for "Molar activation energy" in the TRANSFORMATION tab of the substance parameters should remain at the default value of 65.4 kJ.mol-1 as biodegradation processes in soil are modelled. This value corresponds to the Q10 value of 2.58 assuming a daily temperature correction in FOCUS models in accordance with the EFSA PPR opinion (http://www.efsa.europa.eu/en/efsajournal/pub/622.htm) and the REACH guidance document R.7b.

Plant uptake factor:

A factor of 0 should be used for the plant uptake factor for the purposes of a first-tier assessment. Due to discussions (ref. to TMII2010ENV-item Harmonisation of FOCUS groundwater models PEARL.doc and CA-Dec10-doc 6.2 c) this value is considered as a realistic worst case.

Summary on relevant substance specific input parameters for the groundwater simulations with FOCUS PEARL and FOCUS PELMO:

Parameter	Value	Unit	Origin
Molar mass		[g.mol ⁻¹]	S
Solubility in water (at test temperature)		[mg.L ⁻¹]	S
Molar enthalpy of dissolution	27	[kJ.mol ⁻¹]	D
Vapour pressure (at test temperature)		[mPa]	S
Molar enthalpy of vaporisation	95	[kJ.mol ⁻¹]	D

Diffusion coefficient in water	4.3 • 10 ⁻⁵	[m ² .d ⁻¹]	D
Gas diffusion coefficient	0.43	[m ² .d ⁻¹]	D
Reference temperature to degradation, vaporization and dissolution	20	[°C]	D
Exponent for the effect of liquid (degradation moisture relationship)	0.7	[-]	D
Sorption to soil organic carbon (Koc or Kom (Kom = Koc / 1.724)		[dm ³ .kg ⁻¹]	S
Exponent of the Freundlich- Isotherm (1/n)		[-]	D/S (if available) ¹⁾
DT50 (20°C)		[d]	S
Arrhenius activation energy	65.4	[kJ.mol ⁻¹]	D
Q10-factor (increase of degradation rate with an increase of temperature of 10°C – relevant for PELMO)	2.58	[-]	D
Plant uptake factor	0		D

¹⁾For the procedure for selecting the appropriate exponent for the Freundlich-Isotherm please refer to entry ENV 22.

Furthermore, in FOCUS PEARL version 4.4.4 it is possible to divide the annual dose in 12 equal portions, e.g. applied the first day of each month. This is a change compared to FOCUS PEARL3.3.3, which had limitations regarding the maximum number of annual doses (ten).

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Number of safe FOCUS scenarios for Union Authorisation 24

Version 1 (WG-I-2017, BPC-21)

It was concluded that for Union Authorisation all nine different FOCUS EU locations have to show a safe use (for arable land and for grassland).

It was further specified at BPC meeting level that in case not all nine scenarios should be safe, a qualitative approach should be applied using expert judgement in a case-by-case assessment, looking for example at the substance properties.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVSubstance groups for which no groundwater assessment is needed208

Version 1 (WG-III-2019, AHEE-3, AHEE-4, BPC-34)

For inorganic rapidly reacting substances (to be discussed on a case by case discussion if a substance is rapidly reacting, e.g. substances reacting with organic matter) no groundwater exposure assessment is needed since it is very unlikely that any substance will reach groundwater. Rapidly reacting refers to the reaction of the above substance in the soil compartment (for which groundwater is the subsequent compartment). The theory behind is:

- inorganic rapidly reacting substances rapidly react with organic matter
- the soil compartment contains a lot of organic matter
- in case inorganic rapidly reacting substances enter the soil compartment, they react with organic matter in soil
- it is scientifically unlikely that any inorganic rapidly reacting substance will reach the groundwater after a soil passage, therefore no groundwater assessment is necessary since groundwater entries are always assessed after soil passage.

For the majority of biocidal products, the assumption shall be that rapid and sufficient reactions in the soil organic-matter horizons prevents the active substance to ever reach groundwater. However, for certain uses, special attention to groundwater must still be taken. Such uses includes application on land where organic matter is extremely low (e.g grounds like railway roadbeds and other stone/ballast layered areas like surrounding of buildings, specially designed infiltration areas in cities, etc.

Ozone, active chlorine, chlorine dioxide, hydrogen peroxide and free radicals generated in situ from ambient air or water can be e.g. considered as "rapidly reacting".

No groundwater exposure assessment is required for carbon dioxide generated from propane, butane or a mixture of both by combustion because this is not scientifically justified.

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

ENV Clarification on the PECsoil used for derivation of porewater 237 concentration equal to PECgw

Version 1 (WG-I-2021, WG-II-2022)

<u>STP sludge and manure application</u>: for both grassland and arable land, the derivation of porewater concentrations should be based on a PEC soil averaged for 180 days after 10 years of sludge/manure application (180d TWA PEClocalsoil).

In case of sewage sludge application on agricultural soils: this is specified in the Biocides Guidance Vol IV Part B+C, p.93. It is noticed that in Table 9 on page 92, line 2, the term PEClocalagr. soil should be corrected to PEClocalarable soil.

The footnote 16 on the page 93 as well as further chapters of the Guidance (e.g. chapter 2.3.7.6) need to be further clarified, when the guidance will be revised in the future. It is indicated in the footnote that "the worst-case agricultural PEC value for arable land should be used". This refers in fact to Table 9 on page 92, where both lines 2 and 3 are related to the PEC in soil for agricultural soils, where the worst case in arable land (line 2) compared to grassland (line 3) should be used to further assess PECgw (porewater) subsequent to sewage sludge application on agricultural land.

<u>In case of manure/slurry application on agricultural soils</u>: for both grassland and arable land, the derivation of porewater concentrations should also be based on 180 d TWA PECsoils. For the PEC in surface water, after drainage or run-off from soil, the PECgw based on the 30d TWA PEClocalsoils in grassland and arable land shall be used to calculate PECsw.

<u>Direct releases to soil</u>: the derivation of porewater concentrations is based on the initial PEClocalsoil values as a first Tier. For direct releases, the PECsoil as it is currently calculated in the different ESDs (e.g. PT 8, PT 14, PT 19) should be used as basis for the PECgw calculation (porewater), no transfer to a 180d TWA PEClocalsoil is needed unless a refinement using data on degradation in soil is necessary. In this case, a 180d TWA PEClocalsoil can be used to derive the porewater concentrations as a second Tier.

Type of entry:

b) Clarifications/existing guidance

Publication date:

22/07/2021

Date of applicability for active substances:	22/07/2021
Date of applicability for products:	22/07/2021

3 PT specific items

3.1 Cross-PT items

ENV Can the default market share values which are used in several ESDs be 25 refined? In which cases can we accept lower/other values than the indicated market share values in the ESDs?

Version 1 (TM III 2004, TM III 2008, AHEE-1, WG-IV-2015)

The default market share value may be overruled and replaced by other values if the applicant can justify this by market data, providing historical data and including some projections in the future.

The already agreed market share factors in several ESDs shall be used, from which justified deviation is possible. For the remaining product types a market share factor shall be agreed upon, where relevant.

The following specific values for the market share were further agreed at WG-IV-2015:

- For **disinfectants** used in private households (PT 1+2) as well as in private swimming pools (PT 2) (beside substances which mode of action is based on chlorine), the emission rate to water used for risk assessment entails a market share of disinfectant (Fpenetr). By default this factor is set at 0.5.
- For disinfectants used in hospitals (PT 1) or industrial premises (PT 2) however a default value of 1 should be used.
- For **in-can preservatives** (PT 6) used in household products (washing and cleaning fluids, general or hygienic products) the factor is set to 0.5.
- For **repellents** (PT 19) applied by private users to human skin and garments as well as for factory treated textiles, washed in private households, the factor is set to 0.5.
- For **antifouling substances** (PT 21) the default value for the parameter Application factor is 90% for all antifouling paints that include boosters.

The applicant can propose deviation from the default values based on strong justifications, such as market comparison with other substances having the same application pattern.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Application rate of the biocidal product for PT 2 and PT 4 26

Version 1 (WG-III-2017)

In case no application rate for the biocidal product is provided by the applicant, the following default values for V_{form} should be used for PT 2 and PT 4:

- For RTU uses: 0.04 L/m²
- For normal (large scale uses as in the ESD for PT 2 and PT 4): 0.1 L/m²

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENVUse of Fweatherside27

Version 2 (WG-III-2017)

<u>PT 8</u>: $F_{weatherside}$ should be applied in the groundwater assessment for PT 8 (according to the Supplement to Appendix 4 of the revised OECD ESD for PT 8).

<u>City scenario in PT 6, 7, 9 and 10</u>: $F_{weatherside}$ refers to the fact that not all sides are exposed to rain equally. While the value of 0.5 for $F_{weatherside}$ was accepted for houses in the countryside, in cities, buildings are taller and closer to each other so the effect on biocides reaching the environment is different. In cities, also turbulence, direction of rain is different.

F_{weatherside} should therefore not be applied in the city scenario.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENVUse of Fweatherside for groundwater assessment in PT 8 and other PTs27

Version 1 (WG-II-2015)

<u>PT 8</u>: $F_{weatherside}$ should be applied in the groundwater assessment for PT 8 (according to the Supplement to Appendix 4 of the revised OECD ESD for PT 8) and for other relevant PTs, if the groundwater assessment is conducted according to the revised OECD ESD for PT 8.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Direct emissions to surface waters in PT 6, 7, 9 and 10 28

Version 1 (WG-III-2014, WG-II-2018)

The document "*The assessment of direct emission to surface water in urban areas*" was developed by DE, first introduced at TM II 2013 and endorsed at WG-III-2014.

It can be found on the ESD specific ECHA webpage under PT 6, 7, 9 and 10:

https://echa.europa.eu/documents/10162/16908203/pt 6 7 8 9 10 assess ment of direct emission surface water urban areas en.pdf/56073606-24c6-4b77-89ea-bfeec98d5943

https://echa.europa.eu/documents/10162/16908203/pt_6_7_8_9_10_assess ment_of_direct_emission_surface_water_urban_areas_en.pdf/56073606-24c6-4b77-89ea-bfeec98d5943

It was further agreed at WG-II-2018 that the separate sewer system (direct rainwater scenario) scenario should be calculated for PT 6.2/6.3, 7, 9 and 10 in connection with the city scenario, the roof membrane scenario (PT 9) and the noise barrier scenario (PT 8), covering service life and application phase for active substance approval as well as for product authorisation. It should be used for decision making and be considered as Tier 1. A Tier 2 scenario is currently not available. Alternatives for a Tier 2 scenario are submission of e.g. leaching studies or information regarding stability of the preservative in preserved products.

The bypass STP scenario (mixed sewer) currently does not need to be calculated and considered for the above noted PTs, neither for application phase nor for service life.

Type of entry:

e) New guidance, immediately applicable

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Assessment of emissions reaching the STP using the city-scenario forPT 10 in other PTs

Version 1 (TM IV 2013)

The document "*City scenario: Leaching from paints, plasters and fillers applied in urban areas*" developed by NL and endorsed at TM IV 2013 should be applied also for PT 6.2, PT 7 and PT 9, when applications similar to the ones described in PT 10 take place in urban areas.

Type of entry:

d) New guidance, no new data requirement(s)

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Use of the scenario on direct emission to surface water in urban areasfor the application phase

Version 1 (WG-II-2015)

The scenario for direct rainwater discharge (bypass scenario) should not be used for the application since it is unrealistic to assume that application of paint will occur during or shortly before a storm event.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVShould degradation in surface water be taken into account after31release from an STP

Version 1 (WG-IV-2015)

This item was concluded for PT 7 but is considered also relevant for other PTs.

The refinement of the exposure assessment for the aquatic compartment would only be acceptable if the release occurs directly to a static or semi-static water body. If the release occurs via an STP, the standard risk assessment procedure according to guidance BPR IV B v.1.0 should be followed and no further degradation after the release from the STP into the surface water body should be taken into account.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Use of SPERCs for the assessment of biocides

32

Version 1 (WG-V-2015)

At WG-V-2015 it was agreed that for the assessment of biocides the A&B tables in BPR IV B v.1.0 should be used. On a case-by-case basis, default values in the A&B table can be replaced by values that are more specific provided in SPERCs, but such a replacement needs the agreement of the WG.

Replaced default values agreed by the WG will be recorded within this TAB entry.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Use of information provided in BREF documents for the refinement of 33 the exposure assessment

Version 1 (WG-V-2015)

At WG-V-2015 it was agreed that additional information provided in BREF documents on Best Available Technique (BAT) can be taken into account on a case-by-case basis for the refinement of the risk assessment.

If such a refinement is not substance-specific but in general relevant for a scenario, it will be recorded in the TAB at the product type for which it is relevant.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Laboratory and semi-field leaching test methods for PT 7, 9 and 10 34

Version 1 (WG-IV-2015)

Two leaching methods developed by BAM determining the leaching of active substances or other compounds from materials that contain biocidal products in PT 7, 9 and 10 have been agreed by the WG.

The documents are provided in the CIRCABC TAB repository (entries "ENV034...")

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

d) New guidance, no new data requirement(s)

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVReduction of default surface area for brush application for PT 18 and3519

Version 1 (WG-III-2016)

The default length of the treated area for barrier treatments against ants (door steps and windows) is 10 m. The width of the barrier is flexible and should be defined case by case depending on the application technique.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Default crops, application dates, application mode and depth to be used for FOCUS groundwater models when refinement of PECgroundwater following sewage sludge application on soil is needed

Version 1 (WG-II-2014)

In case of running sewage sludge application scenarios in FOCUS groundwater models it was agreed at WG-II-2014 that both grassland (alfalfa) and agricultural land (maize) should be used. In case of grassland application the scenario considers one sewage sludge application per year on 1st of March (absolute application) and 10 cm incorporation depth. In case of agricultural land application the scenario considers one sewage sludge application per year to maize 20 days before crop event "emergence" (relative application) and 20 cm incorporation depth. The application rate of the active substance Appl_rateagr/grass [kg/ha] at one application date as input parameter in FOCUS groundwater models is calculated by:

$$Appl_rate_{agr/grass} = App_{sewage_sludge_agr/grass} \times C_{sludge} \times 10^{-6}$$

with

 $App_{sewage_sludge_agr} = annual sewage sludge application rate on agricultural land = 5,000 kg/ha$

 $App_{sewage_sludge_grass}$ = annual sewage sludge application rate on grassland = 1,000 kg/ha

 C_{sludge} = concentration of a.s. in dry sewage sludge [mg/kg] (ref. to eq. 39 in guidance BPR IV B v.2.0).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVScaling approach for PT 6.2, 7, 9, 10 (City scenario, Roof membranes)37

Version 1 (WG-I-2017)

The scaling approach relates to the city scenario which is used for the environmental risk assessment of service life of active substances/biocidal products in PT 6.2, 7 and 10 and to the specific city scenario for roof membranes in PT 9. It provides a refinement possibility for the parameter $f_{house}/f_{market share}$:

The background document is provided in the CIRCABC TAB repository (entry "ENV037..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Emission pathways via sewage sludge / manure and other appropriate scenarios: is it necessary to demonstrate a save use for both grassland and arable land at the same EU location?

Version 1 (WG-I-2017)

It was concluded that both scenarios, arable land and grassland, should be below the groundwater threshold at the same EU location. However, if there are specific conditions, case-by-case decisions can be made that deviate from this conclusion. For example, in the exposure assessment for mink stables, where only straw is produced which is to be ploughed into soil, only arable land would be relevant.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Degradation in the sewer system before release to STP 39

Version 1 (WG-I-2018)

For substances rapidly reacting with organic matter (e.g. oxidising substances), dissipation in the sewer system following reaction should be taken into account for the emission estimation, according to the equation provided in the ESD for PT 5. In line with the ESD for PT 5 degradation rates used for the calculation should be transferred to an environmental temperature of 12°C (using equation 28 provided in Vol. IV Part B+C, v2.0).

See page 14 of the ESD for PT 5:

https://echa.europa.eu/documents/10162/16908203/pt5 drinking water dis infectants en.pdf/cf79e64e-c83e-4b2d-ba06-4a6351160c30

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Recommendation on refinement of the market penetration factor 40

Version 1 (WG-I-2018)

The recommendation of the Environment WG on the refinement of the market penetration factor (F_{penetr}) is provided in the CIRCABC TAB repository (entry "ENV040..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENVRoom disinfection - Room volume for enclosures and other comparable177applications with a small volume size in e.g. PT 2, 3 and 4

Version 1 (AHEE-4)

A room volume of 150 m³ in line with the agreemetn of EFF WG-IV-2018 and the TAB entry EFF 11 (version 2.1, January 2020) should be assumed as default value for a room disinfection with various application methods (e.g. fogging, smoking, fumigation etc.), when a small room volume size is intended for disinfection.

Type of entry:	b) Clarifications/existing guidance
Publication date:	30/09/2020
Date of applicability for active substances:	30/09/2020
Date of applicability for products:	30/09/2020

ENV Summing up of tonnages of active substances in standard tonnage-based emission scenarios during the active substance approval

Version 1 (WG-III-2020, WG-I-2021)

This TAB entry applies for all standard tonnage-based emission scenarios and for PT 6 also for tonnage-based scenarios in any sub-categories. An active substance approval for a specific product-type is not an individual application but an approval of the substance in the EU and should consider all biocidal uses in one product-type. Therefore, the tonnages of all applicants (per the same use) should be summed up when tonnage-based scenarios are used. Note that this TAB entry does not cover aggregated exposure summing up emissions from different PTs.

A specific procedure for summing up of tonnages in case <u>of only two applicants</u> was agreed in order to protect the confidentiality of the tonnage of the single applicants:

- The eCA sums up the tonnages in the confidential part of CAR which by no means should be shared with applicants
- The eCA further calculates in the non-confidential CAR the maximum tonnage that would still result in a safe use (PEC/PNEC is just below 1)

- In the confidential part of the CAR, this maximum tonnage is compared to the sum of applicants' tonnages and a conclusion on a safe/non-safe use is drawn
- Only this conclusion (safe/non-safe use) is then reported in the nonconfidential part of the CAR.

For more than two applicants, the procedure agreed for "only two applicants" can be followed but might be less relevant as it is more difficult to back-calculate the tonnage of one applicant.

In case an unacceptable risk is identified, suitable RMM to minimise the emission can be used.

This TAB entry is not applicable to biocidal products.

Type of entry:	b) Clarifications/existing guidance
Publication date:	22/07/2021
Date of applicability for active substances:	22/07/2021
Date of applicability for products:	22/07/2021

ENV Equations to be used for PEC calculation for wood and other 186 preservatives applied outdoors

Version 1 (WG-II-2018, WG-IV-2018, AHEE-2, AHEE-3)

Regarding the equations provided in Chapter 3 of the OECD ESD for PT 8, it was agreed not to average the PECs over the assessment period for the assessment of outdoor preservatives (PT06-10) in general irrespective of whether there are losses during in-situ application or only releases due to leaching. Consequently, equations 3.11 and 3.12 from the OECD ESD for PT 8 are now the formulas to be applied in case of all emission to soils and equations 3.7 and 3.8 (the time weighted average forms of equations 3.11 and 3.12) should not be used. The corresponding formulas for direct release to surface water have been updated accordingly, which is covered in TAB entry ENV 209. Equations 3.11 and 3.12 calculate the concentration at the end of the emission period and they apply a fixed leaching rate over the whole assessment period (when following approach 1).

It was further agreed that for the calculation of leaching amount, for the time being approach 1 (starts from the initial concentration - see explanation in the embedded document) should be used, however approach 2 (starts from the previous PEC value) as optional additional approach is acceptable.

Where approach 2 is used, it shall be stated in the assessment report and a clear justification for relying on one method over the other should be provided.

No addition of an AF in the equations of approach 2 is needed, however it should be checked and agreed if there is a need to add an AF on the leaching study case by case, depending on the quality of the leaching study.

The background document is provided in the CIRCABC TAB repository (entry "ENV186..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Default leaching rates if no leaching study is available 187

Version 1 (WG-VII-2018)

In the 2nd EU Leaching Workshop default leached quantities have been defined, in case no leaching test is available, for PT 8 which can be applied also to other PTs. For the new Time 2 of 365 days, an additional default value was agreed, resulting in the following default leached quantities for all relevant times: Time 1 (30 days): 50% of the applied substance leaches out Time 2 (365 days): 75% of the applied substance leaches out Time 3 (service life): 100% of the applied substance leaches out.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Risk assessment for volatile substances 188

Version 1 (WG-VII-2018, AHEE-2, WG-IV-2019, BPC-35)

For products containing very volatile substances (according to the VOC directive) used in general, i.e. it is not distinguished between professionals and non-professionals, there is no need to conduct a risk assessment for subsequent environmental compartments following the release path via air. This conclusion concerns all relevant PTs. Specifically for the subsequent environmental compartment groundwater it should be further noted that exceedance of the groundwater trigger value is not likely.

Type of entry:

b) Clarifications/existing guidance

Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Inclusion of density in emission scenarios where density is not used asan input parameter

Version 1 (WG-IV-2019)

In some emission scenarios, the releases are calculated without taking the density into account. The product density needs to be added as an input parameter in such scenarios and emission calculations need to take it into account in similar manner as done for example in the ESD PT 8.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Temperature correction for degradation during application process 190

Version 2 (WG-III-2020)

In case temperature dependent degradation is relevant in the degradation process (and no temperature is defined in the ESD), the following temperatures have been agreed in general for all PTs:

- For indoor applications (including cooling systems under PT 11 among other): 20°C
- For outdoor applications (including outdoor storage) 12°C and 9°C for marine environments

In case information is available on the temperature that is needed to allow sufficient efficacy for the product, this temperature should be used for the emission estimation.

Regarding PT 11 and PT 12 in general (and all indoor applications), only abiotic degradation (e.g. hydrolysis) should be taken into account. However photodegradation is not a relevant type of abiotic degradation for indoor applications.

If studies of sufficient quality are available showing further degradation in the system (e.g. biodegradation), it can be agreed to take the respective information into account on a case-by-case basis.

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

ENV Temperature correction for degradation during application process 190

Version 1 (AHEE-2)

In case temperature dependant degradation is relevant in the degradation process (and no temperature is defined in the ESD), the following temperatures have been agreed in general for all PTs:

- For indoor applications (including cooling systems under PT 11): 20°C
- For outdoor applications (including outdoor storage) 12°C

In case information is available on the temperature needed to allow sufficient efficacy for the product, this temperature should be used for the emission estimation.

Regarding PT 11 in general only abiotic degradation (e.g. hydrolysis) should be taken into account.

If studies of sufficient quality are available showing further degradation in the system (e.g. biodegradation), it can be agreed on a case-by-case basis if the respective information is taken into account.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Fraction of concentrate in metalworking fluids (PT 6, PT 13) 191

Version 1 (AHEE-2)

PT 13: When biocides are added to concentrates with the intention to preserve the final MWF, the biocidal product must be efficacious after dilution. Consequently, the amount of biocides that must be added to concentrates to archive efficacy after dilution depends on the instructions for dilution of the concentrate as provided by the manufacturer of the concentrate. In other words, the amount of biocides that needs to be added to concentrates is negatively related to the advised dilution.

Considering that biocides must be efficacious in the diluted MWF, it is proposed not to use the formulas for concentrates as presented in the ESD (alternative algorithm), but only the formulas for direct dosing with F_{conc} =0.05 independent on the biocide's K_{ow}. When applicable, additional use instructions must be added to the summary of product characteristics (SPC) explaining that the product must be efficacious after dilution of the concentrate (i.e. XX mg/L) and therefore the dosage of the biocide to the concentrate depends on instructions regarding dilution as provided by the manufacturer of the MWF-concentrate.

PT 6: In case of in-can preservation the concentrate itself must be protected and not the MWF. Therefore, the efficacious concentration in the concentrate is leading for the risk assessment, which is independent on the dilution advised by the manufacturer. However, as the biocide is eventually released to the aquatic environment when spent MWFs are renewed, F_{conc} is required for the environmental risk assessment, which is, as explained previously, K_{ow} dependent.

It is proposed to assess the risk qualitatively when the concerning product is also notified for PT 13 as in-can preservation results in lower concentrations in the MWF. When product or substances are intended for PT 6 only, or when PT 13 turned out in unacceptable risks, emission must be calculated according to the formulas presented for concentrates. The Kow-dependent worst-case value for Fconc must be set as follows¹:

- Kow<23 0.20
- ≥23 K_{ow} <52 0.15
- ≥52 K_{ow} >172 0.10
- K_{ow} ≥172 0.05

 1 Values are derived according to the alternative algorithm as presented in §4.4 of the ESD. The proposed values are independent on the concentration active substance in the concentrate, dilution in the STP, dilution with wastewater from other sources (F_{mwf}), fraction of biocide in mixed wastewater (F_{form}) and possible elimination (F_{elim}).

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV General recommendations for conducting semi-field leaching tests 200

Version 1 (WG-III-2019)

The following recommendations regarding semi-field leaching studies were provided:

 Start the semi-field leaching study in autumn and rather not in the summer season.

- Put a clear statement of the drying time of the wood after application on the label. This drying time should then also be used in the frame of the semi field test to mimic a realistic situation.
- Compare the amount collected (i.e. the run off) with the actual rain amount, this may explain some inconsistencies in the leaching results (slight rain in combination with high evaporation does not lead to major run-off).
- Measure the moisture content of wood measured (e.g. by two electrodes). It may explain deviations in the leaching tests – rather a nice to have than a need to have.
- Leachate should be analysed after each rain event during the first 60 mm and to have more measure points at the beginning since it increases the statistical power (the first rain events have the highest impact)
- Duration of the test (semi-field test) should last at least two years (Refer also to the guidance discussed at BAM in 2016, reflected in the leaching guidelines for PT 7, 10 where a test duration of two years is recommended (at least 5 test points in the first year and three in the second year). It is recommended that the rain amount of two standard rain years is reached (i.e. 1400 mm).

Information on storage of leachate samples should be provided by applicants this should include information on the duration that samples are exposed to ambient conditions in the field prior to collection as well as the duration and temperature of any prolonged storage prior to analysis. Stability of the analytes of concern should be confirmed. In line with Annex B of the 2015 guidance on semi-field test methods stability should ideally be confirmed by spiking the first leachate samples from the blank control panels with target substance(s) at the concentration range expected in the main test. These samples can be used as a stability control and should be stored under identical conditions to the leachate samples from the main test prior to analysis (see respective link under ENV 34). It is recommended that known metabolites as well as known substances of concern should be covered in the analysis of the leachate (note that if no leaching data is available, default leaching rates will be used for the risk assessment).

For very sorptive substances a proof of the recovery rate (e.g from the collection container where the substance may adsorb to) is suggested. In addition during sample storage the container should be protected from sunlight and biotic degradation (by acidification).

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Manure and slurry storage – selection of European standard 245 temperatures

New!

Version 1 (WG-II-2022)

The following harmonised European standard manure storage temperatures have been agreed:

For liquid manure (slurry) of cattle and pigs it was agreed to use a default manure storage temperature of 12°C.

For poultry litter (dry manure) it was agreed to use a default manure storage temperature of 25°C. At this point in time no higher tier assessment including a higher temperature was agreed since it would need to be further evaluated with which mathematical method an extrapolation of measured data at a certain temperature to a higher temperature can be performed (e.g., restriction of Arrhenius equation to up to 30°C).

The background document is provided in the CIRCABC TAB repository (entry "ENV245..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENV Use of trigger sprays

246 New!

Version 1 (WG-II-2022)

It was generally agreed that trigger sprays are only used for small scale applications, and it is independent on if the product is diluted or undiluted (related to ENV 46 and ENV 67).

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENV Degradation during service life

247 New!

Version 1 (WG-II-2022)

It was agreed that there is no need to perform an exposure assessment "without degradation" when considering service life (related to emission scenarios with direct releases to soil using the house scenario or similar emission scenarios from PT 8 or other PTs).

For some substances e.g. SoC, no degradation rates might be available. In this case a very low degradation rate could be applied in the model. The WG agreed to use a default value for any substances for which no degradation rate is available of 1.000.000d, corresponding to a degradation rate of 6.93E-7 d-1 independent of any temperature. In case the implementation in the Chesar Platform would need any link to a temperature, the implementation will be done in line with the current implementation in EUSES.

The assessment of the metabolites should be handled case specific.

The only case where currently no degradation of the parent is applied in the PEC calculations is if the metabolites have the same toxicity profile, in that case the assessment of the parent without taking degradation into account also covers the assessment of metabolites. However, for the groundwater assessment of these metabolites the degradation of the parent and the formation of the metabolites still has to be assessed.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

3.2 PT 1

ENV Professional hand disinfection: how to derive a value for *Qsubst*_{pres_bed} 41 (and *Qsubst*_{occup_bed}) for substances for which no default value is provided in the pick list of the ESD?

Version 1 (WG-V-2014)

The following equation for the calculation of $Qsubs_{tbed}$ for nursing staff (N) and surgical staff (S) was agreed at WG-V-2014:

Nursing :	staff:
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QsubstbedN = NFTE/	ed • QformN •	Fform •	(RHO _{form})	NapplN
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Qsubst _{bedN}	=	Consumption of active ingredient per bed for nursing staff [kg/bed*d]
NFTE/bed	=	Number of hospital personal per bed [FTE/bed] Default value: 1.5 FTE/bed
QformN	=	Efficient dose rate of the hand disinfectant for nursing staff [kg/event] Default: 0.003 kg/event
F _{form}	=	Fraction of active substance in the hand disinfectant []
RHO _{form}	=	Density of the product [kg/L] Default: 1 kg/L
NappiN	=	Number of disinfection events/FTE/day [1/FTE*d] Default: 10 (hand wash with soaps and liquid soaps) or 25 (hand rubs)

To be noted:

- Q_{formN}: The value for the efficient dose rate should be provided by the applicant. Only if no information is provided by the applicant, the default value should be used
- RHO_{form} is only relevant in the equation above if the application rate of the product is provided as volume

Surgical staff:

It was concluded that for surgical hand disinfection, a fraction of 10% using the product should be added to the equation, i.e. NFTE/bed should be multiplied by 0.1.

$Qsubst_{bedS} = (N_{FTE/bed} \cdot 0.1) \cdot$	Qform • Fform •	(RHO _{form}) • N _{applS}

Qsubst _{beds}	=	Consumption of active ingredient per bed for surgical staff [kg/bed*d]
NFTE/bed	=	Number of hospital personal per bed [FTE/bed] Default value: 1.5 FTE/bed
Q _{formS}	=	Efficient dose rate of the hand disinfectant for surgical staff [kg/event]

		Default: 0.007 kg/event (not only hands but also forearms are disinfected)
Fform	=	Fraction of active substance in the hand disinfectant []
RHO _{form}	=	Density of the product [kg/L] Default: 1 kg/L
NappIS	=	Number of disinfection events/FTE/day [1/FTE*d] Default: 10 (hand wash with soaps and liquid soaps) or 4 (hand rubs) ^[1]

^[1] For N_{applS} (Number of disinfection events/FTE/day) the default value of 4 (for products for surgical hand disinfection) was agreed by the Human Health Ad hoc WG.

If a substance is used for both (nursing staff and surgical staff) than the results have to be summed up:

QsubstbedN + QsubstbedS

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which default values should be used for private hand disinfection?42

Version 2 (WG-I-2015, WG-IV-2016)

Finh: There are no data to underpin the default for *F*inh. It was agreed at WG-I-2015 that for the time being for *F*inh a default value of 0.2 should be used in case of soap and liquid soap hand disinfectant.

For other hand disinfectants for private use a default value of 0.5 should be used for*Finh* especially for leave-on products.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018

Date of applicability for products:

ENV Which default values should be used for private and professional use 43 - average consumption (i.e. consumption per application and number of applications of b.p. per day)?

Version 1 (MoI, WG-IV-2017)

Table 4.2.2.1: Parameters for HH and ENV exposure assessment in PT 1 and proposals to address missing values

	Amount/volume of b.p. per application (g or mL)		No. of applicat day	ions of b.p. per (d ⁻¹)
	НН	ENV	HH	ENV
(Anti-dandruff)	2027	2029, 32	0.7127	0.7129
shampoo				
	Antiperspirant /deod	dorant		
Aerosol	327	328	227	230
Stick, roll-on	0.527	0.528	127	128
Foot cream	1.227	1.232	227	232
antiperspirant				
Foot cream	0.127	0.132	227	232
anti-fungal				
Creams (e.g.	-	0.8 31		2 31
anti-acne)				
Face	0.827	0.832	227	232
Hand	1.727	1.732	227	232
Mouthwash	1027	1033	427	432, 33
	Soaps, gel (washing	hands)		
liquid	Consumers:	Consumers:	Consumers:	Consumers:
	1 g/event ²⁷	1 g/event ³⁵	527	535
	Professionals:	Professionals:		
	Nursing staff:	Nursing staff:	Professionals:	Professionals:
	3 g/event ³⁴	3 g/event ³⁷	1036	1037
	Surgical staff:	Surgical staff:		
	7 g/event ³⁴	7 g/event ³⁷		
solid	Consumers:	Consumers:	Consumers:	Consumers:
	0.8 g/event ²⁷	0.8 g/event ³²	527	532
	Professionals:	Professionals:		
	Nursing staff:	Nursing staff:	Professionals:	Professionals:
	3 g/event ³²	3 g/event ³⁷	1032	1037
	Surgical staff:	Surgical staff:		
	7 g/event ³²	7 g/event ³⁷		
Hand rubs (e.g.	Professionals:	Professionals:	Professionals:	Professionals:
alcoholic	Nursing staff: 1-	Nursing staff:	2534,36	2537
disinfectants)	3 g/event ³⁴	3 g/event ³⁷		
	Surgical staff:	Surgical staff:		
	7 g/event ³²	7 g/event ³⁷		
	Soaps, gel (showerin	ng)		
liquid	8.727	8.732	0.927	0.932
solid	727	732	0.927	0.932

27 RIVM, Cosmetics factsheet

28 TGD (EC 2003a): The value in the TGD for ENV was 12 g/mL per application. To harmonise this value with HH, 20 g/mL per application is proposed for ENV calculations.

29 TGD: 2-7 times per week; default 5 times per week = 0.71 times per day

30 TGD: 1-3 times per day

31 TGD: Data for facial cream: 1-2 times per day

32 Consultant proposal 33 ESD for PT 1 (2004): The value in the ESD for ENV was 3 applications per day. To harmonise this value with

HH, 4 applications per day is proposed for ENV calculations. 34 Recommendation 9 of the BPC Ad hoc Working Group on Human Exposure

35 AHEE meeting I/2016

36 Recommendation 1 of the BPC Ad hoc Working Group on Human Exposure

37 Technical Agreements for Biocides

Note: If efficacy data show that the default value is not efficacious, the efficient use rate should be applied for the amount/volume of biocidal product per application and the number of biocidal product applications per day.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

3.3 PT 2

ENV How to calculate releases from the use of biocides for the treatment ofprivate (permanent) pools?

Version 1 (WG-I-2015, WG-IV-2016)

Emission scenarios to assess the treatment of private swimming pools were developed by FR and discussed and endorsed at WG-I-2015.

The background document including the emission scenarios is provided in the CIRCABC TAB repository (entry "ENV044..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Further information on the default settings for the scenarios are provided in the following for information, reflecting the conclusions at WG-I-2015:

Number of private pools connected to the same STP (N_{pool})

Tier 1: consider 550 pools (Southern Europe)

Tier 2: consider 100 pools (Northern Europe)

If the substance fails Tier 1, a statement would need to be provided in the CAR that for product authorisation in Southern European countries the assessment needs to be refined.

For Northern European countries, a value of 100 pools should be assumed (for product authorisation).

• Consider only releases via the STP (no direct release)

For the approval of active substances, it is acceptable to assess only the releases to municipal STP and consider application to permanent installed pools.

For product authorisation an assessment for aboveground small pools (including direct release) should be performed.

Market share to be applied (F_{market})

A market share of 0.5 should be used for AS (beside substances which mode of action is based on chlorine) as first tier. The same approach as provided in other ESD should be followed (the market penetration can be lowered based on market data from the applicant). Nevertheless, the refined number of treated pools must never be lower than 1 when specific market data are used.

Acute scenario pool volume released to STP (F_{acut_rel})

A value of 33% should be used in general for permanent pools (no differentiation is made between North and South Europe).

Time period for peak emission before overwintering $(T_{acut_emission})$.

For the time period for peak emissions, a value of 60 days should be used. In the scenario however in order to simplify the calculations a value of 10 pools per day (for Southern countries) and 2 pools per day (for Northern countries) emitting during 60 days should be used.

At WG-IV-2016 it was further clarified that $F_{acut_{rel}}$ and $F_{chro_{rel}}$ are fractions and therefore dimensionless, the unit should therefore be deleted.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Disinfection of medical equipment - which default value should be used 45 for the volume of the dipping bath and the maximum number of dipping baths used for pre-disinfection dipping?

Version 1 (WG-I-2015)

It was agreed at WG-I-2015 that the following default values (provided by a French hospital expert based on expert judgement) should be used:

For the scenario dipping in hospital the eCA used;

- 1. Volume of dipping bath: 10 L (= 0.01 m³)
- 2. Maximum number of dipping bath: 30

10 L is a volume that is easy to handle using for example a trolley in a care unit or an operating room where pre-disinfection stage of the medical equipment is supposed to be done immediately after each use.

The number of dipping baths is adapted for small medical equipment supposed to be reused after pre-disinfection, disinfection and sterilization processes.

Variable/parameter	Symbol	Value	Unit	Origin	
Input					
Working concentration of active ingredient	Cdisinf		[%]	S	
Volume of solution in dipping bath	Qdipping_bat h	0.01	[m³]	D	
Maximum number of dipping bath per day	Ndipping_bat h	30	[d ⁻¹]	D	
Fraction released to wastewater	Fwater	1	[-]	D	
Output			·	·	
Emission rate to wastewater (standard STP)	Elocal _{water}		[kg.d ⁻¹]	0	
Calculation					
$Elocal_{water} = Cdisinf \cdot Qdipping_bath \cdot Fwater \cdot Ndipping_bath \cdot 10$					
Even of optry: b) Clarifications/existing guidance					

Emission scenario for pre-disinfection dipping:

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVRTU - small scale applications: Definition of default values for the size46of the area to be treated (PT 2)

Version 2 (WG-III-2015, WG-I-2017, WG-VII-2018)

For institutional areas, a default surface area of 25 m² should be used, as the area to be disinfected by small scale RTU products (e.g. spraying flacons or pre-soaked tissues).

The background document including information on the derivation of default values is provided in the CIRCABC TAB repository (entry "ENV046..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

The above noted default surface area specifically for small scale applications takes account of a certain number of applications per day, therefore the default value for "Fappl" of 1 as given in the scenario for the release of disinfectants used in industrial/institutional areas does not need to be changed in the case of RTU uses.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Emission scenario for the disinfection of aquaria 47

Version 1 (WG-IV-2016)

The most likely use pattern for a worst-case situation is the widespread use of algal control products in domestic aquaria. The route of exposure to the environment is via the STP, following routine cleaning of the individual aquaria. Home aquaria range in size from 10 L to > 200 L depending on the type of fish being kept. For emission estimation, a 100 L aquarium as a common size is considered. The routine cleaning of the individual aquaria, which involves removal of 25 % of the total water volume, is carried out every 2 to 4 weeks. This corresponds to 1.79 % of the aquarium's water being replaced on a daily basis. For determining the local emission of a.s. in biocidal products used as algal control in aquaria (PT 2), as a first step for environmental exposure assessment, the scenario is described in the following table. In line with the nomenclature of the ESDs, Fwater represents the fraction released to the STP. For the fraction of water replaced, due to the specific application of the product, an additional parameter is introduced: F_{rep} .

Emission scenario:

Variable/parameter	Symbol	Default	Unit	Origin
Input				
Aquarium volume	Vaquaria	100	L	D
Number of aquaria per STP	Naquaria	600		D

Fraction of water replaced due to product application	Frep	0.0179	d-1	D/S
Concentration of a.s. in aquarium	Caquaria		mg/L	S
Fraction of a.s. released to wastewater	Fwater	1		D
Market share	Fmarket	0.5		D
Output				
Emission rate to wastewater	<i>Elocal_{water}</i>		kg/d	
Calculation				
Elocal _{water} = (V _{aquaria} × N _{aquaria} × Frep × C _{aquaria} × Fwater × Fmarket) / 1,000,000				
Type of entry:		e) New applicable	guidance,	immediately

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Emission scenario for indoor fountain

48

Version 1 (WG-IV-2016)

The standard recommendation given for indoor fountain placement is that only distilled water should be used. The use of distilled water, alongside regular cleaning prolongs the life of the pump. In a worst-case situation, however, the most likely use pattern for a biocidal product would be the widespread use of algal control products in indoor fountains. The route of exposure to the environment is via the STP, subsequent to routine cleaning by discarding the treated water via sewage system. The size of indoor fountains can range widely from tabletop devices (30 cm high) to floor fountains (2 m high), which can hold between 2 to 10 L of water. For emission estimations, a 10 L fountain as a common size is considered. Furthermore, it is assumed that 100 % of the fountain volume is replaced and discarded on a daily basis during cleaning. For determining the local emission of a.s. in biocidal products used for algal control in indoor fountains (PT 2), as a first step for environmental exposure

assessment, the scenario is described in the following table. In line with the nomenclature of the ESDs, Fwater represents the fraction released to the STP. For the fraction of water replaced, due to the specific application of the product, an additional parameter is introduced: F_{rep} .

Emissions scenario:

Variable/parameter	Symbol	Defa	ault	Unit	Origin
Input					
Fountain volume	Vfountain	10		L	D
Number of fountains per STP	N fountain	600			D
Fraction of water replaced due to product application	Frep	1		d-1	D/S
Concentration of a.s. in fountain	Cfountain			mg/L	S
Fraction of a.s. released to wastewater	Fwater	1			D
Market share	Fmarket	0.5			D
Output					
Emission rate to wastewater	Elocal _{water}			kg/d	
Calculation					
Elocal _{water} = (V _{fountain} × N _{fountain} × Frep × C _{fountain} × Fwater × Fmarket) / 1,000,000					
Type of entry:		ه)	Now	quidance	immediately

Type of entry:

e) New guidance, immediately applicable

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Emission scenario for the disinfection of above ground small pools 49

Version 1 (WG-IV-2016)

Above ground small pools can be described as private temporary (summer only) swimming pools. These pools are expected to be completely emptied at the end of the summer season and stored over the winter months. Therefore, the season of an above ground small pool is one summer, in accordance with ESD for PT 19 this corresponds to 91 days. Draining of the pool water occurs through a valve in the pool wall or a hose over the rim of the pool. Drainage water can be released to the STP, nearby surface water, or adjacent soil.

STP: The emission pathway via STP is covered by the assessment for permanently installed private swimming pools described in the TAB, therefore a separate scenario for above ground small pools is not necessary. In case permanent pools are not relevant and only above ground small pools are assessed, the scenario for permanent pools (for peak emissions) should be used and the default pool volume should be adjusted to the volume for above ground small pools (i.e. 14 m³).

Surface water: The direct emission of private temporary swimming pools to surface waters is likely to affect water bodies similar to the 'edge of field' water bodies described in FOCUS Surface Water^[1]. Of the three water body types (pond, ditch and stream) defined in FOCUS Surface Water, a ditch is the most likely water body type to occur in the near vicinity of properties having private temporary swimming pools. The average discharge for a ditch (Flow_{ditch}) in FOCUS Surface Water is therefore 3.63 L/s. With a pool volume (V_{pool}) of 14 m³ and a drainage time (t_{drain}) of 6 hours, the discharge from the pool (Effluent_{pool}) is 0.65 L/s. The dilution and local concentration of the pool water emitted to surface water is calculated based on equation 45 and 46 in the guidance BPR IV B v1.0 (2015):

^[1] FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC, EC Document Reference SANCO/4802/2001-rev2.

$$\begin{split} & \mbox{Effluent}_{pool} = V_{pool} \ / \ t_{drain} \\ & \mbox{DILUTION} = (\mbox{Effluent}_{pool} + \mbox{Flow}_{ditch}) \ / \mbox{Effluent}_{pool} = 6.6 \\ & \mbox{Clocal}_{water} = \mbox{A}_{appl} \ / \ ((1 + \mbox{KP}_{susp} \ ^* \ \mbox{SUSP}_{water} \ ^* \ 10^{-6})^* \ \mbox{DILUTION}) \end{split}$$

Soil: The direct emission of private temporary swimming pools (14 m³) to soil depends on the drainage time and the soils infiltration rate. Depending on the size of the valve or diameter of the hose, the time needed to drain the pool ranges from several hours to a day. For emission estimations, a drainage time (t_{drain}) of 6 hours as typical is considered. It is assumed that the exposed soils are fairly permeable, corresponding to a maximum infiltration rate (f_d) of 1 m.d⁻¹ (FAO, 1985, Irrigation Water Management: Training manual – Introduction to Irrigation, <u>http://www.fao.org/docrep/r4082e/r4082e03.htm</u>). The soil area exposed to the pool's drainage water is estimated according to the following equation:

$$AREA_{soil} = \frac{V_{pool}}{f_d * t_{drain}}$$

where AREA_{soil} $[m^2]$ is the soil area exposed, V_{pool} $[m^3]$ is the pool volume, f_d $[m.d^{-1}]$ is the infiltration capacity of the soil, t_{drain} [d] is the time needed to drain the pool.

For determining the local emission to soil of a.s. in biocidal products used in above ground small pools as part of PT 2, as a first step for environmental exposure assessment, the scenario is described in the following table.

Variable/parameter	Symbol	Default	Unit	Origin
Private pool volume	V _{pool}	14	m³	D*)
Soil area exposed	AREA _{soil}	56	m²	D (see above)
Soil depth	depth _{soil}	0.5	m	D
Bulk density of soil	RHO _{soil}	1700	kg/m³	D
Application rate of a.s. in the pool water	A _{appl}		mg/L	S
Number of b.p. applications for one pool in the emission period	Nappi	1		D/S
Output				
Quantity of a.s. in pool water	Q _{pool}		kg	
Concentration of a.s. in exposed soil	C _{soil}		mg/kg	
Calculation				
$Q_{pool} = (A_{appl} \times V_{pool}) / 1000$				
C _{soil} = (Q _{pool} × N _{appl} × 1,000,000) / (AREA _{soil} × depth _{soil} × RHO _{soil})				

Emissions scenario:

*) Common pool volume is between 7 to 14 m³ (according to investigation in DIY stores). Furthermore, in the discussion table – Summary of the e-consultation on scenarios to assess biocides as PT02 for private pool treatment (Conclusions of the WG-ENV-I-2015), No. 4b. It is indicated: NL stated that inflated and metal frame pools have volumes of 10 to 14 m³ and will probably completely drained.

Type of entry:

e) New guidance, immediately applicable

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Medical sector: disinfection of endoscopes 50

Version 2 (WG-IV-2017)

In the emission scenario for calculating the release of disinfectant used for PT 2 in hospitals for the disinfection of endoscopes and other articles in washers/disinfectors (ESD PT 2 (2001), Table 3.7, p.25), the equation to calculate the maximum emission rate to water Elocal_{water} (once-through) should be:

Elocal3,water =

Nrep-max * Qmachine * 10⁻⁶* Cdisinf

With:

Elocal_{water}: Maximum emission rate to water [kg.d⁻¹] Nrep-max: Maximum number of washers/disinfectors used per day $[d^{-1}] = 3$ Qmachine: Volume of solution in machine [L] = 10 Cdisinf: Working concentration [mg.L⁻¹] kdeg_{disinf}: Rate constant for chemical conversion $[d^{-1}]$ Trepl: Replacement interval [d] The unit for the volume of solution in machine Q_{machine} is litres (L) and not m³. The unit for the working concentration C_{disinf} is mg/L.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Public swimming pool scenario 51

Version 2 (WG-V-2016)

For the emission estimation from public swimming pools (peak emission scenario provided below), with the default size as provided in the ESD (RIVM report 601450009, ESD for all 23 PTs, 2001), it was agreed that these are emptied over three days to the sewer system; i.e. only one third of the pool volume is released on one day.

Variable/parameter (unit)	Symbol	Value	Unit	Origin	
Input					
Number of visitors per day	Nvisit	400	-	D	
Concentration in swimming water	C _{proc}		kg/m³	S	
Water replaced per visitor	Vrepl	0.05	m ³	D	
Emission period	Ep	1	d	D	
Output					
Emission rate to wastewater (standard STP)	Elocal _{water}		kg/d	0	
Calculation					
Elocal _{water} = (Nvisit x Vrepl x C _{proc})/Ep					

Emission scenario for chronic releases:

Emission scenario for peak emissions:

Variable/parameter	Symbol	Value	Unit	Origin	
Input					
Water surface	AREAswim	440	m²	D	
Average depth of water	DEPTH _{swi} m	1.8	m	D	
Fraction released to STP	F _{rel}	1	-	D	
Concentration in swimming water	Cproc		kg/m ³	S	
Emission period (emission in 3 days)	Ep	3	d	D	
Output					
Emission rate to wastewater (standard STP)	Elocalwat er		kg/d	0	
Calculation					

Elocal_{water} = (AREA_{swim} x DEPTH_{swim} x C_{proc} * F_{rel})/Ep

Type of entry:

e) New guidance, immediately applicable

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Default volume for industrial premises in PT 2 when applying thebiocidal product by e.g. vaporizing or fogging? (PT 2)

Version 1 (WG-I-2017)

A value of 4 m for the room height should be used in PT 2 when applying the biocidal product by e.g. vaporizing or fogging. Taking into account a surface area of 1,000 m² according to the ESD for PT 2 (JRC, 2011), the resulting room volume to be considered for vaporizing or fogging in PT 2 is 4000 m³.

The background document including information on the derivation of default values is provided in the CIRCABC TAB repository (entry "ENV052..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV House treatment against algae

53

Version 1 (WG-I-2018)

The scenario for spraying (in line with the new proposed scenario for PT 10) and rinsing should be used for PT 2 (treatment against algae). For rinsing, only Tier 1 is relevant, Tier 2 should be deleted. Service life and removal processes should also be included. The scenario is under preparation and will be included

in the calculation sheet for PT 2 (v1.1) on the ESD ECHA webpage (<u>https://echa.europa.eu/en/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents</u>) once finalised.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Disinfection of drip irrigation systems

192

Version 1 (WG-II-2018)

The following scenario for disinfection of drip irrigation systems was agreed:

In the drip irrigation systems, emitter valves and drip lines can get clogged by biofilm formation which, in turn, results in uneven water distribution and hence yield losses. Two different approaches for disinfection of these systems can be considered.

- Curative approach (shock treatment): The drip lines are filled with water containing a.s. at given concentration, which stays in the lines for some time and is subsequently flushed out with clean water.
- Preventive approach: The a.s. is continuously applied at very low concentrations in the irrigation water, i.e. whenever the plants are irrigated.

There are two different areas of application: commercial greenhouses and commercial open fields.

As the shock treatment of drip irrigation systems only occurs sporadically, i.e. before and after the growing season, the continuous preventive approach is more relevant for the environmental risk assessment and should be further assessed. Disinfection solution used for shock treatment is also often collected and not directly emitted to soil (or after certain decay time), which significantly reduces the emissions to the environment.

Scenario 1: Disinfection of drip irrigation systems in greenhouses (indoor)

The disinfection of drip irrigation systems takes place in commercial greenhouses, where fertigation water containing plant nutrients is appliedseveral times a day for several minutes depending on plant requirements and the climatic conditions. Typically, the excess fertigation water is collected and treated for cleaning before it is released to sewerage, which leads to degradation of the a.s. Furthermore, it can be expected that a large fraction of a.s. is consumed during disinfection and further exposed to abiotic and biotic degradation processes.

Therefore, the emissions to the STP can be considered as negligible.

<u>Scenario 2: Disinfection of drip irrigation systems in agricultural fields</u> (outdoor)

The use disinfectants for drip irrigation systems in agricultural fields may lead to direct emissions to soil. For the assessment, two in-use concentrations may need to be considered:

- The injected in-use concentration. However, where the active substance is highly reactive, the derivation of the emissions to the environment from this concentration is not realistic.
- The residual concentration. Residual concentration may be considered as the realistic concentration, which is emitted to soil in cases in cases of highly reactive active substances and decay processes within the drip irrigation system.

The worst-case amount of irrigation water of 10 L/m^2 per day covering very dry areas and/or crops with a high water demand should be assumed.

Parameters	Symbol	Value	Unit	Origin	
Input					
In-use a.s. concentration (injected)	Cdisinf		[mg/L]	S	
Irrigation water per day and m^2	Virrig	10	[L/m²/d]	D	
Output	Output				
Local emission rate to soil (injected concentration)	Elocalsoil(inj)		[mg/m²/ d]		
Local emission rate to soil (residual concentration)	Elocalsoil(resid)		[mg/m²/ d]		
Calculation: Elocalsoil(inj)=Cdisinf*Virrig					
Type of entry:		e) New applicable	guidance,	immediately	
Publication date:		19/12/201	9		
Date of applicability for active substances:		19/12/201	9		

Date of applicability for products: 19/12/2021

ENV Assessment of disinfection of gloves 193

Version 1 (WG-IV-2019)

For disinfection of gloves, no separate emission scenario and assessment is needed; the emission pathway is considered to be covered by the PT 2 scenario for surface disinfection in industrial areas.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENVAssessment of disinfection of municipal waste water and/or sewage215sludge

Version 1 (WG-VII-2018, AHEE-3, AHEE-4)

Conclusions were drawn at AHEE-4 regarding the assessment of disinfection of municipal wastewater and/or sewage sludge in PT 2.

The background document including further information is provided in the CIRCABC TAB repository (entry "ENV215..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	d) New guidance, no new data requirement(s)
Publication date:	21/07/2020
Date of applicability for active substances:	21/01/2021
Date of applicability for products:	21/07/2022

ENVUse of dilution factor in surface water in the case of disinfection of221water for industrial processes

Version 1 (WG-I-2020)

In the case of direct release of disinfected industrial process water to surface water, a dilution factor of 10 should be applied to calculate the local concentration in surface water during the emission period.

Type of entry:

b) Clarifications/existing guidance

Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

3.4 PT 3

ENV Area of the animal housing to be considered for the application 54

Version 1 (WG-III-2014)

Application by **foaming** or **spraying**: In a first tier assessment <u>all</u> surfaces in the respective animal housing, provided in Table 8 of the ESD for PT 3 (page 51), should be considered. It is acceptable as second tier to take label information on reduced treatment areas in an animal housing into account.

Application by **fogging**: Depending on the information provided on the product label, either the volume of the animal housing (see default values in the ESD for PT 18) or the surface area should be considered. For the calculation of the surface area, <u>all</u> surfaces in the respective animal housing, provided in Table 8 of the ESD for PT 3 (page 51), should be taken into account.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Capacity of dipping bath in PT 3

55

Version 1 (WG-III-2014, WG-IV-2016)

For the capacity of dipping bath in PT 3 a default value of 100 L was considered as a realistic worst case for the disinfection of small items of equipment in livestock farming environment. Several smaller dipping tanks may also be used in the same location (e.g. $4 \times 25 L = 100 L$). The number of applications in one year should remain 365, representing a worst case.

The full scenario for dipping of tools (based on the scenario for disinfection of footwear for veterinary hygiene; ESD for PT 3: Emission scenarios for veterinary hygiene biocidal products; (JRC Scientific and Technical Reports,

2011), section 2.4.1) is provided in the CIRCABC TAB repository (entry "ENV055..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVDefault values for formaldehyde and paraformaldehyde in the ESD for56PT 3

Version 1 (WG-III-2015)

In the pick list for the amount of active ingredient *Qa.i.appl* ($g.m^{-3}$) for disinfection of hatcheries used as defaults for various types of disinfectants (Table 6b), the default value for Formaldehyde should read 7 $g.m^{-3}$ and the default value Paraformaldehyde should read 1.2 $g.m^{-3}$.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Disinfection of vehicles: soil emission

57

Version 1 (WG-II-2016)

It is not necessary to assess direct emission to soil from disinfection of vehicles used for animal transport. The scenario is not included in the ESD and treatments are usually done on hard standing.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Disinfection of pet case and litter trays: soil emission 58

Version 1 (WG-II-2016)

Direct emission to soil from disinfection of pet case and litter trays does not need to be assessed, since disinfection of pet cases and litter trays is usually performed indoors.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Water volume in the reservoirs / tubs in hoof disinfection scenario 59

Version 1 (WG-IV-2016)

For hoof disinfection, an additional default value has been agreed for the disinfection with mats: a default value of 60 L b.p./100 animals should be used for *V* reserv. The number of fillings per day (*N*tub_filling) should not be changed compared to the standard scenario for hoof disinfection (i.e. remain twice a day).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Calculation of nitrogen and/or phosphate immission standards 60

Version 1 (WG-IV-2016)

For active substance approval it is sufficient to provide a risk assessment only based on **nitrogen** immission standards.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Teat disinfectant products for other animals than cows 61

Version 1 (WG-V-2016)

The ESD for PT 3 (and PT 18) as well as the corresponding guideline for Veterinary Medicinal Products (EMEA/CVMP/ERA/418282/2005-Rev.1-Corr.^[1]) does not provide default values for relevant parameters for e.g. buffaloes, sheep and goats.

For products intended to be used on e.g. buffaloes, sheep and/or goats the following was agreed:

Cows are considered worst-case with reference to teat disinfection, as herds are larger than herds of buffaloes, sheep and goats. In addition cows have a higher number of teats compared to other dairy species like sheep and goats, resulting in a lower consumption per treatment.

In conclusion, the default values provided for cows are realistic case to cover also buffaloes, sheep and goats.

^[1]http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009 /10/WC500004386.pdf

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Applicability of the AHEE recommendation for PT 18 to PT 3 62

Version 1 (WG-IV-2017)

"Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems, ENV/JM/MONO(2006)4" (2015) is applicable to PT 3 uses with the following aspects being confirmed specifically:

- Tmanure-int_{ar2} (manure storage time arable land in new scenario) should be derived from applicant's data as a period between two subsequent insecticide treatments (specific for PT3: between two disinfectant applications) in the animal housing assuming that Tar-int will be equal to Tbioc-int. Note thatTar-int should also be derived from the applicant's data as a period between two subsequent treatments in the animal housing, assuming thatTar-int will be equal toTbioc-int. This applies to situations when degradation in manure is not taken into account.
- Nlapp-grass (number of land applications for grassland per year) of 4 is equally relevant for PT 18 as well as PT 3.
- The land application interval for grassland Tgr-int of 53 days is applicable to PT 3.
- Sections 3.2-3.6 of the Addendum (2015) establishing PEC/PIECsoil calculation routines are applicable to PT 3 (including any changes to these sections to be agreed for PT 18 also in the future).

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENVDefault value for a dairy cowherd size and consideration of lactation63period

Version 1 (WG-I-2018)

The number of days of the lactation period for dairy cows (corresponds to the number of emission days) is indicated in Table 3a ESD for PT3 (2011) with *Nday-lact* (=*Temission*) = 300. This value is used for release estimation to the STP (ref. to Table 3d), where the calculation for local emission to a standard STP or an on-site waste water treatment plant *Qai-stpi1,i2,i3,i4* =*Elocalwaste water* (see Table 3b) is based on *Nanimali1* = 100 dairy cows corrected by a factor *Temission*/365.

In HEAdhoc Recommendation no. 13, the lactation period of dairy cows is also taken into account for exposure estimation: the value for the number of milk producing cows is refined to 82.

 \rightarrow "100 (cows) * 300/365 = 82.2 = 82 milk producing cows per day".

Such a "correction factor" or comparable factor for consideration of realistic worst case number of cows producing milk in a model housing is currently not used for release estimation to slurry.

Modification of the equation[1] for calculation of the amount of active ingredient $Qai_{i1,i2,i3,i4}$ in the relevant stream i4 = slurry/manure after one application for all animals:

$$Qai_{i1,i2,i3,i4} = F_{slurry/manure} \times Qai - prescr_{i1,i2,i3} \times N_{mp_animal}$$

With

Parameter	Symbol	Value	Unit	Origin
Fraction of a.i. released to slurry/manure	Fslurry/manure	$1-F_{teat} = 0.5$	-	D
Amount of active ingredient to be used for one application (one treatment of one animal)	-		kg	0
Number of milk producing animals per day	Nmp_animal ^{*)}	82 ^{*)}	-	D/S

*) in case of dairy cows the value should be equal to 82, whereas in case of b.p. specifically designed for further animal types (e.g. buffaloes, sheep) another value might be defined/set

^[1] Table 3c in the ESD for PT 3: https://echa.europa.eu/documents/10162/16908203/pt3_veterinary_hygiene_en.pdf/ 949c57b2-a511-48bb-acf3-72cf58c526de

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENVNumber of milking events per day/consideration of pre- and post-64milking events

Version 1 (WG-I-2018)

In HEAdhoc Recommendation no. 13, it is stated that in general, teat disinfection is performed either pre- or post-milking. However, as a worst-case, it is considered that teat disinfection takes place pre- and post-milking, unless the intended uses clearly proposes either pre- or post-milking only. Taking into account 2 milking events per day per cow, a total number of 4 teat disinfection events per day per cow have to be assumed.

To harmonise environmental and human health exposure estimation and to map a realistic worst-case the following modifications were agreed (parameter from Table 3a, chapter 2.3.4 in ESD PT3 (2011)):

Variable/parameter	Symbol	Value	Unit	Origin
Number of teat dipping events for one animal and one day (dipping of four teats of one animal = one disinfectant event application)				D/S
 Manual milking: in case of both pre- and post- milking application and 2 milking events per day 	Napp- teat	4	[-]	D/S
 Robot milking: both pre- and post milking application and 3 milking events per day 		6	[-]	
Number of disinfectant applications in one year (equals number of disinfectant applications in one lactation period)	<i>Nарр-</i> bioc	=Napp-teat × Nday-lact	-	0
Interval between two disinfectant applications	Tbioc- int ¹)	= 1d/ Napp- teat	d	0

1) For the calculation result it is irrelevant whether pre- and post-milking is expressed as disinfection events close to each other (pre- and post-milking) or as separate, equally distributed disinfection events.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018

Date of applicability for products: 29/08/2018

ENV Emission to sewer for different animal categories 194

Version 1 (WG-IV-2019)

In line with the agreements for PT 18 (see TAB entry on "Environmental exposure pathways from poultry houses"), in case the scenario 2.1 (disinfection of animal housings) has to be assessed, a.s. emission to the sewer system should only be considered for poultry stables (animal (sub)categories 8, 11, 12, 16 - 18).

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Disinfection of animal housing - assessment approach for the 220 disinfection of calf igloos

Version 1 (WG-I-2020)

In the "ESD for product type 3: Veterinary hygiene biocidal products" (EUR 25116 EN, 2011) no emission scenario for the assessment of calf igloos in chapter 2.1 "disinfection of animal housings" is available. The default parameters of the animal (sub)category 'veal calf' are not appropriate to cover this intended use, as calf igloos are located on dairy farms. Therefore a new emission scenario was developed and agreed.

The document containing the full emission scenario is provided in the CIRCABC TAB repository (entry "ENV220..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	10/12/2020
Date of applicability for active substances:	10/12/2020
Date of applicability for products:	10/12/2022

ENVAreas for indoor disinfection of non-domestic veterinary healthcare252scenarios

New!

Version 1 (AHEE-7)

For the indoor disinfection of non-domestic veterinary healthcare premises (such as veterinary cabinets, animal shelters and kennels), in situations not covered by the animal housing scenarios, only releases to STP are considered. Two areas to disinfect are proposed depending on the intended use and the application method:

- Small-scale application in veterinary healthcare sector (for trigger spray/wipes only): an area of 25 m² is considered disinfected per day.
- Large-scale application in veterinary healthcare sector (for all application methods on surfaces): an area of 1000 m² is considered disinfected per day. In case of fogging/fumigation, a value of 2500 m³ is proposed (considering a room of 2.5 m height).

The number of applications per day is set to 1 by default as the proposed areas already consider potential multiple applications. The total surface considered for treatment is per STP.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENV Spray/foam disinfection of outer surfaces of animal transport vehicles 253 – supplement to the existing PT 3 scenario on interior disinfection of vehicles for animal transport

New!

Version 1 (AHEE-7)

The supplement to the existing PT 3 scenario on interior disinfection of vehicles for animal transport - Spray/foam disinfection of outer surfaces of animal transport vehicles was agreed at AHEE-7 and is provided in the CIRCA TAB repository (entry "ENV253xx..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022

Date of applicability for products:

14/10/2022

ENV Default values for an emission scenario for disinfection of wheels of vehicles for animal transport via drive-through basin

New!

Version 1 (AHEE-7)

The default values for an emission scenario for disinfection of wheels of vehicles for animal transport via drive-through basin was agreed at AHEE-7 and is provided in the CIRCA TAB repository (entry "ENV254xx..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2024

3.5 PT 4

ENV Which default value should be used for Fmainsource and Temission when 65 calculating the annual amount of active substance used in an industrial food processing plant via the tonnage based approach?

Version 1 (WG-III-2014)

In an ad-hoc follow-up post WG-III-2014 it was concluded that for $F_{mainsource}$ a value of 0.05, considering a 10 % (generic) market share, and for $T_{emission}$ a value of 231 days (according to the ESD for PT 4) should be used when calculating the annual amount of an active substance used in a food processing plant using the tonnage-based approach as calculation aid. This value for $F_{mainsource}$ was calculated to cover worst case emissions from large plants.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which volume should be considered for slaughterhouses/large kitchenin case application is performed by e.g. fogging/smoke generation?

Version 1 (WG-V-2014)

Since the ESD for PT 4 refers to a surface area to be disinfected, the default values need to be converted to a volume in case of e.g. fogging or disinfection by smoke generators. The following default values for room volumes have been agreed at WG-V-2014:

- <u>Slaughter house</u>: 50,000 m³: assuming a surface area of 10,000 m² multiplied by a room height of 5 m (reference for room height:<u>http://www.fao.org/docrep/003/x6509f/X6509E01.htm</u>, see there page 3 and Annex I)
- Large kitchen: 6,000 m³: assuming a surface area of 2,000 m² multiplied by a room height of 3 m.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVRTU - small scale applications: Definition of default values for the size67of the area to be treated (PT 4)

Version 1 (WG-III-2015, WG-I-2017)

The following default values for the surface areas to be disinfected by small scale RTU products (e.g., spraying flacons or pre-soaked tissues) should be used:

Large scale kitchens: a default surface area of 50 m^2 should be used, corresponding to 2.5% of the total kitchen area of 2000 m^2 .

Slaughterhouses: a default surface area of 10 m² should be used, corresponding to 0.1% of the total slaughterhouse area of 10000 m².

The background document including information on the derivation of default value is provided in the CIRCABC TAB repository (entry "ENV067..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869 Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Breweries: cleaning frequency

68

Version 1 (WG-V-2016)

The following default value for the cleaning frequency in breweries have been agreed:

For small breweries, cleaning takes place once per week and 43 weeks/year, corresponding to a number of emission days of 43 d/yr.

For medium size breweries the default values provided in the ESD should be used.

For large breweries, cleaning takes place 10 times per day and 300 days/year, corresponding to a number of emission days of 300 d/yr.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Wine barrel disinfection scenario

69

Version 1 (WG-IV-2017)

The following emission scenario is based on the example of a substance, which is applied in gas form. If it is shown in the future that also application of liquid products is relevant, the default values for F_{air} and F_{water} need to be rediscussed.

Emission scenario:

Parameter	Symbol	Value	Unit	Origin
Input				

Amount of product applied	Qdisinf		L	S	
Concentration of active substance in product	Cdisinf		mg/L	S	
Volume wine barrel	Vbarrel	225	L	D	
Number of barrels	Nbarrel	60	-	D	
Fraction emitted to (waste)water	F _{water}	0	-	D	
Fraction emitted to air	Fair	1	-	D	
Number of applications	Napplication	1	d-1	D	
Output					
Concentration of active substance in barrel	Cas		mg/L	0	
Volume treated	Vtreated		L ⁻¹	0	
Local direct emission rate per winery per day	Elocal _{air}		mg/d	0	
Calculation					
Cas = Qdisinf * Cdisinf / V _{barrel}					
V _{treated} = V _{barrel} * N _{barrel}					
Elocal _{air} = Napplication * C _{as} * V _{treated} * Fair					

Type of entry:

e) New guidance, immediately applicable

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVAssessment of private use of disinfectants used in food and feed areas70

Version 1 (WG-I-2018)

Parameter	Symbol	Value	Unit	Origin		
Input						
Application rate of the biocidal product	Q_{appl}		g/m²	S		
Concentration of active substance in biocidal product	C _{form}		g/g	S		
Number of households feeding one STP	N _{houses}	4000		D		
Fraction of households using product	Fhouse	0.1	-	D		
Disinfected surface area of a private kitchen	AREA _{surfac}	2	m²	D		
Number of applications	Nappl	1	1/d	D		
Fraction released to wastewater	F _{water}	1	-	D/S		
Fraction released to air	Fair	0	-	D/S		
Penetration factor of disinfectant	Fpenetr	0.5	-	D		
Output		·				
Local release to waste water	Elocal _{water}		g/d	0		
Local release to air	Elocal _{air}		g/d	0		
Calculation						
$\label{eq:constraint} Elocal_{water} = C_{form} * Q_{appl} * Nlocal * F_{house} * Nappl * AREA_{surface} * Fpenetr * F_{water}$						
$Elocal_{air} = C_{form} * Q_{appl} * Nlocal * F_{house} * Nappl * AREA_{surface} * Fpenetr * F_{air}$						
Гуре of entry:		e) New applicable	guidance,	immediately		
Publication date:		29/08/201	.8			

The following emission scenario was agreed:

Type of entry:	e) New guidance, immediately applicable
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018

Date of applicability for products:

01/08/2020

ENV Refinement of default value for Felim

195

Version 1 (WG-I-2018, AHEE-2)

The WG agreed to the use of a general default Felim value of 0.7 in PT 4 applications with on-site treatment, for substances with a Kow of \geq 10000.

The WG agreed to keep a default value of 0.9 for Felim for rapidly reacting substances, to be discussed on a case by case basis e.g. if a substance is rapidly reacting (e.g. oxidizing substances).

If Felim is used, it should be stated that eliminating techniques are in place as RMM.

It was further agreed that the above conclusions should be applied as a potential refinement for all scenarios in PT 4, besides if specifically breweries or the disinfection of wine barrels are considered, since fat separators are not relevant in these cases. Note that, although Felim is not relevant for breweries, it is relevant for the current scenario "CIP Breweries" in case this scenario is used for the assessment of milk industries.

In addition, the WG agreed that a restriction to apply the agreed default value for Felim to a surface area of above 2000 m2 is not needed, since in several member states fat separators are also in place in small kitchens/restaurants.

The background document including further information is provided in the CIRCABC TAB repository (entry "ENV195..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/08/2019
Date of applicability for active substances:	02/08/2019
Date of applicability for products:	02/08/2019

ENV Release to manure from milking parlour disinfection 196

Version 1 (WG-II-2019)

For disinfectants used in milking parlour systems, the assessment of the emission via manure also needs to be performed, using the available emission scenarios from the ESD for PT 3.

Type of entry:	e) New guidance, immediately applicable
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2021

ENV Exposure scenario for disinfection of separative membranes in dairyand beverage industries

Version 1 (WG-II-2019)

The use is considered as CIP treatment, the cleaning processes are assumed to always take place under closed system conditions. The main route of exposure to the environment is via the sewer system, disinfectants end up in a sewage treatment plant.

Parameter	Symbol	Value	Unit	Origin/ Remarks	
Concentration of the active substance in the application solution	C _{a.i.}		[g/L]	S	
Volume of the circuit	V _{form}	4500	[L]	D, The volume of the circuit is identical to the total amount of application solution used.	
Number of disinfection events per day	Nappl		[d ⁻¹]	S	
Fraction released to wastewater	F _{water}	1	[-]	D	
Fraction of substance eliminated due to on site pre-treatment of the plant wastewater	F _{elim}	0	[-]	D	
Fraction of substance disintegrated during or after application (before release to the sewer system)	Fdis	0	[-]	D	

Output						
Local Emission to wastewater	Elocal		[kg/d]		0	
Calculation $E_{local} = 0.001 \bullet C_{a.i.} \bullet V_{form} \bullet Nappl \bullet (1 - F_{dis}) \bullet (1 - F_{elim}) \bullet F_{water}$						
Type of entry: e) New guidance, immediate applicable					immediately	
Publication date:			19/12/2019			
Date of applicability for acti	ve substance	s: 19/	12/2019			
Date of applicability for pro	ducts:	19/	12/2021			

ENV Splitting of releases of disinfectants used in entire plants (e.g. 198 breweries, dairies, beverage processing plants) (ESD PT 4, table 5) Updated!

Version 2 (AHEE-3, AHEE-7)

For the entire plants scenario, it is sufficient to assess only one STP including biological treatment. An on-site STP without biological treatment is considered unrealistic. However, the specification of the STP should then follow the specification of the standard municipal STP according to the BPR Vol IV Part B+C (2017) and TAB ENV 9. For the CIP scenario evaluating breweries it was concluded that there is no evidence that the splitting of releases from breweries with regard to on-site and off-site treatment is realistic and it should therefore not be taken into account.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENVDisinfection dipping scenario for medium to small-scale applications217

Version 1 (WG-V-2019)

Emission scenario agreed for the assessment of dipping-disinfection for medium- to small-scale applications:

Variable/parameter	Symbol	Value	Unit	Origin	
Input					
Concentration of active substance in the dipping bath	Cform		g/L	S	
Volume of solution in a dipping bath	V_{bath}	100	L	D	
Number of sites using the disinfection solution connected to the same STP	Nappi	5	[-]	D	
Fraction of substance disintegrated during or after application (before release to the sewage system)	F _{dis}	0	[-]	D (ESD PT 4)	
Fraction of substance eliminated due to onsite pre-treatment of wastewater	Felim	0	[-]	D (ESD PT 4)	
Fraction released to wastewater	F _{water}	1	[-]	D (ESD PT 4)	
Output					
Local emission to wastewater	Elocal _{wate} r		kg/d	0	
Calculation					
$Elocal_{water} = C_{form} \times V_{bath} \times N_{appl} \times (1-F_{dis}) \times (1-F_{elim}) \times F_{water}$					
Type of entry:		e) N applica	ew guidano able	ce, immediately	
Publication date:		02/02,	/2021		
Date of applicability for active substances: 02/02/2021					

Date of applicability for products: 02/02/2023

ENV Revised emission scenario for large breweries

222

Version 1 (AHEE-3, AHEE-5)

The use of a disinfectant in large breweries was previously discussed and the question was raised how to include the release to on-site and off-site sewage treatment plants (STP) in the emission calculations. It was agreed to split up the release to on-site/off-site STP in the case of large breweries, but it was noted that the relevance of the proposed values for an EU wide situation should be further investigated.

A proposal for an adapted generic method to calculate the emission of biocides from breweries was agreed at AHEE-5.

The background document including the revised emission scenario is provided in the CIRCABC TAB repository (entry "ENV222..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	d) New guidance, no new data requirement(s)
Publication date:	18/09/2020
Date of applicability for active substances:	18/03/2021
Date of applicability for products:	18/09/2022

3.6 PT 5

ENV Total water consumption per occupied hospital bed 71

Version 1 (WG-V-2016)

For the disinfection of hospital water, the hospital scenario for PT 1 (Emission scenario for calculating the releases of disinfectants in hospitals based on an average consumption, ESD for PT 1, Table 4.5) can be used as basis, applying the following default value for the water consumption per occupied bed: 0.7 $m^3/d.$

Emissions scenario – hospital drinking water systems:

Parameter	Symbol	Value	Unit	Origin
Number of beds in model hospital	Nbed _{pres}	400	[-]	D
Occupancy rate	Foccup	0.75	[-]	D
Fraction released to wastewater	Fwater	1	[-]	D

Total water consumption per occupied bed	Qwater _{occ} up_bed	0.7	m³/d	D
Concentration in water	Cproc		kg/m³	S
Output				
Emission rate to wastewater (STP)	Elocal _{water}		kg/d	0
Calculation				
Elocal _{water} = Nbed _{pres} x Foccup x Fwater x Qwater _{occup_bed} x Cproc				
Type of entry:		b) Clarifica	tions/existing	guidance
Publication date:		29/08/201	8	
Date of applicability for active subs	stances:	29/08/201	8	
Date of applicability for products:		29/08/201	8	

ENVRevision of the emission scenario for drinking water disinfectants228

Version 1 (AHEE-5)

The current ESD calculates a concentration while subsequent mdoelling with SimpleTreat requires a daily discharge in kg. This is fixed by a revised equation.

The current ESD for drinking water disinfectants (final version 2003) overestimates emission to the STP as dilution with rainwater is not included.

A default city with 10 000 inhabitants produces 2000 m³ wastewater daily from which 600 m³ concerns rainwater, which results in a voluem of drinking water discharged daily of 1400 m³.

Parameter	Symbol	Value	Unit	Origin
Input				
Concentration active substance in drinking water	Cdrinking water		mg.L ⁻¹	S
Volume drinking water discharged daily	Vdrinkingwat er	1400	m ³	D
Degradation rate constant of active substance in the sewer	k		h ⁻¹	S

Residence time in the sewer	Т	1	h	D
Output				
Local emission to waste water	Elocal _{wate}			0
Calculations				
$Elocal_{water} = 0.001 \times C_{drinkingwater}$	er X Vdrinking	water $X e^{-kT}$		
Type of entry:		b) Clarifica	tions/existing	guidance
Publication date:		02/02/202	1	
Date of applicability for active subs	stances:	02/02/202	1	
Date of applicability for products:		02/02/202	1	

ENV Disinfection of drinking water for animals 229

Version 1 (AHEE-5, WG-IV-2020)

The emission scenario is in general an update of existing PT03-scenarios with additional data on drinking water consumption.

The amount used for one application (Qai_prescri, kg/d) is estimated by multiplying these volumes of consumed drinking water with the efficacious concentration in the drinking water and the fraction of water that is spilled by the animals. The amount to the manure (Qai) and PECs are subsequently calculated according to the ESD for PT03 including the addendum PT18 and accompanying additions.

In a first tier, for the emission factor to manure/slurry via spilled drinking water a default value of 0.9 should be used. This value includes both release via urine and spillage, without accumulation in animal bodies. Also spillages during mixing/loading are covered.

For very reactive and/or oxidative active substances, a qualitative assessment is sufficient as no active substance might reach the environment

Refinement is possible when the absence of the active substance in urine is demonstrated: it was agreed to apply 20% spillage for cows and pigs (=> emission factor of 0.2), which is a realistic worst case for cows, and the average of the range for pigs. For poultry, which are predominantly nipple drinkers, a value of 14.5% spillage (=> emission factor of 0.145) was agreed.

The emission scenario including the agreed default values is provided in the CIRCABC TAB repository (entry "ENV229..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2023

ENV Disinfection of stored drinking water in mobile water tanks 230

Version 1 (AHEE-5, WG-IV-2020)

Emission from preserved water in mobile water tanks in e.g. campers, caravans, and pleasure crafts is calculated as follows:

Parameter	Symbol	Value	Unit	Origin
INPUT				
Concentration in drinking water	C _{form}		mg.L ⁻¹	S
Application interval	T _{int}		d	S
Number of water tanks	Ntank	231	-	D
Volume of the water tank	V_{tank}	50	L	D
Fraction of water tanks to which biocides are added	F_{tank}	0.5	-	D
Fraction of active substance disintegrated during or after application (before release to the sewer)	Fdis	0	-	D
Fraction released to the waste water	F _{water}	1	-	D
OUTPUT				
Local emission to waste water	Elocal _{wate} r		kg.d ⁻¹	0

CALCULATIONS:

Elocalwater = Cform X Ntank / Tint X Vtank X Ftank X (1-Fdis) X Fwater X 10⁻⁶

Type of entry:	e) New guidance, immediately applicable
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2023

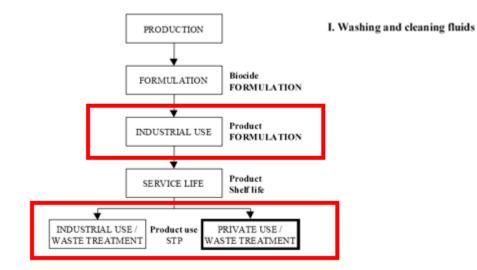
3.7 PT 6

3.7.1 PT 6 - general items

ENV Do product formulation and product use have to be evaluated?72

Version 1 (TM IV 2008)

Both phases (product formulation and product use) have to be assessed as illustrated in the figure below.



Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which approach should be used for the exposure assessment of PT 6?73 Which IC/UC category from the TGD has to be used?

Version 1 (TM IV 2008)

For the product formulation stage the tonnage approach has to be used for the assessment. With regard to the IC/UC category, a worst-case approach based on the proposed uses by the applicant shall be followed. The worst-case approach then would consist of:

- 1. considering the uses applied for;
- 2. investigating, for example via a sensitivity analysis using EUSES, which IC/UC category leads to the highest emissions;
- 3. assuming the whole tonnage applied for as input value for the assessment.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV How should the sub-categories and sub-scenarios for PT 6 during product use be numbered?

Version 1 (TM IV 2008)

The following numbering of sub-categories and sub-scenarios should be used:

- 6.1. Washing and cleaning fluids and human hygienic products
 - 6.1.1 Washing and cleaning fluids (human hygienic products)
 - 6.1.2 Washing and cleaning fluids (general) and other detergents
- 6.2 Paints and coatings (P, N)
- 6.3 Fluids used in paper, textile and leather production (P)
 - 6.3.1 Fluids used in paper production (P)
 - 6.3.2 Fluids used in textile production (P)
 - 6.3.3 Fluids used leather production (P)
- 6.4 Metal working fluid

6.4.1 Lubricants (P)

6.4.2 Machine oils (P)

6.5 Fuel

6.6 Glues and adhesives

6.7 Other

If an applicant has identified a use as "6.7 Other", then the applicant must extensively describe its use and emission routes.

Type of entry:

a) Editorials/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVDo in-can preservatives used in cosmetics fall into the scope of the BPD75(BPR)?

Version 1 (TM I 2011)

It has been agreed that emissions of in-can preservatives applied to prolong shelf-life of cosmetics for the risk assessment in PT 6 is outside of the scope of BPR.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVDo emissions from waste disposal of biocidal products have to be76evaluated under the BPR?

Version 1 (TM I 2011)

It is not necessary for this specific PT. Any disposal issue may be addressed appropriately by the relevant EU and/or national legislation.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

3.7.2 PT 6.1 Washing and cleaning fluids, human hygienic products and detergents

ENV Which type of risk assessment should be considered?

77

Version 1 (TM I 2011)

For "washing and cleaning fluids" it is not advised to use the worst-case ESD as most appropriate solution. Cumulative risk assessment should be considered. It should be done by summation of all single uses. Or simplified tonnage-based approach (with 100% release to STP for all uses with this emission pathway) could be considered. If this show no risk, detailed calculation will not be necessary.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Summing up of emissions from uses in PT 6.1 Washing and cleaning fluids, human hygienic products and detergents

New!

Version 1 (WG-II-2021)

In the risk assessment of PT 6 uses in "Detergents and cleaning fluids", the emissions from uses in 6.1.1 Human hygienic products (non-professional users) are not to be added to the emissions from the uses in 6.1.2 Detergents. That is, the assessment of 6.1.1 is independent of 6.1.2.

Type of entry:	b) Clarifications/existing guidance
Publication date:	11/11/2021
Date of applicability for active substances:	11/11/2021
Date of applicability for products:	11/11/2021

3.7.3 PT 6.2 Paints and coatings

ENV Which emission scenarios are more appropriate for the risk assessment evaluation?

Version 1 (TM I 2011)

The general scenarios (e.g. tonnage approach) do not cover all specific emission pathways. Therefore, the risk for some environmental compartments may be underestimated (e.g. emission to soil). To overcome this, specific scenarios (e.g. for PT 8, PT 10 and PT 21) selected on a case-by-case basis should be used. However, it should be kept in mind that in order to use the above mentioned ESD several specific parameters, e.g. theoretical coverage of the paint needed for PT 21, daily flux or fluid application rate needed for PT 8 or 10, should be provided by the applicant.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Are leaching tests required for paints and coatings?

79

Version 1 (TM I 2011)

Leaching tests are not necessary. Assumption that the emission occurs during Time 1 represents the worst-case.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

3.7.4 PT 6.3 Fluids used in paper, leather and textile production

Paper production

ENV Which additional ESDs can be considered for emission calculations?80

Version 1 (TM I 2011)

For paper application several scenarios are available:

- EU TGD (EC 2003a) IC-12 Pulp, paper and board industry. Assessment of the environmental release of chemicals used in the pulp, paper and board industry.
- EUBEES (2001) PT 6, 7 and 9 Biocides used as preservatives in paper coating and finishing. Assessment of the environmental release of biocides used in paper coating and finishing.
- RIVM/NL and FEI/Finland ESD for biocidal products applied in the paper and cardboard industry (Van der Poel and Braunschweiler 2002). This ESD is described in detail in document Harmonisation of Environmental Emission Scenarios for Slimicides (product type 12) EUBEES 2003 (Van der As and Balk 2003)
- OECD (2009) ESD No. 23. Emission Scenario Documents on pulp, paper and board industry.

Additionally, there are other 3 ESDs concerning paper industry:

- OECD ESD No. 15 (ESD on Kraft Pulp Mills, 2006),
- OECD ESD No. 16 (ESD on Non-integrated Paper Mills, 2006) and
- OECD ESD No. 17 (ESD on Recovered Paper Mills, 2006).

However the EUBEES (2001) is the preferred one as first tier. Degree of closure of the water system is not included into calculation in OECD (2009) document. This may overestimate the emission.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which default parameters should be used for the risk assessment if nospecific information by the applicant is given?

Version 1 (TM I 2011)

The following default values shall be used:

- Q_{paper} = 449 t/d (according to EUBEES scenario);
- F_{fix} = 0 (according to EUBEES scenario);
- F_{closure} = 75% (value for newsprint according to EUSES scenario).

Concerning the Q_{active} , the problem is the number of additive types used in a realistic worst-case paper mill: around 20 for stock preparation and 15 for the paper machine, with different concentrations in in-can preservatives. Thus, no default value is proposed; instead it is proposed to deduce the concentration of PT6 substance in these additives using efficacy data. Additives used in paper mills are listed in the ESDs.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

Textiles production

ENV Which additional ESDs can be considered for emission calculations?82

Version 1 (TM I 2011)

For textile production several scenarios are available:

- EU-TGD (EC 2003) IC-13 Textile processing industry;
- EUBEES (2001), Emission scenario document for biocides used as preservatives in textile processing industry (PT 9 and PT 18);
- OECD 2004. Emission scenario document on textile finishing industry.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which is the value to be used for the fixation rate (Ffix) for textile in-83 can preservatives?

Version 1 (TM I 2011, WG-II-2015)

Active substances in PT 6 are not intended to preserve textiles therefore a fixation factor of 0 is proposed as a worst case.

As a consequence, the service life of in-can preservatives in preserved textiles does not need to be assessed.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which values are to be used for the calculation of releases from different application steps?

Version 2 (TM I 2011, WG-II-2014)

The following default values are proposed (TM I 2011):

- Amount of additive applied per tonne of textile (*Q*_{product}) =
- For pre-treatment: 120 kg/t of fabric (as product used in textile industry)
- Efficacious preservative concentration in additive (*Q_{active}*) will be deduced from the efficacy data and the *Q_{product}*.
- Quantity of fibre/fabrics treated per day $(Q_{textile}) = 13 \text{ t/d of a.s.}$

N.B.: At WG-II-2014 the default value for $Q_{product}$ was corrected from 20 to 120 kg/t: the value of 120 kg/t for pre-treatment step, represents the combined value for preparation agents (= 20 kg/t) and sizing agents (= 100 kg/t) provided in Table 10 of the OECD ESD on textile finishing industry (OECD 2004).

Concerning the fraction of fabric treated with product containing the substance of interest, two different values are proposed, 0.3 (default in ESD) and 1 as a worst case.

Type of entry:

b) Clarifications/existing guidance

Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

Leather production

ENV Which additional ESDs can be considered for emission calculations for85 leather production?

Version 1 (TM I 2011)

For leather in-can preservatives several scenarios are available:

- EU-TGD (EC 2003) IC-7 Leather processing industry;
- EUBEES (2001), Emission scenario document for biocides used as preservatives in textile processing industry (PT 9).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVWhich is the value to be used for the fixation rate (Ffix) for leather in-86can preservatives?

Version 1 (TM I 2011)

Active substances in PT 6 are not intended to protect leather therefore fixation factor of 0 is proposed as a worst-case.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which is the value to be used as Qactive for leather in-canpreservatives?

Version 1 (TM I 2011)

The Q_{active} cannot be set by default, but it would probably be useful to set a $Q_{tanningproducts}$ (kg/t leather) which would represent an average quantity of products used for the tanning process.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

3.7.5 PT 6.4 Metal Working Fluids (MWF)

ENV Which additional ESDs can be used to evaluate PT Metal Working Fluids (WMF)?

Version 1 (TM I 2011, WG-IV-2017)

The ESD for PT13 is the first choice to calculate emission of a.s. used to preserve MWF during shelf-life. Additionally, using the EU-TGD ESD for IC 8 can be considered as a possibility to calculate emissions. Since applicants do not have detailed knowledge concerning the use of the preserved products the worst case agreed for a.s. in PT 13 should be used (fraction of concentrate in processed liquid should be 0.2).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

3.7.6 PT 6.5 Fuels

ENV Which additional ESDs can be used to evaluate PT 6 Fuels?

89

Version 1 (TM I 2011)

EU-TGD IC 9 ESD for the Mineral oil and fuel industry (EC 2003a) is proposed as first choice to calculate emission of in-can preservatives of fuels.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Do emissions of fuels have to be calculated if the fuel ends up in anengine?

Version 1 (TM I 2011)

For fuel ending up in an engine, it is assumed that 100% of the substance will be burnt thus, emissions should not be considered.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

3.7.7 PT 6.6 Glues and adhesives

ENV Which additional ESDs can be considered for PT 6: Glues and 91 adhesives?

Version 1 (TM I 2011)

The general tonnage scenario and the TGD- scenarios (for glues and adhesives UC 2) can be used. ESD for PT 7 should be also considered.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which input values should be used to calculate fractions of activesubstance reaching the STP if no data is available?

Version 1 (TM I 2011)

If no data is available, calculations should be performed using 50%, 10% and 1%.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

3.8 PT 7

ENV Service life to be considered for coating? 93

Version 1 (WG-IV-2015)

For the exposure assessment of industrially applied film preservatives using surface treatments (e.g. automated spraying or dipping), a service life of 15 years should be considered for Time 2, in line with the default value provided in the OECD ESD for PT 8.

Vacuum treatment is not foreseen for coatings in PT 7, therefore, no default value is proposed.

For in-situ treated commodities by amateurs/professionals, a service life of 5 years should be considered for Time 2, in line with the default value provided in the OECD ESD for PT 8.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Leaching rate to be used for the assessment of storage phase 94

Version 1 (WG-III-2015)

For the assessment of the two storage phases (initial and longer period), the leaching rate calculated for Time 1 should be used for both storage phases, i.e. for the initial as well as the longer period.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Time period for the service life for the storage place (Time 2) 95

Version 1 (WG-IV-2015)

For the service life for the longer storage period on a storage place, i.e. Time 2, a default value of 7300 days (i.e. 20 years) should be used, which corresponds to the average life span of an industrial treatment plant.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Time period for the service life for the storage place (Time 2) 181

Version 1 (WG-IV-2015)

For the service life for the longer storage period on a storage place, i.e. Time 2, a default value of 7300 days (i.e. 20 years) should be used, which corresponds to the average life span of an industrial treatment plant.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

3.9 PT 8

ENV How should the PEC surface water be calculated for industrially treated96 wood or industrial on-site storage?

Version 1 (TM I 2006, TM II 2006, TM III 2006)

The emissions from run-off and STP discharge during the application and storage stages of wood treatment shall be added up, in order to calculate the PEC for surface water as these processes occur at the same time in industrial plants. The correction for absorption to suspended matter shall be made where relevant.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Is the fence scenario for wood preservatives always required?

97

Version 1 (TM III 2005, WG-I-2015)

The house-scenario is the worst case scenario (for the soil compartment) and would therefore be sufficient.

This is also reflected in the OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2 - Revised Emission Scenario Document for Wood Preservatives (2013), where worst case scenarios for in-situ treatment and treated wood in service have been defined as follows:

In-situ treatment (soil compartment):

• Worst case for UC 3): House (see chapter 4.2.4.1)

Treated wood in service (soil compartment):

- Worst case for UC 3: House (see chapter 4.3.3)
- Worst case for UC 4a: Transmission pole (see chapter 4.3.4)

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV What is the house density for the assessment of groundwater 98 contamination resulting from the application to and leaching from houses treated with wood preservatives?

Version 1 (TM III 2006, WG-I-2015)

In reference to the revised OECD ESD for PT 8 (OECD, 2013) a number of 16 houses per ha has to be used. Each of the 16 houses is assumed to have an outer wooden area treated with wood preservatives and relevant for leaching of 125 m^2 , resulting in a total (leachable) area of 2000 m² per hectare.

Please refer to: OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2 - Revised Emission Scenario Document for Wood Preservatives (2013): Supplement to Appendix 4 – Scenario for the groundwater exposure assessment for wood preservatives preservatives (link: https://echa.europa.eu/documents/10162/16908203/pt8en.pdf/ddbc2a33-4fcb-47e1-a01f-6c79403a457e groundwater assessment).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Are two different DT50 values needed, one for TIME 1 and a different99 one for TIME 2, to calculate PECsoil?

Version 1 (TM I 2007)

The highest DT50 value should be used to represent the realistic worst case.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Extrapolation of the leaching results to longer time period (TIME 2).100 How should it be done?

Version 1 (TM I 2007)

The long term leaching rate (LR) should be calculated based on the last LR measured in the leaching test. When performing these extrapolations it shall be taken into account that the leached amount does not exceed the applied amount of active substance.

Several options for determination of leaching loss at Time 2 are listed in the minutes following the 2nd Leaching Workshop in Varese, Italy (see document embedded in ENV 90).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV How is the exposure scenario for Professional in-situ spraying defined?101

Version 1 (TM II 2007, WG-I-2015)

A scenario for professional outdoor in-situ spraying was included in the revised OECD ESD for PT 8.

Please refer to: OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2 - Revised Emission Scenario Document for Wood Preservatives (2013), chapter 4.4.5.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Should the bridge over pond scenario for UC3 be included in the CAReven if this is not proposed as an intended use by the applicant?

Version 1 (TM IV 2012, TM I 2013)

The bridge over pond scenario is not used to evaluate the application phase but the use phase, in order to describe the emission pathway into open water bodies, and should therefore be included in the CAR.

Please note that a new scenario covering the risk from in-situ application (e.g. brushing) as well as the leaching from treated timber near or above static water bodies was developed and is provided in the revised OECD ESD for PT 8. This revised scenario should be used for the bridge over pond calculations (1000 m^3) in connection to active substance approval as well as at product authorisation.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVWhen is the assessment of risks to groundwater from on-site storage103necessary?

Version 1 (TM II 2006)

Risks to ground water from on-site storage need to be assessed, even when there is no risk identified for the soil compartment for the industrial scenario since the leaching behaviour and persistence of a substance might still result in a risk for groundwater.

In the case of storage of treated wood (scenarios for industrial preventive processes), a groundwater assessment is not needed if risk mitigation measures are described and applied to prevent losses to soil (e.g. impermeable, hard standing and recovery of leachate as well as covering the storage place by roofs).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Summary of conclusions of the 2nd EU Leaching Workshop 104

Version 1 (TM III 2013, WG-I-2014)

The summary of conclusions of the 2^{nd} EU Leaching Workshop was prepared as an interim solution and contains the conclusions on those items discussed at the 2^{nd} EU Leaching Workshop which have been endorsed at TM III 2013 and WG-I-2014. Remaining open topics will be followed up at a later time point.

The background document is provided in the CIRCABC TAB repository (entry "ENV104..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Acceptability of the current methods to assess the exposure/risk of wood preservatives (PT 8)

Version 1 (WG-III-2015)

The current methods to assess the exposure/risk of wood preservatives (PT 8) were considered as being acceptable enough to derive a realistic worst case PEC value for the soil compartment. Therefore, the exposure assessment should remain as it is currently performed and no change is needed.

It was stated in addition that the item can be re-discussed again if requested by the BPC/CA meeting.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Default flow rate for creek adjacent to a storage place 106

Version 1 (WG-III-2016)

For calculation of $PEC_{surface waters/industrial storage}$, as flow rate of an adjacent creek a default value of 0.3 m³/s should be used.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Bunded storage sites: Need of an assessment of release to the STP 107

Version 1 (WG-III-2016)

For bunded (sealed) storage places, an STP assessment needs to be conducted unless the standard RMM for PT 8 is applied.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVShould the city scenario be applied for PT 8 to cover the release via108STP?

Version 1 (WG-IV-2016)

There is no need to apply the city scenario for PT 8, neither as 'stand-alone' scenario, nor in combination with the storm-water scenario. For the assessment of the release to the STP from in-situ treatment (service life stage) the noise barrier scenario should be used.

The background document including further information is provided in the CIRCABC TAB repository (entry "ENV108..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Wood treated with short term antisapstain 109

Version 1 (WG-V-2016, BPC-17)

The short term antisapstain treatment falls under the scope of the BPR. Assessment of emission during service life of treated wood needs to be performed unless there is proof that there is no emission to the environment.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Clarification on the text of the RMM for PT 8

110

Version 1 (WG-III-2016, BPC-17)

The following revised proposal for the RMM text was agreed: "... and that freshly treated timber shall be stored after treatment under shelter **or** on impermeable hard standing, or both, to prevent direct losses to soil, **sewer** or water, and that any losses of the product shall be collected for reuse or disposal".

It was further noted that there are new alternative methodologies under development (e.g. covering the ground with adsorbing materials), however for the time being they will not be reflected in the RMM.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Time period for the service life for the storage place (Time 2) 111

Version 1 (WG-IV-2017)

For the service life for the longer storage period on a storage place, i.e. Time 2, a default value of 7300 days (i.e. 20 years) should be used, which corresponds to the average life span of an industrial treatment plant.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Groundwater assessment for UC 4 112

Version 1 (WG-IV-2017)

The lack of harmonised guidance on groundwater assessment for UC 4 scenarios (both soil and groundwater) were flagged with regard to transmission poles and fence posts. A number of issues are identified why groundwater determination would be difficult, but no assistance is given in the current guidance like e.g. the area of wood per hectare for UC 4.

It was agreed that the scenario for railway sleepers should be used as a first tier to assess the exposure to the groundwater compartment for UC4.

Type of entry:	d) New guidance, no new data requirement(s)
Publication date:	29/08/2018
Date of applicability for active substances:	01/03/2019
Date of applicability for products:	01/08/2020

ENVTreated wood in service UC 3 - 4 - Vsed default value for bridge over113pond scenario and jetty in a lake scenario

Version 1 (WG-IV-2017, WG-II-2020)

Vsed should have the following default values in equations 3.18/3.19 of the OECD ESD PT 8:

i) For the bridge over pond scenario (treated wood in service UC 3) – Vsed = $3 m^3$, based on a 3 mm sediment layer and a pond surface area of 1000 m²

ii) For the jetty in a lake scenario (treated wood in service UC 4b) – Vsed = 23.56 m^3 , based on a 3 mm sediment layer and a diameter of 100 m.

 V_{sed} is part of the ESD mass balance equation for a 3 phase static pond system (water, suspended matter, sediment) used to calculate a refined $PEC_{surface water}$. PEC_{sed} is also part of this mass balance.

Type of entry:

b) Clarifications/existing guidance

Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

ENVDipping immersion processes, Qai conversion factor (from kg.m⁻² to114kg.m⁻³)

Version 1 (WG-IV-2017)

The quantity of a substance applied per m^3 of wood (Q_{ai} , kg.m⁻³) is a set value, usually however provided in kg.m⁻². To convert the quantity of a substance applied from kg.m⁻² to kg.m⁻³ the application rate in kg.m⁻² should be multiplied by a factor of 40 (worst case).

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Assessment of temporary anti-sapstain wood-preservatives 199

Version 1 (WG-II-2018, WG-III-2019)

The tiered assessment approach for temporary anti-sapstain preservatives from the 2nd EU Leaching Workshop in Varese (2013) was agreed to be substituted by the approach described in the document "PT 8: Assessment of temporary anti-sapstain wood-preservatives" which is provided in the CIRCABC TAB repository (entry "ENV199..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Note that for general preventive treatment also against wood-discolouring fungi, the existing OECD ESD scenarios for UC 3 in PT 8 should be used (and not the "Pallet scenario").

Type of entry:	d) New guidance, no new data requirement(s)
Publication date:	18/10/2018
Date of applicability for active substances:	18/04/2019
Date of applicability for products:	18/10/2020

ENV How to handle sampling points below LOD/LOQ in leaching studies? 201

Version 1 (WG-III-2019)

When the measured concentrations for an active substance are below the LOQ in the leachate in a leaching study, the LOQ or LOD could be used (provided that the test results are reliable/reproducible). If the signal is between LOD and LOQ, the higher one (i.e. LOQ) should be used to calculate the leaching (i.e. as the value measured in the leachate). No sampling points should be excluded.

General recommendation: check if results are reliable, e.g. check if the issue could be the topcoat and secondly check if any adsorption/degradation in the test vessel took place. Check if there are no experimental artefacts and if the analytical method is reliable.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV PEC surface water and PEC sediment 209

Version 1 (WG-I-2018, AHEE-3)

The linked recommendation clarifies questions on how PEC_{surface water} and PEC_{sediment} should be calculated for scenarios with static water bodies in PT 8 (bridge over pond, jetty in a lake) given the equations in the ESD for PT 8. The recommendation explains the basis of the ESD equations, which is a 3-phase mass balance system with linear emission input and first order output. No new elements have been added to this 3-phase mass balance model as compared to the ESD. An excel sheet exemplifies all calculations.

The model results in a PEC for surface water by taking into account dissipation to suspended matter and bulk sediment. The resulting concentration is $PEC_{surface water,dissolved}$. PECsediment is calculated from this dissolved water concentration using standard equilibrium partitioning (eq. 53 from BPR Guidance Vol IV, part B & C). The recommendation also provides corrected versions of equations 3.18 and 3.19 from the ESD as an error was noted in these (Recommendation, Annex B). It is noted that the agreed recommendation no longer uses these equations in the original form. They have been reworked into one equation that suits four emission options described below. It is also noted that the ESD PT 8 only presents equations for the time averaged concentration (viz. eqs. 3.16 to 3.19). The recommendation provides equations for both situations: a concentration at TIMEx (x = 1, 2 or

3) as well as a concentration averaged over time. Please note that it was agreed not to average the PECs over the assessment period (see ENV 186).

Four options are discerned that may occur in the emission scenario. These options are described and clear instructions for calculations of $PEC_{surface}$ water, dissolved and $PEC_{sediment}$ are provided in the linked recommendation. In summary:

- There is prolonged emission after wood treatment (application phase not included here) and there is no information on degradation or degradation does not occur;
- 2. There is only one emission event (the application phase). This results in an initial concentration, hence degradation is not taken into account;
- 3. There is prolonged emission after wood treatment (application phase not included here) and there is data on degradation;
- 4. There is an initial emission event after wood treatment (application phase) followed by prolonged emission and there is data on degradation.

In case degradation is taken into account, the DT50 value for the whole system from water-sediment studies or the DT50 value from aquatic degradation studies should be used, since dissipation to sediment and suspended matter is covered by taking into account Ksed-water and Kpsusp, respectively.

Equations 3.16 and 3.17 (ESD PT 8) are now covered by option 3 in the recommendation. It is noted that the ESD only presents equations to calculate the time averaged concentration (3.16, 3.17 as well as 3.18 and 3.19). The recommendation provides equations for both situations: time averaged concentration and concentration at TIMEx.

The background document is provided in the CIRCABC TAB repository (entry "ENV209..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

ENVAssessment of wood used in vineyards - Adapted default values to be216used in the fence post or transmission pole scenario of UC 4a

Version 1 (WG-I-2020)

The WG agreed that the following adjusted default values for the treated area and related soil volume can be used to assess the treatment of vineyard posts with wood preservatives (scenario as such to be used: fence post or transmission pole scenario for UC 4a in PT 8):

The mean diameter of the end/line posts used in vineyards is typically 9.36 cm so, with a radius of 4.68 cm, the volume of a typical 2.25 m long post would

be $\prod x 4.68^2 x 225 = 15482 \text{ cm}^3$ (0.01548 m³). Only 0.8 m of each post is treated (0.25 m above ground and 0.55 m below ground), representing only 5505 cm³ (0.0055 m³).

- Surface area of treated post above ground: ∏ x 9.36 x 25 = 735 cm² (0.0735 m²)
- Surface area of treated post below ground: (∏ x 9.36 x 55) + (∏ x 4.68²)
 = 1686 cm² (0.1686 m²)
- Volume of post below ground: $\prod x 4.68^2 \times 55 = 3784.5 \text{ cm}^3$

Volume of soil around the treated post at EU level is based upon a distance of 0.5 m (vertically and horizontally) from the post. The volume occupied by soil is:

• $[(\prod x (4.68 + 50)^2 x (50 + 55)] - 3784.5 = 982500 \text{ cm}^3 (0.9825 \text{ m}^3)]$

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

ENVSeparate assessment of UC 4 depending on receiving environmental218compartment

Version 1 (WG-III-2019)

The following conclusion of the PT 8 expert group meeting in 2019 was confirmed by the ENV WG:

Although the definition of use classes (UC) for wood has changed as described in EN 335:2013 - there is only one combined use class 4 ("Exterior in ground contact and/or freshwater") - it is still acceptable to assess for UC 4 the environmental compartments separately, according to the former UCs 4a and 4b in the ESD. To create clarity for applicants, reference is made to the ISO guideline ISO 21887:2007, on which the use classes in the ESD were defined at the time, the ESD was revised.

It is considered important that in the case e.g. only soil is covered (former 4a), the surface water compartment (former 4b) needs to be covered by an RMM (e.g. do not use the wood in direct contact with surface water), since the overall approval will be still only for one UC 4. Treated timber should be labelled accordingly.

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

ENV Use of leaching data from laboratory leaching studies for UC 4 in UC 3and vice versa

Version 1 (WG-II-2019)

Leaching information on use class (UC) 4 can be used for UC 3, considering the same application method for the wood treatment, if no information is available for UC 3 and UC 4 test is seen as protective (e.g. validate by comparing with other UC 3 leaching data performed with a comparable product).

However, the other way round is not possible: UC 4 leaching test results represent the worst case as the treated wood is completely immersed in water in the UC 4 tests, thus leaching is assumed to be higher compared to UC 3 tests.

A correction for the retention needs to be performed.

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

3.10 PT 9

ENV Which tent density per hectare can be used for PECgroundwater 115 calculations?

Version 1 (TM III 2013)

At TM III 2013 it was agreed to consider 150 tents per hectare for groundwater assessment. The number is based on an internet search. If sufficient information of tonnage data is supplied a market share of 0.5 can be applied to the number of tents.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Use scenarios for PT09 roof membranes 116

Version 1 (WG-III-2014)

The document "Use-based approaches for the estimation of environmental exposure due to roof membranes" was developed by DE, first introduced at TM IV 2013 and endorsed at WG-III-2014.

It can be found on the ESD specific ECHA webpage, PT 9: <u>http://echa.europa.eu/guidance-documents/guidance-on-biocides-</u><u>legislation/emission-scenario-documents</u>

Type of entry:

d) New guidance, no new data requirement(s)

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Preservation of shoes in shoeboxes - emission scenario 117

Version 1 (WG-IV-2017)

The emission scenario is based on the example of an in-situ generated active substance. Substance specific measured values or output values have been deleted for the purpose of including the scenario in the TAB.

The background document including the emission scenario is provided in the CIRCABC TAB repository (entry "ENV117..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	01/08/2020

3.11 PT 10

ENV Which input values should be used to calculate emissions reaching the118 STP for the city-scenario in PT 10?

Version 1 (TM III 2010, TM II 2012, TM IV 2012, TM II 2013, TM III 2013, TM IV 2013)

The document "*City scenario: Leaching from paints, plasters and fillers applied in urban areas*" was developed by NL and endorsed at TM IV 2013.

It can be found on the ESD specific ECHA webpage, PT 10: <u>http://echa.europa.eu/guidance-documents/guidance-on-biocides-</u><u>legislation/emission-scenario-documents</u>

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV City scenario - calculation of number of houses in which the product is expected during application (indoor applications)

Version 1 (WG-IV-2017)

 $N_{\text{house},\text{applic}}$ should be calculated by the formula below and the result should be rounded up to the nearest integer:

$$N_{house,applic} = \frac{N_{house} * F_{house}}{service \ life * 365}$$

 N_{house} = number of houses in a city (4000)

 f_{house} = fraction of the houses on which paints, plasters, or fillers are applied (market share = 1.0);

Service life = service life of the preserved products (yr)

365 = number of days in a year (d.yr⁻¹)

The text in the document "City scenario: Leaching from paints, plasters and fillers applied in urban areas" (page 6) should be amended as follows:

"The number of houses treated daily depends on the service life of the product. For paints and joint sealants having a service life of 5 years 800 houses are treated annually when assuming that the product is applied on 100% of the houses in a city. Although this may suggest that 2.2 houses are

painted daily, $N_{house,applic}$ have to be three houses per day to compensate for days that are not suitable for painting because of the temperature and/or precipitation.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Which soil volume should be considered for the countryside housescenario for PT 10?

Version 2 (WG-IV-2017)

Regarding the soil volume for ESD PT 10, setting "building located in the countryside" the already agreed values for the evaluation of the soil compartment for PT 8 were used. $V_{soil(a)}$ and $V_{soil(d)}$ based on a soil depth of 50 cm for "brushing" and "spraying".

For all PT 10 products an increased soil volume can be accepted for risk assessment (see RCOM_ENV (No. 49) Competent Authority Report of Nonanoic Acid (PT 10) (11-2012) 7/16.

For the assessment of "spraying" application in PT 10 and similar applications in other PTs (e.g. PT 2, PT 6, PT 7), the scenario provided for outdoor in-situ spraying in the OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2 - Revised Emission Scenario Document for Wood Preservatives (2013), chapter 4.4.5, should be used also. The scenario for PT 8 should be used as a first tier for PT 2, PT 6 and PT 7. The first tier can be revised (e.g. default values for F_{drift} and F_{run-off}) based on further information provided in the frame of concrete cases.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Spraying application – dimensions of the receiving soil compartment 121

Version 1 (WG-IV-2017)

The value of 6.9 m is the distance travelled by drift, i.e. it is the maximum distance, which can be reached by spray considering a total height of release of 4.25 m (i.e. height of the façade 2.5 m + height of the roof 1.75 m).

Therefore, the actual total width of the receiving soil compartment should be maximally 6.9 m. Consequently, if the width of the adjacent soil is 50 cm, the width of the distant soil should be 6.9-0.5 = 6.4 m.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Refinement of the cumulative leaching by taking into account 122 Fweatherside for the city scenario

Version 1 (WG-II-2015)

The WG agreed when calculating emissions using the city scenario, the fraction of house surface exposed to weather ($F_{weatherside} = 0.5$) provided in the Supplement to Appendix 4 in the OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2 - Revised Emission Scenario Document for Wood Preservatives (2013) should <u>not</u> be taken into account.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Rinsing of houses

123

Version 1 (WG-I-2018)

The scenario for "rinsing" as provided in the ESD for PT 10 is no longer considered relevant and does not need to be calculated.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

3.12 PT 11

ENV Conclusions on the environmental assessment of biocides in PT 11 124 cooling water systems

Version 1 (TM III 2011, TM IV 2013)

The document "*Note: Environmental assessment of biocides in PT 11 cooling water systems*" was developed by NL and endorsed at TM IV 2013.

It can be found on the ESD specific ECHA webpage, PT 11: <u>http://echa.europa.eu/guidance-documents/guidance-on-biocides-</u><u>legislation/emission-scenario-documents</u>

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVEmission to surface water from small open recirculating cooling125systems

Version 1 (WG-V-2016)

If the use in large open recirculating cooling systems is not relevant and not assessed or if the use is assessed but results in an unsafe use, direct discharge to surface water should be assessed for small open recirculating cooling systems.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVClosed cooling system – drainage of the system and treatment as126hazardous waste

Version 1 (WG-II-2017)

It was questioned if it can be assumed as refinement that the system is completely drained and the content is collected for treatment by a specialised waste water treatment company.

It was agreed that the collection of cooling liquid and disposing it off as hazardous waste is an acceptable assumption for a RMM in the case of closed cooling system in PT 11.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Refinement options for PT 11

202

Version 1 (AHEE-2)

<u>STP connection</u> and treatment of cooling water before release to surface water should be only considered for small recirculating cooling systems.

A<u>pond</u> as risk mitigation measure to refine the exposure of PT 11 was proposed, and it was agreed that the pond can be an acceptable RMM. However, it would need to be verified case by case if this RMM is acceptable for the specific substance.

Direct discharge to a settling pond is not addressed by the ESD for PT 11. A settling pond can be modelled by a one box-model with a constant source (influent) and first order decay in the pond.

The maximum concentration in the settling pond effluent corresponding to a steady state situation can be derived:

C = (Q * Cinfluent) / (Q + kV).

Alternative equation leading to equal results:

$$HRT = \frac{V}{FLOW}$$
$$C = \frac{C_{in}}{1 + k \cdot HRT}$$

Where:

٦

FLOW = Qbld

 $V = V_{\text{pond}}$

Г

HRT: Hydraulic retention time in pond

C_{in}=concentration in blowdown water

C = steady state concentration in pond

The main variable affecting the concentration of a substance in the effluent is the residence time in the pond, thus the size of the pond. To date no standard size for settling pond can be suggested, as these are of site-specific design. The following table presents the default values to support the risk assessment of **large** cooling towers.

Input parameters for calculating the local emission – Large recirculating tower, direct discharge to a settling pond			
Variable: Large recirculating tower	Symbol	Value	Units
Influent concentration in blowdown water	Cinfluent		[mg/L]
Blowdown flow rate for large cooling towers	Q _{bld}	3000	[m ³ .d ⁻¹]
Blowdown flow rate for small cooling towers	Qbld	48	[m3.d ⁻¹]
Volume of pond for large cooling towers	V _{pond}	60 000	[m ³]
Volume of pond for small cooling towers	Vpond	5 000	[m3]
Degradation rate in water (12°C)	k		[d-1]
Effluent concentration at steady state	C_{pond_eff}		[mg/L]
Dilution factor to surface water (high)	DL1	1000	[-]
Dilution factor to surface water (low)	DL2	200	[-]
Concentration of suspended matter in the river	SUSPwater		[mg/L]
Solids-water partition coefficient of suspended matter	Kpsusp		[L/kg]

Local concentration in the receiving water compartment	Clocal, water		[mg/L]
Steady-state concentration in the pond effluent = $C_{pond_{eff}} = (Q_{bld} \times C_{influent}) / (Q_{bld} + k \times V_{pond})$ Steady-state concentration in the receiving compartment (surface water) = $Clocal$, water = $C_{pond_{eff}} / ((1 + Kpsusp \times SUSPwater \times 10^{-6}) \times DL)$			

With regard to the approach to consider large scale open cooling towers under control by other legislations it was agreed that it is not sufficient to refer only to control by other legislation.

Type of entry:	d) New guidance, no new data requirement(s)
Publication date:	19/12/2019
Date of applicability for active substances:	19/06/2020
Date of applicability for products:	19/12/2021

ENVTime frame for the assessment of PT 11 products for the Preservation232of wood treatment solutions (in wood treatment systems)

Version 1 (WG-I-2021)

A service-life of 365 days should be used to conduct the exposure assessment for PT 11, covering wood treatment systems. It is assumed that 100% of the active substance applied is leached out within the 365 days, in case no leaching data is available.

Additionally, a short-term assessment of 30 days (assuming 50% leaching if no leaching data is available) should be conducted. RCRs derived for both assessment periods should be considered for decision making.

Type of entry:	b) Clarifications/existing guidance
Publication date:	22/07/2021
Date of applicability for active substances:	22/07/2021
Date of applicability for products:	22/07/2021

3.13 PT 12

ENVHow to address the use and discharge of offshore chemicals from oil127platforms?

Version 1 (TM II 2003)

The CHARM model (developed under OSPAR) is applicable for estimating emissions of slimicides from oil platforms and is recommended in the ESD for PT 12.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVCan the dilution factor from STP to adjacent surface water be increased128for PT 12?

Version 1 (WG-II-2014)

For PT 12 the same river flow rates as provided in the paper of NL for PT 11 related to the waste water production in the paper industry should be used to calculate the dilution factor (see "*Note: Environmental assessment of biocides in PT 11 cooling water systems*"; ESD specific ECHA webpage, PT 11: http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents)

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Default values for slimicides in offshore processes

129

Version 1 (WG-II-2017)

Different default values are provided in the ESD and the document "Environmental risk assessment for biocides applied in the offshore oil exploration industry" (https://echa.europa.eu/documents/10162/16908203/esd pt 11<u>12</u> final en.pdf) for the parameters average water depth around the platform and dilution factor for batchwise discharges.

It was agreed that the default values provided in the document "Environmental risk assessment for biocides applied in the offshore oil exploration industry" should replace the respective default values in the ESD for PT 12:

- average water depth around the platform: 20 m instead of the default value 150 m in the ESD;
- dilution factor for batchwise discharges: 1000 instead of the default value 13000 in the ESD.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Input for degradation – Hydraulic retention times 203

Version 1 (WG-III-2019)

The parameter hydraulic retention time Ttreat in Table 5.3 on p. 43 of ESD for PT 12 (and Table C on p. viii) is not correct. According to the original scenario described on p. 74 Table 4.2 in the ESD, the parameter T_{treat} should be divided into two parameters:

- hydraulic retention time for primary settling Tps = 0.167 d and
- hydraulic retention time for chemical/mechanical treatment Tcm = 0.167 d.

This leads to changes of the following formulas of the ESD for PT 12 on p. 44 and p. viii:

 $Clocal_{effl-treat} = C_{infl-ps} * (1 - F_{ads,settling} - F_{ads,cm}) * e^{-kdeg2*(Tps+Tcm)}$

 $Clocal_{infl-WWTP} = C_{paper}*(1-F_{ads,settling})*e^{-kdeg1*(Tpr+Tps)}$

This mistake was noted in the scope of EUSES validation.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Degradation in PT 12 (paper industry) 238

New!

Version 1 (WG-IV-2021)

As for PT 11, also for PT 12 in general only abiotic degradation (e.g. hydrolysis) should be taken into account in the paper mill system (during paper making process).

If studies of sufficient quality are available showing further degradation in the paper mill system (e.g. biodegradation), it can be agreed on a case-by-case basis if the respective information is taken into account.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

3.14 PT 13

ENV Should Cinfl calculations be based on the total Fsplit (= Fsplit,evap + 130 Fsplit,kow)?

Version 1 (WG-II-2017)

It was agreed that both reduction approaches should be taken into account and be calculated (Fsplit,evap and Fsplit,kow) but they need to be evaluated separately, i.e. they should not be summed up in a total Fsplit. In addition, both approaches need to result in a safe use (i.e. for approval it is not sufficient if only one of the procedures shows a safe use).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVFraction of MWF concentrate in diluted MWF fluid (Fconc)131

Version 1 (WG-IV-2017)

The fraction of metal working fluid (MWF) concentrate in the diluted fluid is not a property of the active substance, but depends on the instructions given by the manufacturer of the fluid depending on its composition and purpose. Therefore, this parameter should be a default (D) instead of a variable (S/P). In the ESD for PT 13, the range of default values for F_{conc} is between 0.05 and 0.2, with 0.05 being the worst case as the lowest amount of active substance will be removed from the aqueous phase during phase separation.

For active substances that are dosed via concentrates, no defaults can be given, as the worst-case now depends on the substance hydrophobicity and could be every value between 0.05 and 0.2. For hydrophilic substances, 0.2 is worst-case as this results in the maximum mass of substance in the system. For hydrophobic substances, however, 0.05 is worst-case. If the biocide is applied via a concentrate (and not used as a ready to use product) the worst case F_{conc} should be used depending on the K_{ow} of the active substance.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Calculation of degradation of biocide since last dosing 132

Version 1 (WG-IV-2017)

On the calculation of "degradation of biocide since last dosing", a realistic time span between last dosing and the start of waste treatment ("t") can only be given for waste management companies. The calculation of $F_{elim,storage+more}$ applies only for waste management companies and this refinement should not be used for end-users/on-site treatment.

The time span between last dosing and the start of waste treatment ("t") should be a set value and no default value should be defined.

As a guidance, reference was made to the questionnaire in the ESD where a value of 7 days was provided for the shortest storage period in case of disposing off the MWF to an external WWTP.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018

Date of applicability for products: 29/08/2018

ENV Storage of fluids - DT50/kdeg

133

Version 1 (WG-IV-2017)

For the purposes of calculating $F_{\text{elim,storage+more}}$, kdeg (or DT 50) should be derived from the following studies:

Tier 1: Use the DT50 from the hydrolysis study.

Tier 2: Use the DT50 from a degradation test in MWF.

Biodegradation is not applicable here as the microbial density in the MWF is not high enough.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

3.15 PT 14

ENV Can the default release factor (1% as recommended in EUBEES) to 134 estimate direct releases during application and use of a rodenticide be lowered to 0.1%?

Version 1 (TM I 2006)

When justified by data on releases of the formulation (e.g. paste formulations), the release factor can be lowered.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Should primary mechanical screening (sieves) of the STP be taken into account for PT 14? Can the PEC in surface water be reduced by a certain factor and if so, what will be the value for that factor?

Version 1 (TM I 2006, TM III 2006)

In a first tier, the ESD shall be followed, implying no removal in a STP. If data is provided, this information can be used in a qualitative way, if a second tier is needed.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Lipid normalisation for anticoagulant rodenticides 136

Version 1 (WG-I-2016)

Lipid normalisation should in general not be performed for anticoagulant rodenticides when the substances accumulates mainly in the liver.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Bioconcentration factor (BCF) for anticoagulant rodenticides

137

Version 1 (WG-I-2016)

For the derivation of the BCF for rodenticides with high *K*ow, a bioaccumulation study with dietary exposure is more relevant than an aqueous exposure bioconcentration test. Either an aquatic dietary exposure test or a soil bioaccumulation test would be therefore preferred. This is due to the exposure

via terrestrial food chain: rodenticides do not enter the food chain via passive uptake by partitioning at the lowest level, but via active uptake of feed at higher trophic levels. A non-lipid-normalized kinetic BCF is preferred for anticoagulant rodenticides in general when the substances does not primarily accumulate in the lipid tissue.

In addition, existing monitoring data on residues of the rodenticide in nontarget species need to be taken into account as weight-of-evidence information.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVGroundwater assessment for rodenticides (including hot spot138applications)

Version 1 (WG-IV-2016)

A groundwater assessment should always be performed for rodenticides, also in cases when only hot spot applications are considered. For rodenticides and their metabolites, the same threshold values as for other biocides apply.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Assessment of bank slopes emission scenario

180

Version 1 (WG-II-2020, AHEE-5)

The scenario "bank slopes" from the ESD for PT 14 should be evaluated when uses in "open area" as well as "in and around buildings" are claimed and it shall be assessed at the active substance approval stage.

If the use of rodenticides is not allowed on national level near open water, then the scenario can be omitted during product authorisation at national level.

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

3.16 PT 15

ENV Clarification on default values in the ESD for PT 15

139

Version 1 (WG-IV-2016)

The value to be used for the parameter $AREA_{soil}$ " (ESD section 2.4.2.3), i.e. the "Exposed area under a treated nest (nest + surrounding surface), is 0.3317 m²

In the ESD page 39, Elocal_{water} calculation (equation 12), it should read 10^{-6} instead of 10^{6} .

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

3.17 PT 18

ENV Biocidal product applications in slurry/manure storage systems in 234 exposure assessment of PT 18

Version 1 (WG-I-2021)

The OECD ESD No. 14 PT 18 Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (2006), Appendix 5 distinguishes between slurry ("wet") and manure ("dry") storage systems depending on the animal (sub)category. Sometimes, product applications may talk about "indoor" vs. "outdoor" but the ESD is not clear whether the description "indoor"

also means manure/slurry storage systems below the actual housing area. Therefore, in case of b.p. use descriptions "under the slatted area" or "manure storage systems below the stables" or "indoor" the following should be adhered to:

- For animal (sub)categories 1-7, 10, 13-15 the surface area of rectangular slurry tanks should be used for the assessment (defaults as provided in Appendix 5 of ESD PT18 No. 14).
- For animal (sub)categories 8, 9, 11, 12, 16-18 the surface area of manure heaps should be used for the assessment (defaults as provided in Appendix 5 of ESD PT18 No. 14).

For manure heaps (animal (sub)categories 8, 9, 11, 12, 16-18) both indoor and outdoor storage systems should be considered in the environmental exposure assessment. Therefore, in case of b.p. use description "dry storage" or "manure heaps", the assessment is independent of the use description "indoor" or "outdoor". But the use description should be distinguished from those b.p. applications described in Table 5.3. In Table 5.3 default areas for manure storage inside the housings are mentioned like e.g. manure belts which are in the stable where the animals are kept.

Type of entry:	b) Clarifications/existing guidance
Publication date:	22/07/2021
Date of applicability for active substances:	22/07/2021
Date of applicability for products:	22/07/2021

3.17.1 Household and professional use

ENVDistinction between "crack and crevice" and "spot" applications144(indoor)

Version 1 (WG-IV-2017)

The following definitions were agreed:

- Spot application (domestic houses): treatment of a restricted surface of 2 $$\rm m^2$$
- Barrier treatment (domestic houses): larger scale treatment, >2 m² (i.e. 10 m long stripe, width depends on the application device)
- Crack and crevice treatment depends on the way the product is applied: it can be either applied as a spot application or a barrier treatment. Depending on the way of application, the default surface area of either spot application or barrier treatment should be used in combination with the cleaning efficiency for cracks and crevice treatment.

Type of entry:b) Clarifications/existing guidancePublication date:29/08/2018

Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Use of treated water for irrigation of private gardens 205

Version 1 (AHEE-2)

The emission scenario for the use of treated water for irrigation of private gardens (exposure of soil compartment) is provided in the CIRCABC TAB repository (entry "ENV205..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	02/08/2019
Date of applicability for active substances:	02/08/2019
Date of applicability for products:	02/08/2021

ENV Emission scenario for Aircraft disinsection 206

Version 1 (WG-IV-2019)

The scenario was prepared by UK in the frame of an active substance and was confirmed to be used for such uses in a general way at WG-IV-2019.

The background document including the emission scenario is provided in the CIRCABC TAB repository (entry "ENV206..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2021

Household and professional use - general items

ENV Emission estimation for insecticides for household and professional uses – general treatment

Version 2 (WG-IV-2017)

Number of houses:

- For outdoor use a number of 2500 households will be used;
- For indoor use a number of 4000 households will be used as default

Surface of a standard house: A surface area of a standard house of 130 m² is considered as default for general treatment. A wet cleaning zone leading to a release to the STP of 38.5 m² will be used. This surface area of 38.5 m² relates to the wet cleaning zone in a private household and is not related to specific rooms like kitchen and bathroom.

Number of commercial buildings: For the number of commercial buildings 300 will be used as default, for both indoor and outdoor use (commercial buildings include hotels).

Number of hospitals: No separate assessment for hospitals will be included. The number of commercial buildings of 300 is considered to include also hospitals.

Surface of commercial buildings: For the surface area to be treated for general treatment the default value is 609 m^2 .

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Safe use approach in product authorisation

141

Version 1 (WG-IV-2017)

The "safe use approach" cannot be applied for PT 18. Products need to be authorised for general surface treatment, barrier treatment, spot treatment and/or crack and crevice. It is not possible to authorise products based on certain amount of m^2 where a safe use can be found.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018

Date of applicability for products:

29/08/2018

Indoor application

ENV Emission estimation for insecticides for households and professional uses: targeted applications

Version 2 (TM II 2010)

Targeted applications for which default values are available: i) spot treatment and ii) barrier treatment;

- Default value for spot treatment for a domestic house is 2 m^2 as stated in the ESD. The default value for barrier treatment for a domestic house is 20 m^2
- The same relation between the treated and total surface for the commercial building as for the domestic house is used. This leads to 9.3 m² and 93 m² for spot treatment and barrier treatment, respectively.
- These values for barrier treatment are corrected for the wet cleaned zone. The wet cleaned zone for a domestic house is 38.5 m², equivalent to the surface of the kitchen plus the bathroom (ConsExpo) but not necessarily related to those particular rooms (see previous entry). This leads to a correction factor of 38.5 / 131 = 0.294. The same factor will be used for commercial buildings. This leads to the following default values for barrier treatment: 5.9 m² for a domestic house, and 27 m² for commercial buildings. No correction is applied for spot application.

Type of entry:	a) Editorials/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV How should the environmental risk assessment for indoor gel bait application be performed?

Version 1 (TM I 2008)

In case of indoor gel bait application a quantitative environmental risk assessment will have to be performed according to the ESD as a first tier. In a second tier, additional data of measured release factors, area to be cleaned and risk mitigation measures as proposed in the label instructions can be considered.

Additionally it is proposed that in case of a risk, a back calculation could be performed to estimate the maximum levels resulting in safe use and to subsequently assess the 'realism' of these levels.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Simultaneity factor for calculating local releases to the STP 145

Version 3 (WG-II-2019)

The simultaneity factor ($F_{simultaneity}$) for calculating local release to STP should not be doubled to take into account seasonality of a use.

In addition, F_{simultaneity} is also applicable for professional users.

For products that are specifically used against pet fleas or ticks only, $F_{\text{simultaneity}}$ can be refined as follows:

Fsimultaneity (Tier 2) = 0.45 * Freq * Npets * Fpen,

Where:

0.45 = EU-wide data suggest that 45% of households own cats and/or dogs (For example European Pet Food Industry Federation (FEDIAF) Facts and Figures 2016http://www.fediaf.org/who-we-are/facts-and-figures.html);

Freq = frequency of use (for example for a product applied monthly Freq=1/30);

Npets = fraction of number of pets requiring treatment for fleas; default value = 0.5;

Fpen = market penetration value; default value = 0.5.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Simultaneity factor for calculating local releases to the STP 145

Version 2 (WG-II-2016, WG-IV-2017)

The simultaneity factor ($F_{simultaneity}$) for calculating local release to STP should <u>not</u> be doubled in order to take into account seasonality of a use.

In addition, F_{simultaneity} is also applicable for professional users.

For products that are specifically used against pet fleas only, $F_{\mbox{simultaneity}}$ can be refined as follows:

F_{simultaneity} (Tier 2) = 0.45 * Freq * Npets * Fpen,

Where:

0.45 = EU-wide data suggest that 45% of households own cats and/or dogs (For example European Pet Food Industry Federation (FEDIAF) Facts and Figures 2016 http://www.fediaf.org/who-we-are/facts-and-figures.html);

Freq = frequency of use (for example for a product applied monthly Freq=1/30);

Npets = fraction of number of pets requiring treatment for fleas; default value = 0.5;

Fpen = market penetration value; default value = 0.5.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Wet cleaning zone for large buildings

146

Version 2 (WG-II-2016)

The treatment area was harmonised in line with the general treatment:

For large buildings, the wet cleaning zone is calculated based on the relation of surface area and wet cleaning zone in the house scenario: the surface cleaning area of the house is 130 m^2 and the wet cleaning area is 38.5 m^2 . This relation transferred to large buildings, where the total surface is 609 m^2 , results in a wet cleaning zone of 180 m^2 .

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018

Date of applicability for products:

29/08/2018

ENV Scenario for spraying application to treat against cat fleas (indoor) 147

Version 2 (AHEE-5)

Linked to entry ENV 227: Spray products to treat against cat fleas will be applied on soft furnishings, textiles and carpeted areas, for which the general surface area is 22 m² according to the ESD (non-professional use in private houses). However, it is not expected that these treated objects will be subject to regular wet cleaning. Thus an area of 5.9 m² should be used to reflect the area wet cleaned in a domestic home (barrier taken from the TAB v1) and use the default cleaning efficiency of 20 % for a surface application (taken from the ESD).

In this scenario losses during mixing/ loading will be zero.

This scenario is summarised in the following table.

Parameter		Value	Unit	S/D/O *
Emission to a	ir			
Q _{prod}	Quantity of product applied		kg.b.p.m -2	S
F _{AI}	Fraction of active substance in the commercial product		[-]	S
AREAtreated	Area treated with the product	22	m²	D
${f N}_{appl}$, building	The no. of applications per day per building for non- professional use	1	d-1	D
Fapplication, air	The fraction emitted to air during application	0.02		D
Eapplication, air	The emission to air during application step = $N_{appl, building} \times F_{application, air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$		kg d ⁻¹	0
Emission to floor				

			1	
Fapplication, floor	The fraction emitted to floor during application	0.11	[-]	D
Eapplication, floor	The emission to floor during application step = $N_{appl, building} \times F_{application, floor} \times Q_{prod} \times F_{AI} \times AREA_{treated}$		kg d ⁻¹	0
Emission to a	pplicator			
Fapplication, applicator	The fraction emitted to applicator during application	0.02	[-]	D
Eapplication, applicator	The emission to applicator during application step Nappl, building X Fapplication, applicator X Qprod X FAI X AREAtreated		kg d ⁻¹	0
Emission to t	reated area			
Fapplication, treated	Fraction emitted to treated area during application	0.85	[-]	D
Eapplication, treated	The emission to treated surface during application step = $N_{appl, building} \times F_{application,}$ treated $\times Q_{prod} \times F_{AI} \times AREA$ treated		kg d ⁻¹	D
Emission via cleaning				
From the applicator				
Fapplicator, ww	Fraction emitted to wastewater during cleaning	1	[-]	D
E _{applicator, ww}	Emission from applicator to wastewater during cleaning Eapplication, applicator X Fapplicator, ww		kg d ⁻¹	0
From the treated area and floor				

Fww	Fraction emitted to wastewater during cleaning	1	[-]	D
F _{CE}	Cleaning efficiency	0.20	[-]	D
Etreated, ww	Emission from treated surfaces/ floor to wastewater during cleaning = (E _{application, floor} +(5.9 m ² /22 m ²) x E _{application, treated}) x F _{ww} x F_{CE}		kg d ⁻¹	0
Total				
Eww	Eapplicator, ww + Etreated, ww		kg d ⁻¹	0
*S=Set, D=Default, O=Output				
Type of entry: b) Clarifications/existing guidance			guidance	
Publication date:		02/02/2021		
Date of applicability for active substances: 02/02/2021				

Date of applicability for products: 02/02/2021

ENVScenario for spraying application to treat against cat fleas or bedbugs147(indoor)

Version 1 (WG-IV-2017)

Spray products to treat against cat fleas or bedbugs will be applied on soft furnishings and carpeted areas, for which the general surface area is 22 m^2 according to the ESD (non-professional use in private houses). However, both of these are not expected to be subject to regular wet cleaning. So, an area of 5.9 m^2 should be used to reflect the area wet cleaned in a domestic home (barrier taken from the TAB v1) and use the default cleaning efficiency of 20 % for a surface application (taken from the ESD).

In this scenario losses during mixing/ loading will be zero.

This scenario is summarised in the following table:

Parameter	Value	Unit	S/D/O *
Emission to air			

Q_{prod}	Quantity of product applied		kg.b.p.m ⁻ 2	S
F _{AI}	Fraction of active substance in the commercial product		[-]	S
$\underset{\text{ed}}{AREA_{treat}}$	Area treated with the product	22	m²	D
Nappl, building	The no. of applications per day per building for non- professional use	1	d ⁻¹	D
Fapplication, air	The fraction emitted to air during application	0.02		D
Eapplication, air	The emission to air during application step = N _{appl} , building X F _{application} , air X Q _{prod} X F _{AI} X AREA _{treated}		kg d ⁻¹	0
Emission	to floor			
Fapplication, floor	The fraction emitted to floor during application	0.11	[-]	D
Eapplication, floor	The emission to floor during application step = N _{appl, building} x F _{application, floor x Q_{prod} x F_{AI} x AREA_{treated}}		kg d ⁻¹	0
Emission	to applicator	L	I	
Fapplication,	The fraction emitted to applicator during application	0.02	[-]	D
Eapplication, applicator	The emission to applicator during application step Nappl, building X Fapplication, applicator x Qprod X FAI X AREAtreated		kg d ⁻¹	0
Emission to treated area				
F _{application,} treated	Fraction emitted to treated area during application	0.85	[-]	D
Eapplication, treated	The emission to treated surface during application step		kg d ⁻¹	D

	= N_{appl} , building X Fapplication, treated x Q_{prod} x F_{AI} x AREA _{treated}			
Emission via cleaning				
From the	applicator			
Fapplicator, ww	Fraction emitted to wastewater during cleaning	1	[-]	D
Eapplicator, ww	Emission from applicator to wastewater during cleaning Eapplication, applicator X Fapplicator, ww		kg d ⁻¹	0
From the	treated area and floor			
Fww	Fraction emitted to wastewater during cleaning	1	[-]	D
FCE	Cleaning efficiency	0.20	[-]	D
Etreated, ww	Emission from treated surfaces/ floor to wastewater during cleaning		kg d ⁻¹	0
	= $(E_{application, floor} + E_{application, treated}) \times F_{ww} \times F_{CE}$			
Total				
Eww	Eapplicator, ww + Etreated, ww		kg d⁻¹	0
*S=Set, D	=Default, O=Output			
Type of entry	ype of entry: b) Clarifications/existing guidance		g guidance	
Publication date: 29/08/2018				

Date of applicability for active substances:29/08/2018Date of applicability for products:29/08/2018

ENV Diffusers in indoor treatment

148

Version 1 (WG-III-2017)

In case efficacy data is not available the default number of diffusers in a house to be used is 2. This value was deduced by assuming one diffuser per bedroom

and two bedrooms per house. However this value should be used regardless of the place in the house where the treatment takes place.

Resulting emission scenario: two diffusers in a house of 130 m^2 are considered; in this house 30% of the surface area (i.e. 38.5 m^2) are wet cleaned.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Cleaning efficiencies in indoor treatment

149

Version 2 (WG-V-2018)

During spray application (e.g. to walls) a fraction of the product applied will be released to floor or adjacent surfaces. These surfaces might be subject to wet cleaning and the following cleaning efficiencies should be used:

For mixing and loading and for the application step the cleaning efficiency for the target area of the application should be used.

The following changes to Table 3.3-8 of the OECD ESD for PT 18 (No. 18) have been further agreed:

NEW: Formulation: **powder** – Use: **crack and crevice** – Cleaning efficiency: **0.25**

NEW: Formulation: granules - Use: surface - Cleaning efficiency: 0;

In summary, Table 3.3-8 should be replaced by the following

Formulation/use	Max % exposed to cleaning	Cleaning efficiency
Solid baits (in bait stations)	0	0
Gel - bait station	0	0
Gels - crack and crevice	3	0.03
Gels - surface	25	0.25
Dust/powders - voids/cavities Dust/powders - crack and crevice	0 25	0 0.25

Dust/powders – surface Granules - surface	50 0	0.5 0
Spray - crack and crevice	25	0.25
Spray - surface	50	0.5
RTU aerosols - space spray/diffuser	100	1
RTU aerosol - crack and crevice (including foams)	3	0.03
RTU aerosols - surface	20	0.2
Type of entry: b) Clarifications/exi	sting guidance

Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Default values for treatment of wardrobes 150

Version 1 (WG-III-2017, WG-I-2018, AHEE-5)

The treatment of wardrobes should be assessed based on the existing diffuser scenario. Default value for the number of wardrobes per household to be used: 2.5. This value has been derived from the mean number of dwellers of 2.49 (having one wardrobe each).

Wardrobe volume: 1.5 m³.

Agreed fractions:

 $F_{floor} = 0.1$

 $F_{CE} = 1$

 $F_{\text{simultaneity}} = 0.055$

The release from cleaning of textiles is considered negligible and should not be assessed.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018

Date of applicability for products:

29/08/2018

ENV Should emissions from the use of same products by both private usersand professionals be added up?

Version 1 (WG-I-2018)

If a product is intended for household use against a certain organism and it can be used by both professionals and non-professionals, the emissions from professional/non-professional use should not be aggregated for the exposure estimation.

The value for Fsim should in this case be understood as reflecting frequency of use regardless of user category. I.e. it is assumed that the treatment is applied by either a non-professional user or a professional user, during the same treatment period.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Generic treatment areas assigned to each specific pest 204

Version 2 (AHEE-5)

Generic treatment areas for the indoor use of insecticide - assigned to each specific pest - have been agreed.

The background document including the default values is provided in the CIRCABC TAB repository (entry "ENV204..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

The proposed application areas should be assumed if no specific information is proposed by applicants.

With regard to the cleaning efficiency please refer also to ENV 149.

For <u>indoor use against crawling and flying insects</u>, the following additional conclusions were drawn:

A clearer distinction between spot and barrier treatment default values for treated zone and wet cleaned zone was agreed:

Treatment	Treated zone	Wet Cleaned zone
Standard - house	130	38.5
Standard - building	609	180
Spot - house	2	2 (no correction)
Spot - building	9.3	9.3 (no correction)
Barrier- house	20	5.9
Barrier - building	93	27

Assessment of spot applications for spray products against crawling insects:

The full surface treatment or at least barrier treatment should be assessed in case no efficacy data is provided that allows to reduce the assessment on a specific limited area. With regard to the use of nozzles: In case the product for spray application is specifically designed for spot applications, a respective device or design to confine the spraying area should be added. This would be a case by case discussion, to be done within the EFF and APCP sections.

Assessment of spot applications for spray products against flying insects:

The standard scenario for flies (air space treatment) should be used, unless efficacy data and APCP data on the spray application can show that the target spray surface can be reduced to a spot application like size (e.g. by a spray lance, attached to a bottle). This would be a case by case discussion, to be done within the EFF and APCP sections, and a clarification should be included in the ENV section.

For treatment agains spiders the extent of the area treated (spot, barrier, whole wall) depends on the efficacy claim/tests provided. If e.g. efficacy was only shown for a limited area, only this limited area would need to be considered in the risk assessment. Use instructions on how the product should be used however need to be clear also for non-professional users.

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

ENV Generic treatment areas assigned to each specific pest 204

Version 1 (WG-II-2018)

Generic treatment areas for the indoor use of insecticide - assigned to each specific pest - have been agreed.

The background document including the default values is provided in the CIRCABC TAB repository (entry "ENV204..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

The proposed application areas should be assumed if no specific information is proposed by applicants.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENVClarifications on ENV 147 - scenario for spraying application to treat227against cat fleas (indoor)

Version 1 (AHEE-5, WG-IV-2020)

Treatment against fleas:

It should be noted that hard surfaces cleaned regularly (including all types of floor except carpeted areas) are not covered by entry ENV 147.

Regarding the treatment against fleas, in the absence of a specific scenario for washing of pet supplies (soft furnishing such as cover, blanket and soft baskets), the use is covered by the wet cleaned surface area of 5.9 m^2 of the scenario provided in entry ENV 147. No additional assessment is needed. A separate scenario should be developed in the future, clearly distinguishing hard and soft surfaces with related cleaning efficiency; in addition infestation should be used as starting point.

Treatment against bed bugs:

The classical barrier treatment according to the ESD (relates also to TAB ENV 142) taking into account the worst case cleaning efficiency (depending on the way of application) should be calculated as default worst case scenario unless specified otherwise in the use description. The wet cleaned area for barrier treatment is similar (considering 5.9 m²).

If it is clearly detailed in the use description that more limited areas are treated and this can be justified with efficacy evaluation, a deviation from the default scenario is possible.

For spray application on a surface, a F_{CE} value of 0.5 should be used, if a spray treatment in cracks and crevices takes place, a F_{CE} value of 0.25 should be used.

No additional consideration of the scenario for treatment of soft furnishing/textiles is needed. "Bed bugs" should therefore be deleted (from ENV 147, reflected in this clarification).

Treatment against ticks and dust mites:

Entry ENV 147 can be applied in addition also to ticks and dust mites, when considering the use on non-regularly wet-washed surfaces (such as textiles, carpet areas and soft furnishing).

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

Outdoor application

ENVTreatment in and around buildings (outdoor) - default value for152Fspray,wash-off

Version 1 (WG-V-2017)

In the calculations for outdoor application in urban areas a default value of 0.5 should be used for Fspray,wash-off, i.e. 50% of the total amount applied is washed off without any further reduction.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Size of receiving compartment -soil depth in case of outdoor 153 applications in PT 18 (for insecticides, acaricides and products to control other arthropods for household and professional uses)?

Version 1 (TM I 2008, WG-V-2014)

It was first decided at TM I 08 that for Annex I inclusion, for the receiving soil compartment a depth of 10 cm in case of no mixing (urban areas) and 20 cm in case of mixing (rural areas) should be used.

At WG-V-2014 it was however agreed to harmonise the procedure with other product types and use a soil depth of 50 cm, but only in restricted areas (e.g. for the soil adjacent to the building, i.e. 50 cm distance from the treated wall, terraces, etc.)).

The sizes of receiving compartment – soil depths in case of sewage sludge deposition and/or manure deposition on agricultural land remain unchanged according to BPR IV B v.1.0 as well as to ESD PT 18 No. 14 (2006) (ref. to Table 5.10).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Treatment area for bait box scenarios on terraces

154

Version 1 (WG-V-2016)

It was agreed to use a default area for the terrace of 30 m^2 and assume a receiving area of 8.5 m^2 (taking into account three sides of a terrace).

In addition a default value of 4 bait boxes should be used if no data on the application is provided by the applicant, substantiated with efficacy tests.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Terrace scenario for assessment of spot applications on paved surfaces 155

Version 1 (WG-IV-2017)

The terrace scenario should be used only for the treatments of terraces. For product applications around a large building a number of spots per m^2 around the house should be considered.

Type of entry:

b) Clarifications/existing guidance

Publication date:

29/08/2018

Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Fraction of product consumed by the ants versus amount left at thebait station

Version 1 (WG-V-2016)

The OECD ESD No. 18 for PT 18 assumes that 80% of a product is taken up by the ant and brought to the nest and the risk assessment is based on the remaining 20% entering soil after flooding. It was questioned if also the 80% are entering soil via the ants.

It was agreed that the risk assessment should be based on the remaining 20% entering the soil after flooding, the 80% taken up by ants should not be considered.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Groundwater assessment for outdoor applications

157

Version 2 (WG-IV-2017)

Bait stations:

The following inconsistencies were noted: In the table 4.3-17 of the OECD ESD No. 18 for PT 18 it is indicated that emission to groundwater occurs but in the text below this table this emission route is considered negligible.

It was agreed that for insecticides in bait stations a groundwater assessment should be performed on Tier I level (according BPR IV B+C v.2.0) in order to show that the exposure is negligible. If in the light of experience it is shown that the exposure is not negligible, a scenario for a Tier II assessment (e.g. for FOCUS modelling) needs to be developed.

Crack and crevice treatment by spraying:

A groundwater assessment should be performed for this application unless the crawling spaces are not exposed to water (e.g. the crawling space is the ground under the building).

As tier 2 for FOCUS modelling the following should be used:

- Number of houses treated per hectare: 16 houses without considering Fsim (since already taken into account by the number of applications within a period of time);
- Dates of application: those included in the ESD for PT 8 Supplement to Appendix 4 (paragraph 594 c, p.178);
- Crops to be used: grass/alfalfa.

Only private houses in rural areas should be looked at.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Outdoor applications: when is no risk assessment needed? 158

Version 1 (WG-I-2018)

The product is intended either for use in bait stations (general public and professionals) or for any professional use, but only used on paved surfaces, and not on bare soil and the product is to be applied in roof-covered areas, which cannot be affected by flooding, and which are protected from rain fall or cleaning wash, thus emissions are unlikely to occur. Therefore no environmental risk assessment needs to be provided for the aquatic and terrestrial compartment.

A risk assessment for primary/secondary poisoning according to ESD PT18 No.18 however needs to be performed (as well as a risk assessment for bees when specific guidance is available).

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Outdoor spot applications on paved surfaces: Should the release via 159 the STP be assessed (e.g. bait boxes, gel application, solution pouring or spray, the latter when restricted to the treatment of nests, 4 point only on the terrace)?

Version 2 (WG-V-2018)

For outdoor application of insecticides on paved surfaces in urban areas, an assessment should be performed for the release via the STP, except for uses covered by the previous TAB entry (i.e. uses for which no environmental risk assessment is needed for the aquatic compartment and terrestrial compartment).

In case of spot application on paved surfaces around domestic premises the terrace scenario should be used (no release to sewer/STP is assumed, only releases to soil compartment around a terrace).

In case of spot application around commercial larger buildings the application rate around domestic premises should be used.

In consideration of application type and technique (gel, bait box, spray application) the perimeter of a larger building should be used for calculating the number of applications or/and the related application area, which corresponds to 100 m (square root of 609 m², times four).

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENV Ants outdoor (large building) - perimeter treatment: refinement for window/doorstep-only treatment

Version 1 (AHEE-5)

Refinement for window/doorstep-only treatment: This concerns the scenario for large buildings in a city with release to the STP. It was agreed to use a factor of 2 for the refinement (extrapolation of the circumference of a house to a large building).

The length of the treated window frame and doorstep perimeter of a large building is set to 20 m (10 m x factor 2), the width depends on the application technique (in line with ENV 35).

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

ENV Ants – outdoor (large buildings): Spot treatment on terraces 226

Version 1 (AHEE-5)

No additional scenario for terraces in the case of large buildings is needed, since the perimeter scenario represents the worst case (for the emission pathway via STP).

In case an applicant intends a product only to be applied on terraces, the existing terrace scenario (for households) could be used as surrogate.

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

ENV Wasps/hornets outdoor treatment 231

Version 1 (AHEE-5)

The ESD indicates that spray drift should be evaluated for outdoor spray treatment against wasps and hornets. It was noted and confirmed by the AHEE that spray drift is not relevant for this kind of treatment, only deposition should be considered.

The receiving soil surface used for deposition should have a diameter of 50 cm diameter, leading to a soil volume $V_{spray,nest,soil}$ of 0.10 m³ (ref. to Table 4.3-15 in the ESD). The mentioned distance of 3 m between the applicator (sprayer) and the surface treated (nest) is not relevant for the emission scenario. Thus, the variable/parameter in Table 4.3-15 may be adapted to "soil volume for deposition and application".

Type of entry:	b) Clarifications/existing guidance
Publication date:	02/02/2021
Date of applicability for active substances:	02/02/2021
Date of applicability for products:	02/02/2021

3.17.2 Stable and manure application

ENVNitrogen immission standards to be used for release estimation of160insecticides applied in stables and manure storage systems

Version 1 (TM I 2008)

It was decided to use the nitrogen immission standards from the EC Nitrates Directive (91/676/EC) of 170 kg N ha⁻¹ yr⁻¹ for all soils (arable land and grassland).

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Interpretation of the following parameters in the ESD: land application 161 interval for arable land (Tar-int), manure storage time for arable land (Tmanure-intar), time period of biocide application in stables (Tbiocint) and number of repeated treatments prescribed (Napp-prescr)

Version 1 (WG-IV-2017, WG-I-2018)

The following approach is to be used for the **arable land scenario** but only if degradation in manure is not taken into account:

- Tar-int = Tbioc-int;
- Tbioc-int and Napp-prescr values are to be provided by the Applicant (not the default values in EUSES).

The following approach is to be used for the **grassland scenario**:

- The rounding of the number of applications of biocide during a storage period should take place to the first decimal;
- Apart from the calculation of PIECsoil in grassland after 10 years of manure application the approach as provided in the Addendum to the OECD ESD should be used without further changes.

The following tiered approach can be applied (even with a risk that for substances with a DT50>150 d there may be a slight underestimation in Tier 1):

Step 1 (screening): scenario for agricultural land = scenario for arable land with a soil depth of 5 cm.

Step 2:

- Arable land: scenario as proposed above with a soil depth of 20 cm and
- Grassland: standard scenario including a soil depth of 5 cm.

The background document is provided in the CIRCABC TAB repository (entry "ENV161..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Run off from soil to surface water after manure application 163

Version 1 (WG-III-2016)

Run-off to surface water and leaching to groundwater are generally considered as continuous release, unless the criteria for intermitted release as provided in BPR IV B v.1.0 are fulfilled.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Taking into account degradation in manure 164

Version 1 (WG-V-2016)

The AHEE recommendation prepared by NL on how to take into account degradation in manure together with calculation sheets is provided in the CIRCABC TAB repository (entries "ENV164..."); three files are provided, i.e. the recommendation and two Excel Sheets):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:

d) New guidance, no new data requirement(s)

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENVDefault crops, application dates, application mode and depth to be165used for FOCUS groundwater models when refinement of
PECgroundwater following manure/slurry application on soil is needed

Version 1 (WG-II-2014,WG-V-2016)

In case of manure/slurry application scenarios (from animal housings) it was agreed at WG- and CA-Meetings that both grassland and arable land scenarios should be used in FOCUS groundwater models. In case of manure/slurry application on grassland the crop grass (alfalfa) has to be selected and the scenario considers 4 times manure/slurry application per year on fixed dates 1st of March, 23rd of April, 15th of June and 7th of August (considering 53 days between application) and 5 cm incorporation depth. In case of manure/slurry application on arable land the scenario considers either one time application) or two split absolute applications on winter cereals and 20 cm incorporation depth. For the latter option fixed application dates in autumn on 3rd of October and in spring on 15th of March should be used.

The application rate of the active substance Appl_rate [kg/ha] at one specific application date as necessary input parameter in FOCUS groundwater models is calculated on basis of predicted initial environmental concentrations (PIEC).

1. Grassland scenario:

$$Appl_rate_{ar_maize} = PIEC_{ars} \times RHO_{soil_wet} \times DEPTH_{arableland} \times 10^{-2} = PIEC_{ar} \times 3.4$$

With:

Appl rate_{grs} = concentration of active ingredient in grassland soil after 1 manure slurry application based on the nitrogen immission standard for grassland [kg/ha]

 $PIEC_{grs}$ = concentration of the active ingredient in grassland soil after 1 manure/slurry application based on the nitrogen immission standard for grassland [mg/kg] according to OECD ESD PT 18 No.14 (2006)

RHO_{soil_wet} = wet bulk soil density = 1,700 kg/m³

 $DEPTH_{grassland} = mixing depth with soil for grassland = 0.05 m$

The calculated application rate for grassland should be used for each of the 4 above mentioned fixed application dates which display the manure/slurry application time interval of 53 days in grassland.

2. Arable land scenarios:

a) Selected crop: maize

$$Appl_rate_{ar} = PIEC_{ars} \times RHO_{soil_wet} \times DEPTH_{arableland} \times 10^{-2} = PIEC_{ar} \times 3.4$$

With:

Appl rate_{ar_maize} = initial concentration of the active substance in soil of arable land after 1 manure/slurry application based on the nitrogen immission standard for arable land [kg/ha]

*PIEC*_{ars} = initial concentration of the active substance in soil of arable land after 1 manure/slurry application based on the nitrogen immission standard for arable land [mg/kg] according to OECD ESD PT 18 No.14 (2006) and to the Addendum (Nov.2015)

RHOsoil_wet = wet bulk soil density = 1,700 kg/m³

 $DEPTH_{arable \ land} = mixing \ depth \ with \ soil \ for \ arable \ land = 0.2 \ m$

The calculated application rate for arable land scenario in maize should be used for one application (relative) date: 20 days before maize emergence. Thus, the application dates used in the FOCUS simulation routine depend on the specific locations in FOCUS PEARL and will automatically modelled between 15th of February (Sevilla) and 5th of May (Okehampton).

b) Selected crop: winter cereals

The selection of this option needs additional intermittent calculations for the application rate as for reasons of good fertilisation practice the maximum acceptable N-amount per year of 170 kg should be split into at least 2 applications: e.g. in autumn 80 kg per ha and in spring 90 kg per ha.

 $Appl_rate_{ar_cereal_autumn} = 0.47 \times PIEC_{ars} \times RHO_{soil_wet} \times DEPTH_{arableland} \times 10^{-2}$ $= PIEC_{ars} \times 1.6$

 $Appl_rate_{ar_cereal_spring} = 0.53 \times PIEC_{ars} \times RHO_{soil_wet} \times DEPTH_{arableland} \times 10^{-2}$

$$= PIEC_{mr} \times 1.8$$

With:

Appl rate_{ar_cereal_autumn} and Appl rate_{ar_cereal_spring} = initial concentration of the active substance in soil of arable land after 1 manure/slurry application based on the nitrogen immission standard for arable land [kg/ha]

*PIEC*_{ars} = initial concentration of the active substance in soil of arable land after 1 manure application based on the nitrogen immission standard for arable land [mg/kg] according to OECD ESD PT 18 No.14 (2006) and to the Addendum (Nov.2015)

RHO_{soil_wet} = wet bulk soil density = 1,700 kg/m³

 $DEPTH_{arable \ land} = mixing \ depth \ with \ soil \ for \ arable \ land = 0.2 \ m$

The calculated application rates for arable land (winter cereals) should be used for different application dates, Appl_ratear_cereal_autumn for the modelled application on 3rd of October and Appl_ratear_cereal_spring for the modelled application on 15th of March.

Either option a) "maize" or option b) "winter cereals" must be carried out without giving any preference for one option.

The above proposed scenarios and input parameters can be transferred to further PTs (i.e. PT03 and PT05), where refinement of PECgroundwater following manure/slurry application on soil is needed.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Values to be used for the FOCUS PEARL simulations 166

Version 1 (WG-II-2017)

Regarding different active substance contents in each 53 d-interval, in cases where degradation processes in manure are considered, the following was agreed: For simplification reasons until further calculation tools are available, the same maximum value can be used four times as input parameter in PEARL (instead of using four different values taking into account degradation); provided that this does not result in an exceedance of the groundwater limit value.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Which area should be used for the calculations for larvicides and insecticides, for the different application types?

Version 1 (WG-II-2017)

The specific areas relevant to be treated should be specified by the applicant. The ESD Excel sheet will provide for surface and volume applications only the floor areas and housing volumes, respectively by default (according to Table 5.2 of the OECD ESD No. 14 for PT 18). However, these should be overwritten by the areas provided by the applicant if available (e.g. only floor, 2 m high

band around the wall, etc.). The use prescription to be provided by the applicant should be very specific and provide all the areas to be treated.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Environmental exposure pathways from poultry housings 168

Version 1 (WG-II-2017)

Two pathways are evident for emissions from animal breeding / housing units:

Where the site is not connected to the local drainage system, all wastewater would remain on site and be stored with the slurry prior to mixing with dry waste (manure) for application to agricultural land (soil). All potential losses of active substance from treated buildings as prescribed by the ESD for PT 18 No. 14 would lead to direct exposure of soil- this therefore represents a worst case assessment for this compartment.

Where the site is connected to the local drainage system, a fraction of active substance could be released in the wastewater discharging to the local STP (indirectly discharging to terrestrial and aquatic compartment) whilst another fraction could be applied to land after a period of storage in manure / slurry.

Emissions of active substance as liquid waste (slurry) and dry waste (manure) can be pooled as both forms of waste will be applied to land as fertiliser representing a direct exposure of the soil compartment. With regard to wastewater, this will either be directed to local STP via drains or if no connections exist, it will added to dry/liquid waste and applied to land. On this basis and according to the fractions of active substance released to the different streams, animal housing / breeding units have been grouped according to the compartment receiving the generated emissions (slurry, manure and wastewater):

Scenario 1: According to the OECD ESD No. 14 for PT 18, animal housing subcategories **1**, **2**, **3**, **4**, **5**, **6**, **7**, **10**, **13**, **14** and **15** give rise to a discharge fraction of 0.5 in either manure or slurry which will ultimately reach the soil compartment (ref. to Table 5.4). None of these sub-categories are considered to give rise to emissions of wastewater so there are no losses to STP (or additional losses to soil if not connected to an STP).

Scenario 2: Animal housing sub-categories **11, 12, 16, 17** and **18** give rise to a discharge fraction in manure, which will ultimately reach the soil compartment via manure deposition on agricultural land. Furthermore, for

these housing sub-categories a discharge fraction to wastewater should be considered, which could either reach the local STP or must be added to the discharge fraction in manure and increase this fraction reaching soil in cases where no connection to local drainage system is assumed (ref. to Table 5.4).

Scenario 3: Animal housing sub-category **8**: laying hens in battery cages with aeration (belt drying) gives rise to a discharge fraction to slurry, where in Table 5.4 the fraction from wastewater is already added to the "belt dried slurry" fraction and will reach the soil compartment. Furthermore, a discharge fraction to wastewater is provided, which could reach the local STP. In case only belt dried slurry (without wastewater from this animal housing sub-category) is released to agricultural land (arable land and grassland) the wastewater fraction should be subtracted from the slurry fraction indicated in Table 5.4.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Emission from washing of coveralls after PT18 stable applications 169

Version 1 (WG-II-2017)

Coveralls worn during treatment of stables can be washed - in line with OECD ESD No. 18 for household and professional uses. Therefore, emission to the STP / IBA (Individual Wastewater Treatment System) and the receiving aquatic environment from this event may occur. The OECD ESD No. 14, however, does not include this scenario.

It was agreed that the emission form washing of coverall after PT 18 stable applications does not need to be assessed and no additional scenario is needed:

- Coveralls may be disposable in some of the farms.
- It is a single events after insecticide application.
- Coveralls are potentially not washed at the same day when the stable is treated (no aggregated exposure).
- Potentially covered already in the fraction released provided in the ESD.
- Mixing and loading step is not included in the ESD for PT 14.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Wastewater stream in stables

170

Version 1 (WG-II-2017)

It was questioned if cleaning of stables may potentially result in an emission to sewer (farms connected to the STP, releasing to surface water). In one MS this is (legally) allowed and is likely to occur in practice. However, the ESD does not consider emission to waste water as a relevant route for several animal sub-categories.

A focused enquiry amongst MS showed that a release to the waste water stream is not allowed per se. There can be however special agreements for single farms. It was therefore agreed that this exposure pathway does not need to be assessed.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Treatment of animal transport vehicles

171

Version 1 (WG-II-2017)

This type of use would require a separate scenario. It was agreed that for the time being there is no need to either assess this use or develop a corresponding scenario. If there will be in the future a related application (active substance or product) the item will be further followed up.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Emission scenario for insecticides in mink farms 207

Version 1 (WG-II-2018)

The emission scenario for the use of insecticides in mink farms is provided in the CIRCABS TAB repository (entry "ENV207..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	30/08/2018
Date of applicability for active substances:	30/08/2018
Date of applicability for products:	02/08/2020

ENV AHEE recommendation: Addendum to the OECD ESD for PT 18 212 Updated!

Version 2 (AHEE-6)

The Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems is provided in the CIRCABC TAB repository (file "ENV212_Addendum_OECD-ESD_no14_manure_v1-2..."):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENV Changes to Table 5.4 from OECD ESD n.14 PT 18 Emission Scenario 233 Document for Insecticides for Stables and Manure Storage Systems (2006)

Version 1 (WG-I-2021)

The following tables show the changes introduced to Table 5.4, p.40 and 41, from theOECD ESD n.14 PT 18 Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (2006). All other values not included here remain unchanged and theOECD ESD n.14 PT 18 Emission Scenario Document for Insecticides for Stables and Manure Storage Systems (2006) should be consulted.

Excerpt from Table 5.4, p.40, modified and showing changes in different colour:

Changed/new values are shown ingreen font:

For application by Aerosol/Fogging the fractions released (to slurry, manure, and wastewater) were corrected taking account that 2% of the releases will go to the air and 98% will settle (OECD ESD n.14 PT 18 (2006), p.29). This results in e.g. application of a larvicide by aerosol/fogging – fraction emitted to slurry: $0.98 \times 0.34 = 0.343$.

For the new application by <u>Fumigation</u> the fractions defined in the ESD for Aerosol were used as a starting point; was also considered that 98% of the emissions are emitted to air (OECD ESD n.14 PT 18 (2006), p.30). This results in e.g. application of a larvicide by fumigation – fraction emitted to slurry: 0.02x0.34=0.007; fraction emitted to air: 0.98x0.34=0.343.

Emissions to air were added for application by fumigation and are shown ingreen bold font.

Cells highlighted in yellow: the b.p. applied by aerosol/fogging or fumigation is applied to an empty animal housing, i.e. without manure; nevertheless, slurry may be present under the slatted floor. Therefore, was considered that the emissions of b.p. will reach the slurry and not the manure and the emissions previously indicated to manure are now indicated to slurry.

Excerpt from Table 5.4, p.40:

Technical Agreements for Biocides (TAB)- ENV

Excerpt from Table 5.4, p.4

Category (cat-	Type of biocide	Spray	ing / Foami	ng (1)	Aero	sol / Foggin	g (2)
subcat)	(bioctype)	Manure (1)	Waste water (2)	Slurry (3)	Manure (1)	Waste water (2)	Slurry (3)
Livestock							
Cattle, Pigs, Veal cal	ves						
(1,2,3,4,5,6)	All insecticides (1,2,4)	No	further chan	ges	•	•	0.343
(1,2,3,4,5,6)	Larvicides (3)				•	•	0.343
(19)	Larvicides (3)				•	•	0.98
Poultry							
Battery cage							
-conveyor belt with a	eration						
(8)	All insecticides (1,2,4)				•	0.098	0.343
(8)	Larvicides (3)				•	0.098	0.343
(20)	Larvicides (3)				•	•	0.98
-forced drying (deep	pit, high-rise)						
(9)	All insecticides (2,4)				•	•	0.343
(9)	Flies (1)				•	•	0.343
(9)	Larvicides (3)				•	•	0.343
(20)	Larvicides (3)				0.98	•	•
-conveyor belt (no a	eration)						
(7,10)	All insecticides (1,2,4)				•	•	0.343
(7,10)	Larvicides (3)				•	•	0.343
(19)	Larvicides (3)				•	•	0.98
Free range							
-litter floor (11,12,16,17,18)	All insecticides (1,2,4)				•	0.098	0.245
(11,12,16,17,18)	Larvicides (3)				•	0.098	0.245
(20)	Larvicides (3)				0.98	•	•
- gratting floor (13,14,15)	All insecticides (1,2,4)				•	•	0.343
(13,14,15)	Larvicides (3)				•	•	0.343
(19)	Larvicides (3)				•	•	0.98

Technical Agreements for Biocides (TAB) – ENV

		S	mearing (3)			Fumigation		
Category (cat- subcat)	Type of biocide (bioctype)	Manure (1)	Waste water (2)	Slurry (3)	Manure (1)	Waste water (2)	Slurry (3)	Air
Livestock								
Cattle, Pigs, Veal o	calves							
(1,2,3,4,5,6)	All insecticides (1,2,4)	Not	further chan <u>i</u>	ges	•	•	0.007	0.343
(1,2,3,4,5,6)	Larvicides (3)				•	•	0.007	0.343
(19)	Larvicides (3)				•	•	0.02	0.98
Poultry								
Battery cage								
-conveyor belt wit	h aeration							
(8)	All insecticides (1,2,4)				•	0.002	0.007	0.441
(8)	Larvicides (3)				•	0.002	0.007	0.441
(20)	Larvicides (3)				•	•	0.02	0.98
-forced drying (de	ep pit, high-rise)							
(9)	All insecticides (2,4)				•	•	0.007	0.343
(9)	Flies (1)				•	•	0.007	0.343
(9)	Larvicides (3)				•	•	0.007	0.343
(20)	Larvicides (3)				0.02	•	•	0.98
-conveyor belt (no	aeration)							
(7,10)	All insecticides (1,2,4)				•	•	0.007	0.343
(7,10)	Larvicides (3)				•	•	0.007	0.343
(19)	Larvicides (3)				•	•	0.02	0.98
Free range								
-litter floor (11,12,16,17,18)	All insecticides (1,2,4)				•	0.002	0.005	0.343
(11,12,16,17,18)	Larvicides (3)				•	0.002	0.005	0.343
(20)	Larvicides (3)				0.02	•	•	0.98
- gratting floor (13,14,15)	All insecticides (1,2,4)				•	•	0.007	0.343
(13,14,15)	Larvicides (3)				•	•	0.007	0.343
(19)	Larvicides (3)				•	•	0.02	0.98

Excerpt from Table 5.4 (continued), p.40

Excerpt from Table 5.4 (continued), p.41, modified and showing changes in red font.

To be noted that since bait application is not relevant for larvicides, no default value is needed for the combined sprinkling and bait application.

	Type of	Sp	rinkling (1)		Bait (2)		Sprink	ding & Ba	it (3)
Category (cat-subcat)	biocide (bioctype)	Manure (1)	Waste water (2)	Slurry (3)	Manure (1)	Waste water (2)	Slurry (3)	Manure (1)	Waste water (2)	Slurry (3)
Livestock										
Cattle, Pigs, Veal calves										
(1,2,3,4,5,6)	All insecticides (1,2,4)	•	•	0.9	•	•	0.5	•	•	0.75
(1,2,3,4,5,6)	Larvicides (3)	•	•	0.9	•	•	•	•	•	•
(19)	Larvicides (3)	•	•	1	•	•	•	•	•	•
No furth	er changes	No fu	rther cha	nges	No fu	rther cha	nges	No fu	rther cha	nges

Excerpt from Table 5.4 (continued), p.41

Type of entry:	b) Clarifications/existing guidance
Publication date:	22/07/2021
Date of applicability for active substances:	22/07/2021
Date of applicability for products:	22/07/2021

ENV Main animal categories in PT 18

236 New!

Version 1 (WG-II-2021)

The frequency of application of a biocidal product in manure/stables should be defined per main animal category and not per animal subcategory. The following main categories should be used:

- Dairy cattle
- Beef cattle & veal calves
- Pigs
- Chicken (free range or battery cages)[1]
- Non-chicken poultry (turkeys, ducks, and geese)

The worst-case application frequency within a main animal category should be applied for the hole main category.

In case of unacceptable risks for one animal subcategory, the general category can still be considered safe provided RMMs can be applied on that subcategory resulting in safe use.[1]

Keeping hens in conventional battery cages is prohibited from 1 January 2012 (according to Directive 1999/74/EC), while enriched battery cages are currently still allowed and used under certain conditions set in the specific national rules in the different EU countries. Therefore, the battery cages described in the OECD ESD PT 18 No. 14 (2006) are currently used as surrogate for the enriched cages still allowed.

Type of entry:	b) Clarifications/existing guidance
Publication date:	11/11/2021
Date of applicability for active substances:	11/11/2021
Date of applicability for products:	11/11/2021

3.18 PT 19

ENVRefinement of risk assessment: reduction of treated skin surface area172and taking into account dermal adsorption

Version 3 (WG-V-2018)

As first tier for the treated skin area, the value as proposed in the recommendation of the Ad hoc WG on Human exposure should be used, i.e. 55% of 16600cm², i.e. 9130 cm², since this could be considered as a mean value taking into account the different skin areas for women, men and children. See Recommendation 11 - Proposal for harmonisation PT19 assessment - version 2.1 at

https://www.echa.europa.eu/about-us/who-we-are/biocidal-productscommittee/working-groups/human-exposure

As a second tier, the value decided for the treated surface in the human health section for a specific substance can be used.

The same tiered approach also applies for dermal adsorption: as first tier, no dermal absorption should be taken into account, as second tier the lowest value for dermal absorption from the human health assessment (e.g. based on study results) can be used to refine the risk assessment.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019

ENVRefinement of risk assessment: reduction of treated skin surface area172and taking into account dermal adsorption

Version 2 (WG-IV-2016, WG-I-2017)

As first tier for the treated skin area, the value as proposed in the recommendation of the Ad hoc WG on Human exposure should be used, i.e. 64% of 16600cm², i.e. 10660 cm². See WGIII2016_TOX_7-2b.2_HEAdhoc

harmonised exposure PT19_clean.doc at <u>https://www.echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure</u>.

As a second tier, the value decided for the treated surface in the human health section for a specific substance can be used.

The same tiered approach also applies for dermal adsorption: as first tier, no dermal absorption should be taken into account, as second tier the lowest value for dermal absorption from the human health assessment (e.g. based on study results) can be used to refine the risk assessment.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Treated area of skin for animals

173

Version 1 (WG-IV-2017)

The use of skin areas smaller than the ones included in Table 3-9 of the ESD, namely 200 cm², is applicable when it is clear that application to the whole animal will not take place. These small-scale applications should be however reflected in the way of application (e.g. spot treatment with a cream or hand held spray equipment) as well as in the package size.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Correction of equations in the ESD

174

Version 1 (WG-IV-2016)

Concerning the ESD page 32, equation no. 3.14, calculation of $C_{localwater,91d}$, the correct equation is as follows:

Clocal_{water,91d} = Elocal_{water} * 10³ * T_{emission,91d} / V_{waterbody}.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Outdoor large scale spraying scenario

248 New!

Version 1 (WG-II-2022)

The emission scenario for the use of insecticides in outdoor large-scale spraying agreed at WG-II-2022 is provided in the CIRCA TAB repository (entry "ENV248xx...").

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

Type of entry:	e) New guidance, immediately applicable
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2024

3.19 PT 21

ENV Consolidated list of technical agreements – Environment 175

Version 1 (TM IV 2012, TM I 2013, TM II 2013)

The document "Consolidated list of PT 21 technical agreements" with regard to

Environmental Risk Assessment was endorsed by the TM II 2013.

It can be found on the ESD specific ECHA webpage, PT 21:

http://echa.europa.eu/guidance-documents/guidance-on-biocideslegislation/emission-scenario-documents

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Clarification on the text of the RMM for PT 21

176

Version 1 (WG-V-2016, BPC-17)

For further clarification the text of the RMM should be reworded in the future as follows: "...that application, maintenance and repair activities shall (1) be conducted within a contained area to prevent losses and minimize emissions to the environment, meaning (2) on an impermeable hard standing with bunding or (3) on soil covered with an impermeable material. Any losses or waste containing [the substance] shall be collected for reuse or disposal".

The meaning of contained area was further discussed, specifically if it includes wind protection. It was concluded that it needs to be further specified between the boat type and the application method: For pleasure crafts in case the antifouling is applied by brushing, wind protection is not relevant. For commercial ships in case the antifouling is applied by spraying, it may be relevant. It was further noted that wind protection should not be as such part of the standard RMM, but if needed during product authorisation, it could be added as second provision. If identified as being relevant during product authorisation, also the release pathway via air should be covered by an emission scenario to be developed by the AHEE.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

4 Substance-specific WG meeting conclusions

ENVRelevance of performing a quantitative risk assessment for chlorine241substances

New!

Version 1 (WG-IV-2021)

For products containing active chlorine released from sodium/calcium hypochlorite, chlorine or other active chlorine releasers, or active chlorine generated in-situ that have relevant releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water, however, should be assessed quantitatively.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENV Lactic acid

249 New!

Version 1 (WG-II-2020, WG-I-2022)

Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L-(+) lactic acid naturally occurs as a fermentation byproduct of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations - and thus in subsequent groundwater concentrations (tier 1).

For all these reasons, it can be stated that lactic acid does not cause unacceptable risk for soil, groundwater and also the indirect release to surface water (via STP and via manure).

Thus, no further quantitative assessment for soil, groundwater the indirect release to surface water (via STP and via manure) are needed.

For direct release to surface water a quantitative assessment is however still needed. As in the case for other natural occurring substances, a comparison of the PEC with the natural background concentration instead of the PNEC is acceptable.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENV Ozone

250

New!

Version 1 (WG-II-2022)

The WG agreed that for future product authorisations, a quantitative assessment for Ozone would only be needed for direct release to surface water, indirect release via STP can be covered by a qualitative assessment.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

ENV Hydrogene peroxide

251 New!

Version 1 (WG-II-2020)

The WG agreed, that the exposure route via air during treatment with hydrogen peroxide indoors, does not need to be assessed for any products containing hydrogen peroxide, deviating from the assessment as provided in the CAR for the active substance.

Type of entry:	b) Clarifications/existing guidance
Publication date:	14/10/2022
Date of applicability for active substances:	14/10/2022
Date of applicability for products:	14/10/2022

5 Annex: Expired TAB entries

ENVSorption onto suspended matter for calculation of PECsurface water11(via run off)

Version 1 (WG-IV-2017)

Sorption onto suspended matter can be considered in the calculation of PECsurface water (via run off).

 $Clocal_{water} = \frac{PEC_{porewater}}{\left(1 + Kp_{susp} \cdot SUSP_{water} \cdot 10^{-6}\right) \cdot DILUTION}$

Explanation of symbols:

Parameter	Symbol	Valu e	Unit	Comment
Concentration of the substance in the soil's porewater	PECporewater		mg/L	Vol. IV Part B+C, v2.0 - equation 70
Solids-water partition coefficient of suspended matter	Kp, susp		L/kg	Vol. IV Part B+C, v2.0 - equation 26
Concentration of suspended matter in the river	SUSP _{water}	15	mg/L	
Dilution factor	DILUTION	10	-	
Local concentration in surface water	Clocal, water		mg/L	

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV What parameter setting should be applied to FOCUS groundwater 23 scenarios (PEARL) when they are used in biocide exposure assessments (Exposure assessment Groundwater)

Version 1 (TM II 2010, WG-II-2014, WG-V-2015)

Molar activation energy:

In case of using FOCUS PEARL version 4.4.4 the value for "Molar activation energy" in the TRANSFORMATION tab of substance parameters shall be set to 54 kJ.mol-1. This value corresponds to the Q10 value of 2.2 assuming a daily temperature correction in the FOCUS models in accordance to guidance BPR IV B v.1.0. The WG is aware of the use of a different Q10 value in EFSA PPR opinion (http://www.efsa.europa.eu/en/efsajournal/pub/622.htm).

Plant uptake factor:

A factor of 0.0 should be used for the plant uptake factor. Due to the discussions (ref. to TMII2010 ENVitem Harmonisation of FOCUS groundwater models PEARL.doc and CA-Dec10-doc 6.2 c) this value is considered as a realistic worst case.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENV Which default values should be used for private hand disinfection? (PT42 1)

Version 1 (WG-I-2015, WG-IV-2016)

Finh: There are no data to underpin the default for Finh. It was agreed at WG-I-2015 that for the time being for Finh a default value of 0.2 should be used in case of soap and liquid soap hand disinfectant.

For other hand disinfectants for private use a default value of 0.5 should be used for F_{inh} especially for leave-on products.

Qform_inh and Qformappl: The values proposed for consumers in CONSEXPO should be used, i.e. amount of liquid soap = 1 g/event, $N_{appl} = 5 d^{-1}$.

Note: If efficacy data show that the default value is not efficacious, the efficient use rate should be applied for $Q_{forminh}$ and/or $Q_{formappl}$.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENV Medical sector: disinfection of endoscopes (PT 2) 50

Version 1 (WG-IV-2016)

In the emission scenario for calculating the release of disinfectant used for PT 2 in hospitals for the disinfection of endoscopes and other articles in washers/disinfectors (ESD PT 2 (2001), Table 3.7, p.25), the equation to calculate the maximum emission rate to water Elocalwater (once-through) should be:

Elocal3,water = $N_{rep-max} * Q_{machine} * 10^{-2*} C_{disinf} * e^{-kdegdisinf*Trepl} / (1+F_{carry-over})T_{repl}$

With:

Elocalwater:	Maximum emission rate to water [kg.d-1]
Nrep-max:	Maximum number of washers/disinfectors [-] = 3
Qmachine:	Volume of solution in machine $[L] = 10$
Cdisinf:	Working concentration [mg.L-1]
Kdegdisinf:	Rate constant for chemical conversion [d-1]
T _{repl} :	Replacement interval [d]
F _{carry-over} :	Fraction carry-over [-] = 0.015

The unit for the volume of solution in machine Qmachine is litres (L) and not m^3 .

The unit for the working concentration Cdisinf should be noted in mg/L.

It was further clarified:

- If C_{disinf} is noted in %, the factor 10^{-2} in the equation above needs to be omitted;
- If C_{disinf} is noted in mg/L, multiply with 10⁻⁶;
- If C_{disinf} is noted as fraction, no correction needed.
- If the working concentration is noted in %, multiply with 10⁻².

Type of entry:

d) New guidance, no new data requirement(s)

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENV Duration of emptying public swimming pools (PT 2) 51

) T

Version 1 (WG-V-2016)

For the emission estimation from public swimming pools, with the default size as provided in the ESD, it was agreed that these are emptied over three days to the sewer system, i.e. only one third of the pool volume is released on one day.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENV Which values are to be used for the calculation of releases from 84 different application steps? (PT 6.3 Fluids used in paper, leather and textile production, Textile production)

Version 1 (TM I 2011,WG-II-2014)

The following default values are proposed (TM I 2011):

- Amount of additive applied per tonne of textile (*Q*_{product}) =
- For pre-treatment: 120 kg/t of fabric (as product used in textile industry)
- Efficacious preservative concentration in additive (*Q_{active}*) will be deduced from the efficacy data and the *Q_{product}*.
- Quantity of fibre/fabrics treated per day $(Q_{textile}) = 13 \text{ t/d of a.s.}$

N.B.: At WG-II-2014 the default value for $Q_{product}$ was corrected from 20 to 120 kg/t: the value of 120 kg/t for pre-treatment step, represents the combined value for preparation agents (= 100 kg/t) and sizing agents (= 20 kg/t) provided in Table 10 of the OECD ESD on textile finishing industry (OECD 2004).

Concerning the fraction of fabric treated with product containing the substance of interest, two different values are proposed, 0.3 (default in ESD) and 1 as a worst case.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENVWhich soil volume should be considered for the countryside hou120se scenario for PT 10? (PT 10)

Version 1 (TM III 2010, TM IV 2012)

In regard to the soil volume for ESD PT 10, setting "building located in the countryside" the already agreed values for the evaluation of the soil compartment for PT 8 were used. Vsoil(a) and Vsoil(d) based on a soil depth of 50 cm for "brushing" and "spraying". For all PT 10 products an increased soil volume can be accepted for risk assessment (see RCOM_ENV (No. 49) Competent Authority Report of Nonanoic Acid (PT 10) (11-2012) 7/16. For the assessment of "spraying" application in PT 10 and similar applications in other PTs (e.g. PT 6, PT 7), the scenario provided for outdoor in-situ spraying in the OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 2 -Revised Emission Scenario Document for Wood Preservatives (2013), chapter 4.4.5, should be used also.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENVEmission estimation for insecticides for household and professional140uses (PT 18 - Household and professional use)

Version 1 (TM I 2010)

Number of houses:

- For outdoor use a number of 2500 households will be used;
- For indoor use a number of 4000 households will be used as default

Surface of a standard house: A surface area of a standard house of 130 m² is considered as default for general treatment. A wet cleaning zone leading to a release to the STP of 38.5 m^2 will be used.

Number of commercial buildings: For the number of commercial buildings 300 will be used as default, for both indoor and outdoor use.

Number of hospitals: No separate assessment for hospitals will be included. The number of commercial buildings of 300 is considered to include also hospitals.

Surface of commercial buildings: For the surface area to be treated for general treatment the default value is 609 m^2 .

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENVEmission estimation for insecticides for household and professional142uses (PT 18 - Household and professional use)

Version 1 (TM II 2010)

Number of houses:

For outdoor use a number of 2500 households will be used;

For indoor use a number of 4000 households will be used as default.

Surface of a standard house: A surface area of a standard house of 130 m2 is considered as default for general treatment. A wet cleaning zone leading to a release to the STP of 38.5 m2 will be used.

Number of commercial buildings: For the number of commercial buildings 300 will be used as default, for both indoor and outdoor use.

Number of hospitals: No separate assessment for hospitals will be included. The number of commercial buildings of 300 is considered to include also hospitals.

Surface of commercial buildings: For the surface area to be treated for general treatment the default value is 609 m2.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENVSimultaneity factor for calculating local releases to the STP (PT 18 -145Household and professional use)

Version 1 (WG-II-2016)

The simultaneity factor ($F_{simultaneity}$) for calculating local release to STP should not be doubled in order to take into account seasonality of a use. In addition, $F_{simultaneity}$ is also applicable for professional users.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENVWet cleaning zone for large buildings (PT 18 - Household and
professional use)

Version 1 (WG-II-2016)

The treatment area for bait box scenarios was harmonised:

For large buildings, the wet cleaning zone is calculated based on the relation of surface area and wet cleaning zone in the house scenario: the surface cleaning area of the house is 130 m² and the wet cleaning area is 38.5 m². This relation transferred to large buildings, where the total surface is 609 m², results in a wet cleaning zone of 180 m².

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

ENV Cleaning efficiencies in indoor treatment 149

Version 1 (WG-IV-2017)

During spray application (e.g. to walls) a fraction of the product applied will be released to floor or adjacent surfaces. These surfaces might be subject to wet cleaning and the following cleaning efficiencies should be used: For mixing and loading: the cleaning efficiency for the target area of the application should be used. For the application step: the cleaning efficiency for the actual target If a product is intended for use in domestic premises against a certain organism and it can be applied by both professionals and non-professionals, the emissions due to professional and non-professional use of the b.p. in domestic premises however should not be aggregated for the exposure estimation. The F_{sim} -value should in this case be understood as reflecting frequency of use regardless of user category. I.e. it is assumed that the treatment is applied by either a non-professional user or a professional user, during the same treatment period. If the product is intended for use in both domestic premises and larger buildings, these emissions have to be aggregated, regardless of the user category in the domestic premises.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

ENV Outdoor application in bait stations: Should groundwater as anenvironmental compartment be assessed?

Version 1 (WG-V-2016)

The following inconsistencies were noted: In the table 4.3-17 of the OECD ESD No. 18 for PT 18 it is indicated that emission to groundwater occurs but in the text below this table this emission route is considered negligible.

It was agreed that for insecticides in bait stations a groundwater assessment should be performed on Tier I level (according BPR IV B v.1.0) in order to show that the exposure is negligible. If in the light of experience, it is shown that the exposure is not negligible, a scenario for a Tier II assessment (e.g. for FOCUS modelling) needs to be developed.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENV Outdoor spot applications on paved surfaces: Should the release viathe STP be assessed?

Version 1 (WG-I-2018)

For outdoor application of insecticides on paved surfaces in urban areas, an assessment should be performed for the release via the STP, except for uses covered by the previous TAB entry (i.e. uses for which no environmental risk assessment is needed for the aquatic compartment and terrestrial compartment).

In case of spot application on paved surfaces around domestic premises the terrace scenario should be used (no release to sewer/STP is assumed, only releases to soil compartment around a terrace).

In case of spot application around commercial larger buildings the application rate around domestic premises should be used.

In consideration of application type and technique (gel, bait box, spray application) the perimeter of a larger building should be used for calculating the number of applications or/and the related application area.

Type of entry:	b) Clarifications/existing guidance
Publication date:	29/08/2018
Date of applicability for active substances:	29/08/2018
Date of applicability for products:	29/08/2018

Entry published more than 2 years before the publication date of this TAB document.

ENVRefinement of risk assessment: reduction of treated skin surface area172and taking into account dermal adsorption (PT 19)

Version 1 (WG-IV-2016, WG-I-2017)

As first tier for the treated skin area, the value as proposed in the recommendation of the Ad hoc WG on Human exposure should be used, i.e. 64% of 10660 cm².

As a second tier, the value decided for the treated surface in the human health section for a specific substance can be used.

The same tiered approach also applies for dermal adsorption: as first tier, no dermal absorption should be taken into account, as second tier the lowest value for dermal absorption from the human health assessment (e.g. based on study results) can be used to refine the risk assessment.

Type of entry:

b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB document.

ENV Splitting of releases from breweries

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Version 1 (AHEE-3)

For the CIP scenario evaluating breweries it was concluded that there is no evidence that the splitting of releases from breweries with regard to on-site and off-site treatment is realistic and it should therefore not be taken into account. It is sufficient to assess only one STP including biological treatment. It is then irrelevant if it is an on-site or off-site STP. The specification of the STP should then follow the specification of the standard (municipal) STP according to the TGD.

Type of entry:	b) Clarifications/existing guidance
Publication date:	19/12/2019
Date of applicability for active substances:	19/12/2019
Date of applicability for products:	19/12/2019