ECHA
EUROPEAN CHEMICALS AGENCY

Technical Agreements for Biocides

August 2017

This document aims to assist users in complying with their obligations under the Biocidal Products Regulation. However, users are reminded that the text of the Biocidal Products Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Version	Changes
1.1	Taking into account additional conclusions of the WG meetings in Q3/Q4 of 2015
1.2	Adding the APCP WG conclusions
1.3	Adding the EFF WG conclusions Taking into account additional conclusions of the WG meetings in Q1-2016 to Q1 of 2017 in the other sections

Technical Agreements for Biocides

Reference: ECHA-17-R-19-EN
ISBN-13: 978-92-9020-149-6
Catalogue number: ED-01-17-809-EN-N
DOI: 10.2823/888525
Publication date: August 2017
Language: EN

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at: http://echa.europa.eu/contact

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

Table of Contents

Preface

The Technical Agreements for Biocides (TAB) is an information document that intends to provide the agreements of the Working Groups of the Biocidal Products Committee (WGs) in a concise format. The TAB is intended to cover the technical and scientific WG agreements that have general relevance and to create a general database of questions where an agreement has already been reached. The main sources for the TAB are the adopted minutes of the WGs and Technical Meetings (TMs), as well as the Manual of Technical Agreements of the Biocides Technical Meeting (MOTA). In all cases, a reference is given to the WG meeting or TM where the agreement was reached.

Procedure

TAB does not require a formal endorsement by the Biocidal Products Committee or the WGs because the document records agreements made at the WGs and included in their minutes. It is a living document that will be updated over time with new additions. Any suggestions on the need to change the content can be sent at any time to BPC-WGs@echa.europa.eu.

The text will be updated regularly by uploading a revised version in the Newsgroups of the BPC-WG CIRCABC site for a commenting period of 6 weeks for the WG members. After the commenting period, ECHA will revise the TAB if necessary, and publish it on the ECHA website.
The procedure does not involve discussions at the WG. However, the TAB entry may be discussed at the relevant WG if necessary.

A. Environment

1 Effect and Hazard Assessment

ENV 1 **Are additional studies with plants required for the evaluation of the a.s. 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?**

(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.

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

(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.

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?**

(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).

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)?

(WG-IV-2016)

A PBT assessment should be conducted for each constituent occurring in the active substance in a concentration ≥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 ≥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.

2 Exposure assessment

1. General items

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

(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.

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

(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 $PEC_{surface\text{-}water}$ also for strong adsorbing substances and metals.

ENV 7 **Aggregated exposure assessment**

(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.

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?**

(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.

ENV 9 **Use of the model SimpleTreat 4.0 for biocides**

(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 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 embedded document, in which *section 1.3* describes the steps to be followed for transfer:

https://echa.europa.eu/documents/10162/23316520/env9_en.docx/e915cd38-eb0d-beb5-ad08-79807d0e54fd

2. Degradation

ENV 10 **When should indirect photolysis be considered?**

(TM I 2005, Feb. 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.

ENV 11 **Which DT_{50} value is to be used when multiple study results are available? (worst case value vs. geometric mean)**

(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.

ENV 12 Can a water-sediment simulation study be considered instead of a STP simulation test, for the refinement of exposure of non-biodegradable substances?

(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.

ENV 13 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?

(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.*"

ENV 14 Should photolysis metabolites be identified in case the active substance under evaluation is readily biodegradable?

(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.

ENV 15 How shall the results of an STP simulation study in the environmental exposure assessment be used?

(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.

3. Groundwater

ENV 16 What groundwater concentration limits should be applied to single biocide active substance, metabolites and mixtures (e.g. when the active substance is defined as a mixture block)?

(TMIV 2011, TM IV 2012, TM I 2013)

For single biocidal active substances the limit of 0.1 µg/l [1] 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 µg/l should also be applied to all metabolites in a tiered assessment scheme. Any metabolites predicted to occur above the 0.1 µg/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 µg/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 µg/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 µg/l [2].

The 0.1 µg/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 µg/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 µg/l limit (for individual metabolites) and the 0.5 µg/l (for total metabolite mixture concentrations) should both be applied at the first tier. Where

[1] Note that for some substances a lower limit than 0.1µg/l may be set on the basis of, for example, toxicological data. In these situations, the 0.1µg/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.

either of these limits is exceeded, the guidance provided in Vol. IV Part A, Section 1.6 on relevance of metabolites should be applied.

ENV 17 **Cut off criteria for groundwater assessment of biocides**

(WG–II-2014)

The document was developed by UK and endorsed at WG-II-2014.

http://echa.europa.eu/documents/10162/22002949/cut-off_criteria_for_groundwater_assessment_of_biocides_en.pdf

ENV 18 **Threshold values for groundwater assessment**

(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.

ENV 19 **Freundlich adsorption coefficient to be used in FOCUS models**

(WG-V-2016)

The FOCUS models require the Freundlich adsorption isotherm (K_F and 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.

ENV 20 **What parameter setting should be applied to FOCUS groundwater scenarios (PEARL) when they are used in biocide exposure assessments**

(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 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.

ENV 21 **Number of safe FOCUS scenarios for Union Authorisation**

(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.

4. PT specific items

2.1.1 Cross-PT items

ENV 22 **Can the default market share values which are used in several ESDs be refined? In which cases can we accept lower/other values than the indicated market share values in the ESDs?**

(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.

ENV 23 **Direct emissions to surface waters in PT 6, 7, 8, 9 and 10**

(WG-III-2014)

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 at PT 6, 7, 8, 9 and 10

http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents

ENV 24 **Assessment of emissions reaching the STP using the city-scenario for PT 10 in other PTs**

(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.

ENV 25 **Use of the scenario on direct emission to surface water in urban areas for the application phase**

(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.

ENV 26 **Should degradation in surface water be taken into account after release from an STP**

(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.

ENV 27 **Use of SPERCs for the assessment of biocides**

(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.

ENV 28 **Use of information provided in BREF documents for the refinement of the exposure assessment**

(WG-V-2015)

At WG-V-2015 it was agreed that additional information provided in BREF documents on 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.

ENV 29 **Laboratory and semi-field leaching test methods for PT 7, 9 and 10**

(WG-IV-2015)

The following 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:

http://echa.europa.eu/documents/10162/20733977/env_26_lab_leaching_test_en.pdf

http://echa.europa.eu/documents/10162/20733977/env_26_semi_field_leachi ng_test_en.pdf

ENV 30 **Reduction of default surface area for brush application for PT 18 and 19**

(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.

ENV 31 **Default crops, application dates, application mode and depth to be used for FOCUS groundwater models when refinement of $PEC_{groundwater}$ following sewage sludge application on soil is needed**

(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 $Appl\_rate_{agr/grass}$ [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. 36 in guidance BPR IV B v.1.0).

ENV 32 Scaling approach for PT 6.2, 7, 9, 10 (City scenario, Roof membranes)

(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}/ $f_{market\ share}$:

https://echa.europa.eu/documents/10162/23316520/env_32_en.docx/4d85070f-067e-55f2-28e4-aef5da6b8845

ENV 33 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?
(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.

2.1.2 PT 1

ENV 34 Professional hand disinfection: how to derive a value for $Qsubst_{pres\_bed}$ (and $Qsubst_{occup\_bed}$) for substances for which no default value is provided in the pick list of the ESD?

(WG-V-2014)

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

Nursing staff:

$$Qsubst_{bedN} = N_{FTE/bed} \bullet Q_{formN} \bullet F_{form} \bullet (RHO_{form}) \bullet N_{applN}$$

$Qsubst_{bedN}$	=	*Consumption of active ingredient per bed for nursing staff [kg/bed*d]*
$N_{FTE/bed}$	=	*Number of hospital personal per bed [FTE/bed]* *Default value: 1.5 FTE/bed*
Q_{formN}	=	*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*
N_{applN}	=	*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. $N_{FTE/bed}$ should be multiplied by 0.1.

$$Qsubst_{bedS} = (N_{FTE/bed} \bullet 0.1) \bullet Q_{form} \bullet F_{form} \bullet (RHO_{form}) \bullet N_{applS}$$

$Qsubst_{bedS}$	=	*Consumption of active ingredient per bed for surgical staff [kg/bed*d]*
$N_{FTE/bed}$	=	*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)*
F_{form}	=	*Fraction of active substance in the hand disinfectant [--]*
RHO_{form}	=	*Density of the product [kg/L]* *Default: 1 kg/L*
N_{applS}	=	*Number of disinfection events/FTE/day [1/FTE*d]*

Default: 10 (hand wash with soaps and liquid soaps) or 4 (hand rubs)[3]

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

$$Qsubst_{bedN} + Qsubst_{bedS}$$

ENV 35 **Which default values should be used for private hand disinfection?**

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

***F*inh**: 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.

***Q*form$_{inh}$ and *Q*form$_{appl}$**: The values proposed for consumers in CONSEXPO should be used, i.e. amount of liquid soap = 1 g/event, Nappl = 5 d^{-1}.

Note: If efficacy data show that the default value is not efficacious, the efficient use rate should be applied for *Q*form$_{inh}$ and/or *Q*form$_{appl}$.

2.1.3 PT 2

ENV 36 **How to calculate releases from the use of biocides for the treatment of private (permanent) pools?**

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

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

http://echa.europa.eu/documents/10162/22002949/pt02_private_pool_scenarios_en.pdf

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).

[3] 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.

- 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.

ENV 37 Disinfection of medical equipment - which default value should be used for the volume of the dipping bath and the maximum number of dipping baths used for pre-disinfection dipping?

(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;

i. Volume of dipping bath: 10 L (= 0.01 m³)
ii. 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 bath is adapted for small medical equipment supposed to be reused after pre-disinfection, disinfection and sterilization processes.

Pre-disinfection dipping scenario:

Variable / parameter	Unit	Symbol	Value	S / D / O / P

INPUT				
Working concentration of active ingredient	[%]	*Cdisinf*		S
Volume of solution in dipping bath	[m^3]	*Qdipping_bath*	0.01	D
Maximum number of dipping bath per day	[d^{-1}]	Ndipping_bath	30	D
Fraction released to wastewater	[-]	*Fwater*	1	D
OUTPUT				
Emission rate to wastewater (standard STP)	[$kg.d^{-1}$]	$Elocal_{water}$		O
CALCULATION				
$Elocal_{water}$ = *Cdisinf* • *Qdipping_bath* • *Fwater* • *Ndipping_bath* • *10*				

ENV 38 RTU – small scale applications: Definition of default values for the size of the area to be treated (PT 2)

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

For institutional areas, a default surface area of 25 m^2 should be used, as the area to be disinfected by small scale RTU products (e.g. spraying flacons or pre-soaked tissues).

Background information on the derivation of the default value:

https://echa.europa.eu/documents/10162/23316520/env38_en.docx/0a064257-fc80-7f4a-e34d-bf66be33f8d2

ENV 39 Emission scenario for the disinfection of aquaria

(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}.

Input and output values for local emissions of scenario – Aquaria				
Input	**Symbol**	**Value**	**Unit**	**Remarks**

Aquarium volume	$V_{aquaria}$	100	L	D
Number of aquaria per STP	$N_{aquaria}$	600		D
Fraction of water replaced due to product application	*Frep*	0.0179	d^{-1}	D/S
Concentration of a.s. in aquarium	$C_{aquaria}$		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	
Formula: $Elocal_{water} = (V_{aquaria} \times N_{aquaria} \times Frep \times C_{aquaria} \times Fwater \times Fmarket) / 1{,}000{,}000$				

ENV 40 Emission scenario for indoor fountain
(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}.

Input and output values for local emissions of scenario – Indoor fountains				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Fountain volume	$V_{fountain}$	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	$C_{fountain}$		mg/L	S
Fraction of a.s. released to	*Fwater*	1		D

wastewater				
Market share	*Fmarket*	0.5		D
Output				
Emission rate to wastewater	$Elocal_{water}$		kg/d	
Formula: $Elocal_{water} = (V_{fountain} \times N_{fountain} \times Frep \times C_{fountain} \times Fwater \times Fmarket) / 1{,}000{,}000$				

ENV 41 **Emission scenario for the disinfection of above ground small pools** (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 m^3).

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[4]. 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 m^3 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):

$Effluent_{pool} = V_{pool} / t_{drain}$
$DILUTION = (Effluent_{pool} + Flow_{ditch})/Effluent_{pool} = 6.6$
$Clocal_{water} = A_{appl} / ((1 + KP_{susp} * SUSP_{water} * 10^{-6}) * DILUTION)$

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

Soil: The direct emission of private temporary swimming pools (14 m^3) 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, http://www.fao.org/docrep/r4082e/r4082e03.htm). 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.

Input and output values for local emissions of scenario – Above ground small pools				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Private pool volume	V_{pool}	14	m^3	D *)
Soil area exposed	$AREA_{soil}$	56	m^2	D (see above)
Soil depth	$depth_{soil}$	0.5	m	D
Bulk density of soil	RHO_{soil}	1700	kg/m^3	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	N_{appl}	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	
Formula: $Q_{pool} = (A_{appl} \times V_{pool}) / 1000$				
Formula: $C_{soil} = (Q_{pool} \times N_{appl} \times 1{,}000{,}000) / (AREA_{soil} \times depth_{soil} \times RHO_{soil})$				

*) Common pool volume is between 7 to 14 m^3 (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 m^3 and will probably completely drained.

Medical sector: disinfection of endoscopes

ENV 42 (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 $Elocal_{water}$ (once-through) should be:

$$E_{local3,water} = N_{rep\text{-}max} * Q_{machine} * 10^{-2} * C_{disinf} * e^{-kdeg_{disinf} * T_{repl}} / (1+F_{carry\text{-}over})^{T_{repl}}$$

With:
$Elocal_{water}$: 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}]
$kdeg_{disinf}$: Rate constant for chemical conversion [d^{-1}]
Trepl: Replacement interval [d]
Fcarry-over: Fraction carry-over [-] = 0.015

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} 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}.

ENV 43 **Duration of emptying public swimming pools**
(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.

ENV 44 **Default volume for industrial premises in PT 2 when applying the biocidal product by e.g. vaporizing or fogging? (PT 2)**
(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 are of 1,000 m^2 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.

Background information on the derivation of the default value:
https://echa.europa.eu/documents/10162/23316520/env44_en.docx/67708042-0cd3-6a80-8813-7dc343a73980

2.1.4 PT 3

ENV 45 **Area of the animal housing to be considered for the application**
(WG-III-2014)

Application by **foaming** or **spraying**: In a first tier assessment all 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, all surfaces in the respective animal housing, provided in Table 8 of the ESD for PT 3 (page 51), should be taken into account.

ENV 46 **Capacity of dipping bath in PT 3**
(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 x 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 following embedded document:

https://echa.europa.eu/documents/10162/23316520/env46_en.docx/6c917f3a-08c1-a49c-442c-80d87fa02c15

ENV 47 **Default values for formaldehyde and paraformaldehyde in the ESD for PT 3**
(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 $g.m^{-3}$.

ENV 48 **Disinfection of vehicles: soil emission**
(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.

ENV 49 **Disinfection of pet case and litter trays: soil emission**
(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.

ENV 50 **Water volume in the reservoirs / tubs in hoof disinfection scenario**
(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).

ENV 51 **Calculation of nitrogen and/or phosphate imission standards**
(WG-IV-2016)

For active substance approval it is sufficient to provide a risk assessment only based on **nitrogen** imission standards. See also the conclusions in section 2.4.17.2 for PT 18 below.

ENV 52 **Teat disinfectant products for other animals than cows**
(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.[5]) 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.

2.1.5 PT 4

ENV 53 **Which default value should be used for $F_{mainsource}$ and $T_{emission}$ when calculating the annual amount of active substance used in an industrial food processing plant via the tonnage based approach?**
(WG-III-2014)

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

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.

ENV 54 Which volume should be considered for slaughterhouses / large kitchen in case application is performed by e.g. fogging / smoke generation?

(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:

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

ENV 55 RTU – small scale applications: Definition of default values for the size of the area to be treated (PT 4)

(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 m^2 should be used, corresponding to 0.1% of the total slaughterhouse area of 10000 m^2.

Background information on the derivation of the default value:

https://echa.europa.eu/documents/10162/23316520/env55_en.docx/ec91450e-041e-646e-1846-e799030c984e

ENV 56 Breweries: cleaning frequency

(WG-V-2016)

The following default value for the cleaning frequency in breweries have been agreed:
For mall breweries, cleaning takes place once per week and 43 weeks/year.
For large breweries, cleaning takes place 10 times per day and 300 days/year.

2.1.6 PT 5

ENV 57 **Total water consumption per occupied hospital bed**
(WG-V-2016)

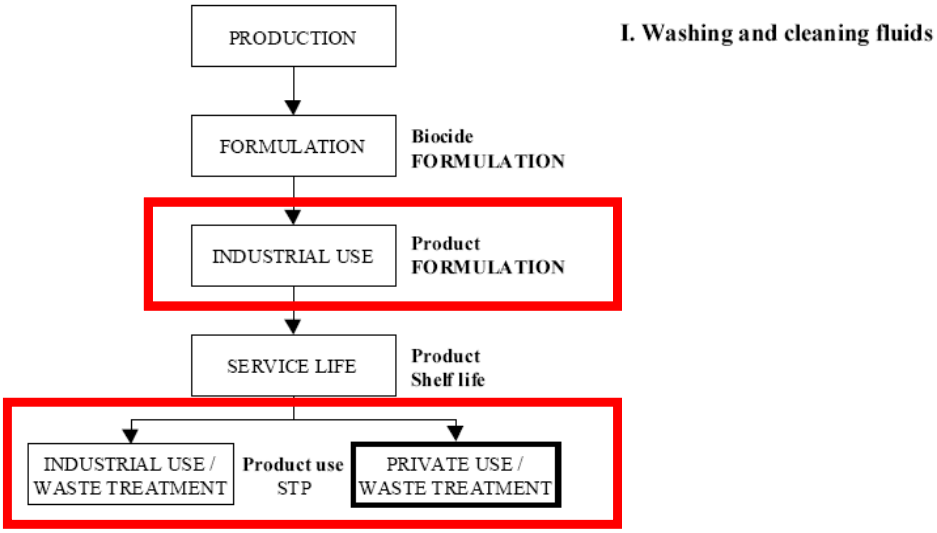
For the disinfection of hospital water, the hospital scenario for PT 1 (Emission scenario for calculating the releases of disinfectants in hospitals based on an average consumption, ESD for PT 1, Table 4.5) can be used as basis, applying the following default value for the water consumption per occupied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

2.1.7 PT 6

2.1.7.1 PT 6 general items

ENV 58 **Do product formulation and product use have to be evaluated?**
(TM IV 2008)

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



ENV 59 **Which approach should be used for the exposure assessment of PT 6? Which IC/UC category from the TGD has to be used?**
(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.

ENV 60 How should the sub-categories and sub-scenarios for PT 6 during product use be numbered?

(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.

ENV 61 Do in-can preservatives used in cosmetics fall into the scope of the BPD (BPR)?

(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.

ENV 62 Do emissions from waste disposal of biocidal products have to be evaluated under the BPR?

(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.

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

ENV 63 Which type of risk assessment should be considered?

(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.

2.1.7.3 PT 6.2 Paints and coatings

ENV 64 **Which emission scenarios are more appropriate for the risk assessment evaluation?**

(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.

ENV 65 **Are leaching test required?**

(TM I 2011)

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

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

Paper production

ENV 66 **Which additional ESDs can be considered for emission calculations?**

(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.

ENV 67 Which default parameters should be used for the risk assessment if no specific information by the applicant is given?

(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.

Textiles production

ENV 68 Which additional ESDs can be considered for emission calculations?

(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.

ENV 69 Which is the value to be used for the fixation rate (Ffix) for textile in-can preservatives?

(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.

ENV 70 Which values are to be used for the calculation of releases from different application steps?

(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 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.

Leather production

ENV 71 Which additional ESDs can be considered for emission calculations for leather production?

(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).

ENV 72 Which is the value to be used for the fixation rate (Ffix) for leather in-can preservatives?

(TM I 11)

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

ENV 73 Which is the value to be used as Qactive for leather in-can preservatives?

(TM I 2011)

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

2.1.7.5 PT 6.4 Metal Working Fluids (MWF)

ENV 74 Which additional ESDs can be used to evaluate PT Metal Working Fluids (WMF)?

(TM I 2011)

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).

2.1.7.6 PT 6.5 Fuels

ENV 75 Which additional ESDs can be used to evaluate PT 6 Fuels?

(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.

ENV 76 Do emissions of fuels have to be calculated if the fuel ends up in an engine?

(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.

2.1.7.7 PT 6.6 Glues and adhesives

ENV 77 Which additional ESDs can be considered for PT 6: Glues and adhesives?

(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.

ENV 78 Which input values should be used to calculate fractions of active substance reaching the STP if no data is available?

(TM I 2011)

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

2.1.8 PT 7

ENV 79 **Service life to be considered for coating?**
(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.

ENV 80 **Leaching rate to be used for the assessment of storage phase**
(WG-IV-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.

ENV 81 **Time period for the service life for the storage place (Time 2)**
(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.

2.1.9 PT 8

ENV 82 **How should the PEC surface water be calculated for industrially treated wood or industrial on-site storage?**
(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.

ENV 83 **Is the fence scenario for wood preservatives always required?**
(TM III 2005, Feb. 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)

ENV 84 What is the house density for the assessment of groundwater contamination resulting from the application to and leaching from houses treated with wood preservatives?

(TM III 2006, Feb. 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 m², 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.

ENV 85 Are two different DT50 values needed, one for TIME 1 and a different one for TIME 2, to calculate PECsoil?

(TM I 2007)

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

ENV 86 Extrapolation of the leaching results to longer time period (TIME 2). How should it be done?

(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)

ENV 87 How is the exposure scenario for Professional in-situ spraying defined?

(TM II 2007, Feb. 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.

ENV 88 Should the bridge over pond scenario for UC3 be included in the CAR even if this is not proposed as an intended use by the applicant?

(TM V 2007, 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.

ENV 89 When is the assessment of risks to groundwater from on-site storage necessary?

(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).

ENV 90 Summary of conclusions of the 2nd EU Leaching Workshop

(TM III 2013, WG-I-2014)

Note: *The following embedded document was prepared as an "interim solution" and contains the conclusions on those items discussed at the 2nd EU Leaching Workshop which have been endorsed at TM III 2013 and WG-I-2014.*

The final conclusions will be uploaded to the ECHA ESD specific webpage as soon as the remaining open points, currently still under discussion, are agreed.

http://echa.europa.eu/documents/10162/22002949/summary_on_conclusions_2nd_eu_leaching_ws_on_wood_preservatives_en.pdf

ENV 91 Acceptability of the current methods to assess the exposure/risk of wood preservatives (PT 8)

(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.

ENV 92 **Default flow rate for creek adjacent to a storage place**
(WG-III-2016)

For calculation of $PEC_{surface\ waters/industrial\ storage}$, as flow rate of an adjacent creek a default value of 0.3 m^3/s should be used.

ENV 93 **Bunded storage sites: Need of an assessment of release to the STP**
(WG-III-2016)

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

ENV 94 **Should the city scenario be applied for PT 8 to cover the release via STP?**
(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.

Background information:

https://echa.europa.eu/documents/10162/23316520/env94_en.docx/9277ed70-6b57-dc60-1180-ddcd9ffc026c

ENV 95 **Wood treated with short term antisapstain**
(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.

ENV 96 **Clarification on the text of the RMM for PT 8**
(WG-V-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.

2.1.10 PT 9

ENV 97 **Which tent density per hectare can be used for $PEC_{groundwater}$ calculations?**

(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.

ENV 98 **Use scenarios for PT09 roof membranes**

(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: http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents

2.1.11 PT 10

ENV 99 **Which input values should be used to calculate emissions reaching the STP for the city-scenario in PT10?**

(TMIII 10, TM II 2012, TMIV 2012, TMII 13, TMIII 13, 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: http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents

ENV 100 **Which soil volume should be considered for the countryside house scenario for PT10?**

(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.

ENV 101 Refinement of the cumulative leaching by taking into account $F_{weatherside}$ for the city scenario

(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 not be taken into account.

2.1.12 PT 11

ENV 102 Conclusions on the environmental assessment of biocides in PT 11 cooling water systems

(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: http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation/emission-scenario-documents

ENV 103 Emission to surface water from small open recirculating cooling systems

(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.

ENV 104 Closed cooling system – drainage of the system and treatment as hazardous waste

(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.

2.1.13 PT 12

ENV 105 How to address the use and discharge of offshore chemicals from oil platforms?

(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.

ENV 106 Can the dilution factor from STP to adjacent surface water be increased for PT 12?

(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)

ENV 107 Default values for slimicides in offshore processes

(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_11-12_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.

2.1.14 PT 13

ENV 108 Should Cinfl calculations be based on the total Fsplit (=Fsplit,evap+Fsplit,kow)?

(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).

2.1.15 PT 14

ENV 109 **Can the default release factor (1% as recommended in EUBEES) to estimate direct releases during application and use of a rodenticide be lowered to 0.1%?**

(TM I 2006)

When justified by data on releases of the formulation (e.g. paste formulations), the release factor can be lowered.

ENV 110 **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?**

(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.

ENV 111 **Lipid normalisation for anticoagulant rodenticides**

(WG-I-2016)

Lipid normalisation should in general not be performed for anticoagulant rodenticides when the substances accumulates mainly in the liver.

ENV 112 **Bioconcentration factor (BCF) for anticoagulant rodenticides**

(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 non-target species need to be taken into account as weight-of-evidence information.

ENV 113 **Groundwater assessment for rodenticides (including hot spot applications)**

(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.

2.1.16 PT 15

ENV 114 **Clarification on default values in the ESD for PT 15**
(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 m^2

In the ESD page 39, $Elocal_{water}$ calculation (equation 12), it should read 10^{-6} instead of 10^6.

2.1.17 PT 18

2.1.17.1 Household and professional use

ENV 115 **How should the environmental risk assessment for indoor gel bait application be performed?**
(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.

ENV 116 **Size of receiving compartment -soil depth in case of outdoor applications in PT 18 (for insecticides, acaricides and products to control other arthropods for household and professional uses)?**
(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).

ENV 117 **Emission estimation for insecticides for household and professional uses**
(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 m^2 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.

ENV 118 Emission estimation for insecticides for households and professional uses: targeted applications

(TM II 2010)

Targeted applications for which default values are available: i) spot treatment or crack and crevice treatment, and ii) barrier treatment;

- Default value for spot or crack and crevice 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 m^2 and 93 m^2 for spot treatment or crack and crevice 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 m^2, equal to the surface of the kitchen and bathroom (ConsExpo). 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 m^2 for a domestic house, and 27 m^2 for commercial buildings. No correction is applied for spot application.

ENV 119 Simultaneity factor for calculating local releases to the STP

(WG-II-2016)

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.

ENV 120 Wet cleaning zone for large buildings

(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 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.

ENV 121 Treatment area for bait box scenarios on terraces
(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.

ENV 122 Fraction of product consumed by the ants versus amount left at the bait station
(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.

ENV 123 Outdoor application in bait stations: Should groundwater as an environmental compartment be assessed?
(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.

2.1.17.2 Stable and manure application

ENV 124 Nitrogen immission standards to be used for release estimation of insecticides applied in stables and manure storage systems
(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).

ENV 125 **AHEE Recommendation for PT 18**

(WG-V-2015)

The AHEE recommendation as Addendum to the OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: *Emission Scenario Document for Insecticides for Stables and Manure Storage Systems* was endorsed at WG-V-2015 and is provided in the following:

http://echa.europa.eu/documents/10162/20733977/env_89_addendum_to_es_d_for_pt18_en.pdf

ENV 126 **Run off from soil to surface water after manure application**

(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.

ENV 127 **Taking into account degradation in manure**

(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 following:

https://echa.europa.eu/documents/10162/23316520/env_127_recom_en.docx/af1ef9e4-73f7-0e7c-88a5-64e1127ce802

https://echa.europa.eu/documents/10162/23316520/env127_pt18_anure_arable_en.xlsx/6305fe82-2033-5195-a45a-6eaa23986f9c

https://echa.europa.eu/documents/10162/23316520/env127_pt18_anure_grass_en.xlsx/cf8154b5-7a67-ab85-0ec9-9549cba58c19

ENV 128 **Default crops, application dates, application mode and depth to be used for FOCUS groundwater models when refinement of PECgroundwater following manure / slurry application on soil is needed**

(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 per year to maize 20 days before crop event “emergence” (relative 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:**

$$Appl\_rate_{grs} = PIEC_{grs} \times RHO_{soil\_wet} \times DEPTH_{grassland} \times 10^{-2} = PIEC_{grs} \times 0.85$$

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

$$Appl\_rate_{ar\_maize} = PIEC_{ars} \times RHO_{soil\_wet} \times DEPTH_{arableland} \times 10^{-2} = PIEC_{ar} \times 3.4$$

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.

$$Appl\_rate_{ar\_cereal\_autumn} = 0.47 \times PIEC_{ars} \times RHO_{soil\_wet} \times DEPTH_{arableland} \times 10^{-2}$$
$$= PIEC_{ars} \times 1.6$$

$$Appl\_rate_{ar\_cereal\_spring} = 0.53 \times PIEC_{ars} \times RHO_{soil\_wet} \times DEPTH_{arableland} \times 10^{-2}$$
$$= PIEC_{ars} \times 1.8$$

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_rate$_{ar_cereal_autumn}$ for the modelled application on 3rd of October and Appl_rate$_{ar_cereal_spring}$ 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 PEC$_{groundwater}$ following manure/slurry application on soil is needed.

ENV 129 Values to be used for the FOCUS PEARL simulations
(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.

ENV 130 Which area should be used for the calculations for larvicides and insecticides, for the different application types?
(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.

ENV 131 **Environmental exposure pathways from poultry housings** (WG-II-2017)

Two pathways are evident for emissions from animal breeding / housing units:

1) 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;

2) 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 waste water, 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 waste water):

Scenario 1: According to the OECD ESD No. 14 for PT 18, animal housing sub-categories **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 waste water 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 waste water 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 waste water is already added to the “belt dried slurry” fraction and will reach the soil compartment. Furthermore, a discharge fraction to waste water is provided, which could reach the local STP. In case only belt dried slurry (without waste water from this animal housing sub-category) is released to agricultural land (arable land and grassland) the waste water fraction should be subtracted from the slurry fraction indicated in Table 5.4.

ENV 132 **Emission from washing of coveralls after PT18 stable applications**
(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.

ENV 133 **Waste water stream in stables**
(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.

ENV 134 **Treatment of animal transport vehicles**
(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.

2.1.18 PT 19

ENV 135 **Refinement of risk assessment: reduction of treated skin surface area and taking into account dermal adsorption**
(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 cm^2.
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.

ENV 136 **Correction of equations in the ESD**
(WG-IV-2016)

Concerning the ESD page 32, equation no. 3.14, calculation of $C_{localwater,91d}$, the correct equation is as follows:
$Clocal_{water,91d} = Elocal_{water} * 10^3 * T_{emission,91d} / V_{waterbody}$.

2.1.19 PT 21

ENV 137 **Consolidated list of technical agreements – Environment**
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-biocides-legislation/emission-scenario-documents

ENV 138 **Clarification on the text of the RMM for PT 21**
(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.

B. Human health

1 Dermal absorption

TOX 1 **If a biocidal product is applied directly on human skin, should other products that may be applied on the skin at the same time be taken into account? Such products could enhance the dermal absorption of the biocidal product.**

(TM I 2009)

Enhanced dermal absorption due to simultaneous application of a product other than the biocidal product in question should not be considered at active substance approval stage. If information of such interactions is available, it should be included in the CAR under *Elements to be taken into account by MSs when authorising products*.

TOX 2 **Derivation of dermal absorption values.**

(TM II 2012)

Detailed information should be provided by the Evaluating Competent Authority (eCA) on the dermal absorption value(s) in the LOEP. This should indicate how the value(s) was derived (in vitro and/or in vivo studies) and what exactly was tested (concentration of the a.s. and type of formulation). The text should also indicate the basis of the applicability of such values to the representative product (both the concentrate and the in-use dilution). This information is crucial at the product authorisation stage when a decision is required whether the dermal absorption values established in the LOEP can be extrapolated to other products.

2 AEL derivation and assessment factors (AF)

TOX 3 **Is it acceptable to have different AELs for professionals and non-professionals?**

(WG-IV-2014; TM III 2013)

It is in general not acceptable to have different AELs for professionals and non-professionals. However, when there is information related to age specific kinetic differences, different AELs can be set for professionals and non-professionals.

This exception was accepted in TM III 2013 for a specific substance for which it had been shown via PBTK modelling that variations in toxicokinetic dose metrics averaged during different life stages (from birth to 75 years of age) and were within a factor of 2 for all age groups (0-75 y) and within a factor of 1.2 for 5 to 75 years of age. The toxicokinetic AF of 3.2 was substituted with a chemical specific of AF 2 for the general population resulting, together with a toxicodynamic AF of 3.2, in an overall intraspecies AF of 6.4. Similarly for professional workers, a chemical specific AF of 1.2 resulted in an overall intraspecies AF of 3.8.

TOX 4 Should developmental studies be used for AEL derivation if their NOAEL is the lowest available?

(MOTA v.6)

When valid developmental studies are available, all relevant critical effects should be evaluated together with other observations from other studies. If the NOAEL derived from relevant effects in a valid developmental toxicity study is lower than those from short-term and long-term studies, and this cannot be explained by dose spacing, the NOAEL from the developmental toxicity study should be used for the derivation of the AEL value. This will apply to the global population (thus protecting both pregnant and non-pregnant women).

Developmental studies are often the only studies to use gavage dosing with the aim of determining a NOAEL. This can give rise to C_{max} related effects, such as certain clinical signs, that might not be relevant to dermal exposures where a spike of absorption is not normally seen.

It should be noted that due to their inherent limitations, developmental studies cannot be considered as surrogates for other repeated-dose toxicity studies when these are missing or invalid.

TOX 5 In case where a risk characterisation is based on a maternal effect, should the intra-species factor remain at 10 or should it be reduced for taking into account the higher sensitivity of the pregnant subpopulation?

(MOTA v.6)

There is no evidence that pregnant women are always more sensitive than the rest of the population. The AEL derived from maternal effects will cover the whole population, and the intra-species factor is 10 unless there are specific reasons to deviate from this.

TOX 6 Should an extra AF be added for using a 1-year dog study in deriving the long-term AEL?

(TM IV 2009)

No extra AF is normally necessary, since a 1-year dog study should be considered sufficiently chronic for deriving the long-term AEL without additional AFs, unless there is a clear justification to the contrary.

TOX 7 PT 14: Which studies can be used in setting the acute AEL for anticoagulant rodenticides?

(TM II 2007)

The general problem in selecting the appropriate study for anticoagulants is that, in general, acute studies are not suitable for setting AELs due to the cumulative effect of anticoagulants. In terms of exposure and study duration, teratogenicity studies in the existing dossiers have been more relevant for AEL setting, and the developmental study in the most sensitive species should be used.

TOX 8 PT 14: If subchronic studies are used for chronic scenarios of anticoagulant rodenticides, will an extra assessment factor be needed? Which AF would then be appropriate?

(TM I 2007)

The AF will depend on the available data set, and the decision will have to be made case by case. If an extra AF is concluded to be necessary, a factor of 3 is considered sufficient to provide safe margins to cover for the use of subchronic studies for chronic exposure scenarios.

This agreement is maintained although the current default value is 2 for extrapolation from subchronic studies to chronic exposure (Guidance for Human Health Risk assessment part B).

TOX 9 Is there an agreement on using an extra AF for anti-vitamin K (AVK) anticoagulants for the severity of the effect?

(TM III 2006)

An extra AF of 3 will be used for all AVKs, while it was recognised that this factor is not scientifically derived.

TOX 10 How should the systemic AELs be derived for pyrethroids, given that there is extensive first pass metabolism following oral administration?

(TM III 2009)

When appropriate data exists for dermal and inhalation routes, this data should be used to derive route-specific systemic AELs, rather than using oral data and route-to-route extrapolation. Extrapolation would be problematic due to extensive hepatic first-pass metabolism.

This approach requires that 1) appropriate route-specific data is available, and 2) large first-pass metabolism is demonstrated or likely.

3 Local reference values

TOX 11 For the derivation of local reference values, is it possible to deviate from the default value in setting an assessment factor (AF) for intraspecies difference?

(WG-V-2015)

When reference values are set based on animal studies and there is no information of effects in humans at similar dose/concentration levels, the intraspecies AF should normally be 10.

When setting the intraspecies AF based on human data, normally the dynamic factor of 3.2 should not be changed. The kinetic factor 3.2 cannot be excluded if the study population is small and no sensitive populations are studied.

It is nevertheless possible to set an intraspecies AF lower than 10 (e.g. 3.2) even when dynamic and kinetic differences cannot be excluded, taking into account factors such as mode of action (e.g. pH-related irritancy at the first site of contact and no local metabolism involved) and low severity of the effects at LOAEC.

4 Specific toxicological effects

TOX 12 How should unpalatability be considered when the NOAEL is set based on reduced body weight gain?

(WG-II-2014)

Reduced body weight gain should usually be considered as an adverse effect and as a basis for setting the NOAEL. Although unpalatability may contribute to the reduced body weight gain, it should be clearly shown that there is a causal relationship between reduced palatability and reduced bodyweight gain/food consumption. If the effect is present also in e.g. gavage or inhalation studies, it cannot be explained by unpalatability.

TOX 13 Should emesis (e.g. in dogs) be considered as an adverse effect and used as a basis for setting the NOAEL?

(WG-V-2014)

Emesis is considered as an adverse effect and can be used as a basis for setting the NOAEL.

5 Corrosive substances

TOX 14 For active substance approval, is systemic risk characterisation necessary for corrosive concentrations?

(WG-III-2016)

Dermal and oral routes. The use of appropriate personal protective equipment and risk mitigation measures will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substances. Exposure to corrosive concentrations would thus be negligible. Therefore, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations.

It should be mentioned in the CAR that for corrosive concentrations the systemic risks are covered by the local risk characterisation.

Inhalation route. If inhalation exposure is possible following the use of a corrosive concentration of the active substance, systemic risk characterisation should be performed, independently of whether or not the substance is corrosive as inhaled.

TOX 15 How should corrosivity be estimated for formulations that have not been tested?

(WG-III-2016)

For formulations that have not been tested, bridging principles and the calculation method should be applied where relevant in estimating corrosivity.

For the calculation method, specific or generic concentration limits should be applied.

TOX 16 How should dermal absorption values be derived for corrosive concentrations of the active substance?

(WG-III-2016)

A default dermal absorption of 100 % should be indicated for corrosive concentrations unless there is data indicating lower dermal absorption. This value would normally not be used in the risk assessment because dermal exposure should be avoided using risk mitigation measures.

6 Exposure assessment

5. General issues

TOX 17 Can exposure assessment be performed by averaging the exposure e.g. over a year, if this information is needed?

(TM III 2007, TM IV 2009)

As a general rule, averaging of exposures will not be attempted unless there is sufficient justification and a Working Group agreement. It should be noted that in ConsExpo the chronic exposure is defined as a year average dose, which would not accurately describe a situation where exposure occurs seldom or sporadically.

TOX 18 What is the most relevant exposure determinant in the spray application scenario?

(TM III 2011)

The application duration of 120 minutes is the most relevant exposure determinant and should be used as default for spraying applications in stables. According to minutes from TM III 2011 (2b.10 Spray application in animal house scenario) animal house scenario was obtained from the median of wall and roof area of all types of stables.

TOX 19 Should exposure assessment for non-professionals be performed with the use of gloves as Tier II?

(WG-IV-2014, WG-I-2015)

The exposure assessment for non-professionals should be performed in light of both the CA meeting document *Authorisation of biocidal products classified as skin sensitizers requiring PPE for non-professional users* (CA-Sept13-Doc.6.2.a – Final.Rev1, amended by CA-May14 – Doc.5.2.a) and the guidance on local risk characterisation (ECHA Guidance for Human Health Assessment, Vol III part B).

Where an applicant has proposed the use of a sensitising active substance for non-professionals or, in the case of PT 21 an unacceptable systemic risk has been identified for non-professionals, the exposure assessment should be performed both with and without assuming gloves.

The CAR should state whether the eCA considers it acceptable to perform the risk characterisation assuming the use of gloves, clearly justifying the proposal. The BPC will then conclude on the acceptability of the RMMs.

In systemic risk characterisation, default protection factors for gloves can be applied. Local risk characterisation should be performed in a qualitative way and no numerical protection factor is thus needed.

For PT 21 substances, the CA document *Approach for antifoulings PT 21* (CA-March14-Doc.4.2) states that "Persons making products containing [the substance] available on the market for non-professional users shall make sure that the products are supplied with appropriate gloves".

TOX 20 Which protection factor for coveralls should be used in low pressure (1-3 bar) spraying or wiping applications?

(WG-III-2014)

According to HEEG opinion "impermeable" coveralls should provide a high degree of protection (95 %) against heavy contamination. It was considered that a low pressure (1-3 bar) spraying or wiping does not cause such a heavy contamination and therefore the default 90 % protection factor of a coated coverall applies.

6. PT 1

TOX 21 PT 1: What retention factor value in hand wash should be used?

(WG-I-2015)

The default value of 1 % from the SCCS's Notes of Guidance for testing of cosmetics ingredients and their safety evaluation (7th Revision) should be used until a recommendation of the HEAdhoc is developed.

TOX 22 PT 1: How is sufficient contact time determined for disinfection of hands?

(WG-V-2014)

It is important that efficacy is demonstrated with the contact time used for the exposure scenario. In addition, there must be practical considerations as to whether the disinfection can in practice be performed during the time indicated. A contact time of 30 seconds would usually be considered sufficient for hand disinfection, provided that efficacy of the product after a 30-second contact is demonstrated. Default values can thus be replaced in the assessment when relevant information is available.

TOX 23 PT 1: How many facial tissues can be considered adequate for the estimation of acute and chronic exposure for non-professionals?

(WG-IV-2014)

For the acute exposure scenario a use of 15 tissues per day is assumed, and 4 tissues a day over one year for chronic scenario. This should be considered as a temporary agreement in the absence of appropriate guidance.

TOX 24 PT 1: Which is the adequate transfer efficiency of an active substance from a facial tissue (PT 1) to hand?

(WG-IV-2014)

A transfer efficiency of 50 % is considered a realistic worst case scenario based on the value of transfer efficiency of cotton substrate to wet hands (30 %), described in the Biocides Human Health Exposure Methodology[6] (2015). This should be considered as a temporary agreement in the absence of appropriate guidance.

7. PT 2

TOX 25 PT 2, swimming pool: What exposure duration should be used for swimming in a pool?

(WG-I-2015)

The duration of exposure should be 1 h, in line with the values indicated in the ConsExpo Fact Sheet for Disinfectants.

TOX 26 PT 2, swimming pool: What is the thickness of the product layer around the swimmer?

(WG-I-2015)

The thickness of the product layer on the skin is assumed to be 0.1 cm for liquids (Biocides Human Health Exposure Methodology[3], 2015). The value of 1 cm, as given in the ConsExpo Disinfectant Fact Sheet, is considered overly conservative. This should be considered as a temporary agreement in the absence of appropriate guidance.

TOX 27 PT 2, swimming pool: Which model should be used for inhalation exposure of consumers in swimming pools?

(WG-IV-2016)

Inhalation exposure assessment for consumers in swimming pools should be performed by assessing exposure to vapour using ConsExpo 4.1 evaporation model. Exposure to aerosol does not need to be assessed due to the lack of a suitable model.

[6] Available here: http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure.

8. PT 6

TOX 28 PT 6: Which model should be used to estimate exposure associated with the cleaning and maintenance operations of dispersing pumps as the post-application phase?

(WG-I-2015)

In the absence of more appropriate models, the "*Cleaning of spray equipment*" scenario in the BEAT database should be used.

TOX 29 PT 6: Which work phases will be considered when performing the exposure assessment for an in-can preservative?

(TM II 2008)

Exposure should be assessed from mixing the in-can preservative into the product which is to then to be used (for example, the addition of the in-can preservative to a formulation which is to be marketed as a laundry-washing detergent). This operation will usually be undertaken during the factory manufacture of the laundry-washing detergent. This should be considered as a 'primary exposure' scenario.

Details are sometimes given of exposure during the production of an intermediate product which is then placed on the market. It was agreed that the following situation will not be assessed since it can be considered equivalent to manufacture/formulation: *Solution containing 50 % of in-can preservative active Z DILUTED TO a solution containing 20 % in-can preservative active.*

9. PT 8

TOX 30 PT 8: What wood density should be used? This will have an effect in the exposure assessment of cutting and sanding treated wood.

(TM III 2008)

A wood density of 0.4 g/cm^3 will be used as a worst case scenario. This is an average value for softwoods given in the website www.csudh.edu/oliver/chemdata/woods.htm.

10. PT 18

TOX 31 PT 18: Which models should be used to assess exposure of professional users (farmers) during watering / pouring application?

(WG-I-2015)

The *Mixing and Loading model 5* from TNsG 2007 ("Model for pouring into a portable reservoir") should be used for the mixing and loading phase. The TNsG 2007 model for watering cans should be used as Tier 1 for the application phase. A reverse reference scenario, focused on duration exposure, can be performed as Tier 2 if necessary.

TOX 32 PT 18: Which model should be used to assess exposure of non-professional users during hand-held pump sprayer applications?

(WG-I-2015)

The *Consumer spraying and dusting model 1 – hand-held pumped spray for handheld applications* (TNsG 2002, page 194) should be used. In a higher tier assessment, ConsExpo 4.1 may be used for the specific consumer product, using the spray model and product specific defaults (where available).

11. PT 19

TOX 33 PT 19: Should the simultaneous use of sun lotions be considered in the exposure / risk assessment?

(WG-IV-2016)

For the purpose of risk assessment for active substance approval in PT 19, the possible simultaneous use of sun lotions does not need to be considered.

12. PT 21

TOX 34 PT 21: Does the scenario of a toddler touching wet and dry paint need to be assessed for non-professional applications of PT 21 active substances?

(WG-II-2014)

This scenario needs to be assessed in line with the recommendation of the HEAdhoc Recommendation no. 5 "*Non-professional use of antifouling paints: exposure assessment for a toddler*".

TOX 35 PT 21: Does exposure during cleaning of spray equipment for antifoulings (PT 21) need to be assessed?

(WG-IV-2014)

The scenario of cleaning of spraying equipment need to be assessed according to the HEAdhoc Recommendation no. 4 "*Cleaning of spray equipment in antifouling use (PT 21)*".

7 Waiving

TOX 36 Can extra assessment factors be used to cover the lack of data in waiving cases?

(TM I 2007)

In a case where there was scientific justification for waiving the 2-generation study, it was decided that an extra assessment factor (AF) of 3 should be used. Using an extra AF of 10, as was suggested, was considered over-conservative. An extra AF was however considered necessary since, although waiving was scientifically based, the data that was to be lacking could not be covered by other

studies. Furthermore, there was not a possibility for reading across from a 2-generation study of another substance.

Applying extra assessment factors to cover for lack of data cannot be considered a general rule, but will be assessed on a case-by-case basis.

TOX 37 Is it possible to waive mutagenicity studies?

(TM IV 2012)

Waiving of genotoxicity data will not be possible by default, since no other types of studies than studies employing test methods specifically designed to detect genotoxic effects can provide the required information. However, under certain circumstances studies could be waived on a case-by case basis. In such cases a weight of evidence approach could be adopted, including all relevant information and data, e.g. (Q)SAR, grouping, read across, carcinogenicity data and reproductive toxicity data.

Mutagenicity is a toxicological endpoint per se and cancer data cannot replace mutagenicity data in the evaluation of the mutagenic potential of a substance. Negative carcinogenicity studies can however be used to judge the relevance of testing site of contact genotoxicity.

Note: As stated in the minutes of TM IV 2012, SE did not agree with the view suggesting that carcinogenicity studies could be used to inform on local genotoxicity.

See also the text on mutagenicity resulting from a refinement based on agreed version at the TM IV 2012 (Annex 1).

8 Companion animals

TOX 38 Should risks to companion animals be taken into account in the assessment? How should this be done?

(TM IV 2009)

Risks to companion animals (pets) should be considered at the member state level, at the product authorisation stage. The predominant approach should be to use appropriate risk management measures, e.g. labelling instructions.

The underlying assumption is that the hazard assessment, which is performed for humans, will cover the companion animals as well, while the exposure patterns will differ. It would not be sensible to try to perform an exposure assessment and risk characterisation for all companion animal species, especially given that suitable methodology is lacking. Risks to companion animals will therefore be left for the member state authorities to consider at product authorisation.

9 Appendices to the Human health section

Appendix 1. Mutagenicity

The importance of following data requirements and accomplishing appropriate weight of evidence analyses when assessing mutagenicity

(Agreed at TM IV 2012)

Effects of mutation

It is important to remember that mutagenicity is an endpoint that may lead to severe consequences, since it can cause (i) heritable mutations, i.e. changes in the DNA of germ cells that may be transmitted from a parent to a child in which they may result in malformations or genetic disorders, and (ii) mutations in somatic cells, which may lead to cancer.

Overall conclusion on mutagenicity

Overall conclusions from the evaluation of mutagenicity studies in a dossier should be based on overall weight of evidence analyses that should be done separately for the genotoxic endpoints for which information is required according to the Biocidal Products Directive (i.e. gene mutations in bacterial cells, structural chromosome aberrations in mammalian cells, numerical chromosome aberrations in mammalian cells, gene mutations in mammalian cells and, where required, the relevant endpoint *in vivo*). In the guidance for the implementation of REACH (Guidance on information requirements and chemical safety assessment, Chapter R.7a: Endpoint specific guidance) this generally applied approach is explained by the following text:

"For each test type and each genotoxic endpoint, there should be a separate *Weight of Evidence* analysis. It is not unusual for positive evidence of mutagenicity to be found in just one test type or for only one endpoint. In such cases the positive and negative results for different endpoints are not conflicting, but illustrate the advantage of using test methods for a variety of genetic alterations to increase the probability of identifying substances with mutagenic potential. Hence, results from methods testing different genotoxic endpoints should not be combined in an overall *Weight of Evidence* analysis, but should be subjected to such analysis separately."

Consequently, a data package of, for example, 12 in vitro studies (all of acceptable quality) including six negative gene mutation studies in bacteria, five negative gene mutation studies in mammalian cells, and one positive chromosome aberration study in mammalian cells would support an overall conclusion that the test substance has mutagenic potential in vitro, since the study on chromosome aberrations was positive. Furthermore, it can be concluded that the test substance does not have potential to induce gene mutations in vitro, neither in bacterial cells, nor in mammalian cells. It would be incorrect to draw the overall conclusion that the substance has no mutagenic potential in vitro by taking into consideration the inappropriate weight of evidence analysis based on the observation that only one of twelve mutagenicity studies was positive. In a real case it is likely that the results of the available data will be more complex, making it more demanding to analyse the results. However, in order to arrive at a relevant overall conclusion, the above considerations must be taken into account during the evaluation of genotoxicity test data.

Waiving of genotoxicity data

The TM is of the opinion that waiving of mutagenicity data requirements in the common core data set would not be possible by default, since no other types of studies than studies employing test methods specifically designed to detect genotoxic effects can provide the required information. In addition, results from a gene mutation test in bacteria are not sufficient to predict the potential of a substance to induce gene mutations in mammalian cells in vitro, since results from both types of studies are required according to the mutagenicity data requirements of the Biocidal Products Directive. Therefore, data could be waved on a case-by-case basis only, i.e. where it is technically not possible or where it is scientifically not justified to perform a mutagenicity study, as mentioned in the legal text of the Biocidal Products Regulation (BPR) 528/2012 and in the Technical Notes for Guidance on Data Requirements. A WoE evaluation may include data from other than actual standard test data, (Q)SAR data, grouping and read across, carcinogenicity data and others.

In particular, (Q)SARs are explicitly mentioned in the BPR 528/2012 (Annex IV, General rules for the adaption of the data requirements), where it is stated that (Q)SARs may be used to indicate the presence, but not the absence of a given dangerous property. However, this limitation is not stated for the grouping and read-across approach. The OECD toolbox provides (Q)SARs but also grouping and read-across approaches for the AMES test, in vitro UDS, in vitro chromosomal aberration test, in vitro COMET assay, in vitro sister chromatid exchange assay, mouse lymphoma assay, in vivo dominant lethal assay, in vivo drosophila SLRL test, in vivo micronucleus test – and in vivo carcinogenicity models as well as TD50. In the public VEGA software also AMES and carcinogenicity QSAR is available and it contains a combination of QSAR and an independent read-across tool. The OECD toolbox as well as VEGA contains also a user friendly possibility to evaluate the applicability domain, i.e. the suitability of the model for the specific substance. (Q)SARs are developed from a large database of substances and thereby may also overcome uncertainties from borderline or uncertain single testing results. They may be considered more objective compared to read across and grouping approaches. However all three non-testing approaches, i.e. (Q)SAR, read across and grouping are explicitly recommended for consideration in the BP Regulation 528/2112 (Annex IV).

As regards exposure-based waiving of mutagenicity data, this would be very rarely possible, since mutagenic effects resulting from direct interaction of a substance with the DNA are considered to show a no-threshold dose-response relationship. However, in very specific cases of extremely low exposure the (Q)SAR based approach “Toxicological Threshold of Concern (TTC)” approach may be considered.

Use of Cancer data for the evaluation of mutagenicity in the frame of a Weight of Evidence approach

In evaluations of the mutagenic potential of active substances, data from cancer studies are frequently referred to, particularly when the results from the available mutagenicity studies are not fully conclusive, e.g. some studies may not have produced reliable results due to inadequate quality, or studies on one of the genotoxicity endpoints for which data is required may be missing. However, carcinogenicity data are not sufficient to determine whether a substance is mutagenic or not; for this, results from studies employing test methods specifically designed to detect genotoxic effects are required. Even though there is a certain concordance between mutagenicity and carcinogenicity, carcinogenicity studies are neither sensitive enough, nor discriminating enough to discern between a mutagenic substance and a non-mutagenic substance. However, in an overall weight of evidence approach for the evaluation of mutagenicity, all available relevant data should be included.

For a number of different reasons, for example interspecies- and animal to animal variability in metabolism, toxicokinetics and toxicodynamics, a mutagenic substance may not give rise to cancer in a particular carcinogenicity study. However, according to Billington et al. 2010 (Critical Reviews in Toxicology 40(1), 35-49), “Assessment of 202 pesticide evaluations from the European Union review programme under Directive 91/414/EEC indicated that the mouse carcinogenicity study contributed little or nothing to either derivation of an acceptable daily intake (ADI) for assessment of chronic risk to humans, or hazard classification for labelling purposes”. From this study Billington et al. concluded that there were practically no mouse to rat interspecies differences that appeared relevant for a regulatory decision.

EFSA 2011 (EFSA Journal 2011, 9(9):2379) addressed the issue of a weight-of-evidence approach which takes into account all the available relevant data with the following conclusion: "The Scientific Committee recommends a documented weight-of-evidence approach to the evaluation and interpretation of genotoxicity data. Such an approach should not only consider the quality and reliability of the data on genotoxicity itself, but also take into account other relevant data that may be available, such as physico-chemical characteristics, structure-activity relationships (including structural alerts for genotoxicity and ‘read-across’ from structurally related substances), bioavailability, toxicokinetics and metabolism, and the outcomes of any repeated-dose toxicity and carcinogenicity studies." It also is acknowledged that there is practically no evidence for genotoxicity to germ cells without genotoxicity to somatic cells. This consideration is relevant when integrating negative carcinogenicity data in a WoE evaluation for genotoxicity.

The potential WoE based use of negative carcinogenicity data for the evaluation of genotoxicity is further supported by an actual evaluation of Annex VI (Harmonised classification and labelling for certain hazardous substances) of the CLP Regulation. Among all the 4138 entries there are 3068 entries without Carcinogenicity classification. Only 6 of those are classified for mutagenicity Cat 1A/1B. However, for these 6 entries the following information was retrieved from CCRIS, CPDB, HSDB Database (accessed via TOXNET): For one entry (CAS 17804-35-2) 2 positive mouse carcinogenicity studies and 2 US conclusions on positive carcinogenicity are available. For the other entries no carcinogenicity studies could be identified in these databases (CAS: 2040-90-6, 10605-21-7, 64-86-8, 2451-62-9, 59653-74-6). This analysis supports that at the CLP level there is no evidence for non-carcinogenic substances with clear genotoxicity.

A non-mutagenic substance may induce tumours in a carcinogenicity study because it has other modes of action in carcinogenesis than genotoxicity. On the other hand, some genotoxic mechanisms lead to developmental toxicity rather than to carcinogenicity (e.g. inhibition of mitotic spindle). Mutation is a toxicological endpoint *per se* and it is generally recognised that a substance which is considered to be mutagenic also causes concern for a possible carcinogenic potential, i.e. mutagenicity is a predictor of carcinogenicity.

In conclusion, cancer data cannot replace mutagenicity data in the evaluation of the mutagenic potential of a substance, but they should be used in a careful Weight of Evidence evaluation carried out on a case-by-case basis.

Note: As stated in the minutes of TM IV 2012, SE did not agree with the principle that carcinogenicity data are adequate for the evaluation of the mutagenic potential of a substance and, hence, SE did not agree with the parts of the document presenting views aiming to support this principle.

C. APCP

1 Substance Information

1.1 Reference specification and reference source

1.1.1 Reference source under the Biocidal Products Regulation (BPR) (EU) No 528/2012

In summary, the following definitions have been agreed:

- A source is defined by the following information:
  - the applicant
  - the manufacturer
  - the manufacture location/plant location
  - the manufacturing process

- The specification is set by the applicants and should be in general derived from a 5-batch analysis. Quality control data might be used to refine or support the specification set by the applicant. In specific cases, it might be possible to refer to specifications set by other pieces of legislation e.g. the European Pharmacopeia or specifications set for food additives. Nevertheless, these specifications need to be supported by analytical data.

- Reference specification can be defined as the specification compared to the test substance used for the provided studies and adjusted by the experts of toxicology, ecotoxicology and chemistry taking into account the content of the different constituents in the (test) substance. Hence, it can be regarded as a scientific refinement of the specification.

  - The experts can narrow or expand the specification based on quality control data, the composition of the test substance or expert judgement based on the physico-chemical, toxicological and eco-toxicological properties of the substance. A sound scientific justification should always be provided when the reference specification deviates from the specification.

  - There should always be one reference specification for one application. This also applies for an application, which includes several applicants, e.g. task forces. In cases of several applicants with their own active substance dossier, the reference specification with the lowest purity is taken for the inclusion in the Union list.

  - Reference source is the combination of a source and the set reference specification considering the provided studies (including the composition of the test substance). Each applicant (including consortia and task forces)

might have its own reference sources.
(WG II 2014, WG III 2014, WG II 2015)

1.1.2 More than one reference specification

More than one reference specifications have been established due to the fact that more than one dossier for the same substance has been submitted and separately evaluated. The reference specification is one characteristic of the agreed reference source(s) therefore the reference source(s) is/are bond to their reference specification(s). Can a reference source of one dossier use the reference specification of another dossier of the same active substance?

The following is agreed:

- The purity of the active substance should not be lower than the minimum purity indicated in the inclusion regulation.
- The impurity profile remains the same (i.e. no new relevant or significant impurities are present).
- The limits of all significant but not relevant impurities as certified on the basis of a five batch analysis for the reference source cannot exceed by more than the following limits:

`

Limits of significant but not relevant impurities in the technical specifications of the reference source	Acceptable maximum increase in the alternative source
≤6 g/kg	3 g/kg
>6 g/kg	50% of the certified limit

If one of these conditions is not met, the applicant has to submit an application for the assessment of technical equivalence.
(WG II 2016)

1.1.3 Reference specification for in situ generated substances

To set the reference specification for in situ generated active substances the following information should be provided:

- Generation process including the conditions and their variation.
- Information on the starting materials and reaction products (complete specification of the starting materials and possible maximum concentrations of the reaction products).
- Information on the equilibrium (individual constituents measured with validated methods on one batch of the equilibrium at a defined condition).
- Quality control data of the in situ generated active substance as an indicator for the level of variation of the composition at different conditions: pH, temperature,

dilution. Further conditions of the equilibrium might be required for product authorisation.
(WG II 2014)

1.1.4 Number of reference sources

The CAR can include as many (reference) sources as complying with the reference specification. However, these sources must be included in the CAR for approval of the active substance. All sources, which are not included in the CAR but used for biocidal products, must apply for the assessment for technical equivalence to ECHA before they can be used for product authorisation.
(WG III 2016)

1.2 Substance composition and 5-batch analysis

1.2.1 GLP requirement for 5-batch analysis

The 5-batch analyses including the method development and validation of the method shall be conducted by a GLP certified laboratory. In cases the study was not (e.g. for dossiers submitted under the BPD) conducted under the GLP requirements, quality control data need to be presented to support the analysis.
(WG IV 2014 and WG V 2015)

1.2.2 5-batch analysis older than 5 years

In case the 5-batch analysis is older than 5 years a justification has to be provided by the applicant (e.g. quality control data) to support that the results of the 5-batch analysis and to proof that, the batches are still representative for the manufacturing process and that the proposed specification still applies.
(WG III 2014)

1.2.3 For a substance that is not stable as such, should the Annex I inclusion be for a dry form, or should the water content and/or stabilizers be included? Does it matter whether the substance is not stable as the dry form?

The dry form will be listed on Annex I. Where testing cannot be performed using the dry form, this will affect the testing approach but not the content of the Annex I inclusion.
The applicant has to provide an explanation on why data on the dry form cannot be generated. The CAR should give clear information on what the actual tested substance was.
(TM V 2007)

1.2.4 How to derive the theoretical dry weight specification? Calculation method

The dry weight composition needs to be calculated and included in the CAR. For Union list inclusion, it was agreed that the REACH guidance for identification and naming needs to be followed and the purity should refer to the dry matter. For the Union list inclusion, the actual content of the substance is to be considered.

Following considerations need to be taken into account:

- 5-batch analyses are to be performed on the technical concentration and not on the dry material since the data should reflect what it is actually manufactured. Meanwhile the purified material is to be used for determination of the physico-chemical properties.

- The dry weight can be calculated with the method of calculations:

$$CDWn\ (\%) = \frac{Cn(concentration\ in\ TK)\ (\%)}{\Sigma\ Cn\ (concentration\ in\ TK\ without\ solvent)(\%)} * 100\ \%$$

CDWn = dry weight concentration of constituent “n”

OR

$$content\ active\ (TC, dry)\left(\frac{g}{kg}\right) = \frac{measured\ value\ (TK)\left(\frac{g}{kg}\right)}{sum\ of\ measured\ values\ except\ solvent\ in\ \left(\frac{g}{kg}\right)} * 1000\frac{g}{kg}$$

- Solvents and additives. Additives are constituents of substances, which do not contribute to the naming of the substance, but they have to be considered for the substance composition. Therefore, a change of an additive triggers a technical equivalence assessment. Solvents, which are not needed for stabilisation of the substance or can be removed without impacting the substance composition, should be not considered for the substance composition.

(WG II 2014, WG III 2014)

1.2.5 Iodate in biocidal products: stabiliser or active substance?

Should iodate and iodide present in biocidal products be regarded as stabiliser or as active substance generator?
It was concluded that four cases need to be distinguished:

1. IO_3^- + I^- without I_2

The biocidal product does not contain iodine itself (in the beginning) but iodine is generated from iodate and iodide. In this case, iodate and iodide are not stabilisers. Hence, iodate and iodide are regarded as a new active substance either as iodine-releaser

or as an in-situ system generating iodine.

2. IO_3^- + I_2 without I^-

The biocidal product does not contain iodide. But iodide is generated as a degradation product, e.g. during storage. Iodate is reacting with iodide to re-generate iodine and keep the concentration of iodine stable in the biocidal product. Hence, iodate is acting as a stabiliser.

3. IO_3^- + I^- + I_2

The biocidal product contains iodate, iodide and iodine. Iodate and iodide are generating iodine. Hence, the concentration of iodine is increasing steadily in the biocidal product or at the place of use. Iodate and iodide are not stabilisers. Hence, iodate and iodide are regarded as new an active substance either as iodine-releaser or as an in-situ system generating iodine. The biocidal product contains actually two active substances iodine and 'iodate / iodide' as iodine-releaser or as in-situ system generating iodine.

4. IO_3^- + I^- + I_2

The biocidal product contains iodate, iodide and iodine. Iodate and iodide are not generating iodine. Hence, the concentration of iodine is stable in the biocidal product. Iodate and iodide are regarded as additives, which might have stabilising properties.

The cases number 3. and 4. can only be distinguished if the iodine concentration is monitored. Therefore, it was agreed by the working group members that a shelf-life study under normal storage conditions of a batch of the biocidal products needs to be provided for product authorisation. This shelf-life test shall include the monitoring of the iodine content after one day, one week, four weeks and 26 weeks after the production of the biocidal product. Iodate and iodide are only regarded as stabilisers if the concentration of iodine is not increasing during the storage.
(WG IV 2015)

1.2.6 How much information on the isomeric ratio should be required?

The exact chemical identity and composition of the substance must be known. This includes detailed information about isomers and their ratio.
(TM III 2006)

1.2.7 Minor concentration isomers (<10% w/w)

According to REACH guidance for identification and naming of substances, a mono-constituent substance is a substance in which one constituent is present at a concentration of at least 80% w/w and which contains up to 20% w/w of impurities. A substance as manufactured that contains an individual isomer of at >80% w/w are considered as a mono-constituent substance. All other isomers present in the substance at <10% w/w are generally considered impurities, unless it can be demonstrated that these isomers

contribute to the efficacy of the substance. Isomers that are present at <10% w/w and make a contribution to efficacy of the substance can be considered as “minor isomers” in order to differentiate them from general process impurities.
(TM II 2011)

1.3 Technical equivalence and chemical similarity

1.3.1 Chemical similarity checks for the evaluation of multiple dossiers of the same active substance

For the evaluation of multiple dossiers of the same active substance, the assessment of chemical similarity check is not regarded as necessary as the applicants provided their own complete and compliant data packages, which allow individual evaluations of the substance. Hence, the applications refer to their own reference sources. Therefore, a chemical similarity check is not necessary as sufficient information is provided to support the approvals of the active substance. However, in such cases more than one reference specification might be acceptable. It has to be noted that a combined CAR and list of endpoint needs to be provided by the eCA.
(WG II 2014)

2 Physico-chemical Properties

2.1 General issues

2.1.1 Can data on physico-chemical properties be put into classes? For example, can water solubility be expressed verbally, based on threshold values: very slightly soluble – slightly soluble – moderately soluble – readily soluble?

The TM agreed that this should not be done, except for volatility and with respect to classification and labelling criteria.
Instead of verbal descriptions, actual values should be used in the report, avoiding terms like “high” or “low” as far as possible.
(TM I 2006)

2.2 Surface tension

2.2.1 What is the trigger for the surface activity?

The trigger value for surface activity has been set to 60 mN/m. This value is in accordance with the cut-off value of 60 mN/m as stated in point A.5 of COUNCIL REGULATION (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation,

Authorisation and Restriction of Chemicals (REACH). In this regulation, it is stated "Considering that distilled water has a surface tension of 72.75 mN/m at 20 ºC, substances showing a surface tension lower than 60 mN/m under the conditions of this method should be regarded as being surface-active materials." The method described is based on OECD test guideline 115.
(TM III 2011, TM IV 2012)

2.3 Flammability and auto-flammability

2.3.1 Can the studies on flammability and auto-flammability be waived?

Either a scientific sound justification needs to be provided or the tests must be conducted.
(WG IV 2015)

2.4 Storage stability

2.4.1 Consideration for the storage stability tests

A degradation of content of the active substance by more than 10% should be assessed on a case-by-case basis as the request of further information depends on the active substance and the product. Hence, the setting of maximum degradation limits are regarded as not appropriate. In general, if a decrease of the active substance content by more than 10% should be assessed it requires further efficacy data, information on the degradation products and information on the toxicity and eco-toxicity of these degradation products.
Overdosing is not acceptable and there are no criteria on overdosing available.
Due to the complexity of the different groups of UVCB substances, the assessment should be done case by case. It has to be highlighted that for UVCB substance not only the analytical data should be considered but also other parameters such as the analytical finger-print, physico-chemical properties, toxicity and eco-toxicity data may be used along with efficacy data after storage.
(WG I 2016)

3 Analytical Methods

3.1 General

3.1.1 Do the analytical methods used to support environmental studies need to be validated?

Analytical methods have to be validated in order to ascertain that the method is suitable for the purpose. In case that a specific method is not validated a scientific sound

justification need to be provide to conclude whether the method is acceptable for the purpose.
(TM I 2004)

3.2 Analytical methods for residues

3.2.1 Is there any flexibility for the delivery of the confirmatory analytical methods for residues?

TM I 2012 accepted to leave the applicants some more time for the development of confirmatory methods for residues and/or their validation, in some specific cases granting the permission to provide the information to the RMS 6 months before product authorisation.
The TM also accepted to allow applicants not to submit confirmatory methods for residues in air when same methods are sufficiently validated in soil and water, as these matrices that are more complex.
(TM I 2012)

D. EFFICACY

1. Disinfection of packaging before filling (WGII2017)

What are the testing requirements for aseptic packaging applications (PT 4) before filling in relation to:

1. Tests needed to demonstrate efficacy, taking into account that standard phase 2, step 1 and phase 2, step 2 tests cannot be validated for the high temperatures and short contact times,
2. Typically high temperature of application for this use,
3. Variations in packaging machines for testing,
4. Target organisms relevant for this claim (basic requirement?) - which test organisms should be used?

The following data should be provided to demonstrate efficacy of a product for aseptic packaging applications:

1. Efficacy should be demonstrated by validation of the product in the disinfection process using aseptic filling devices and packaging material that are representative for the intended use of the product. Phase 2, step 1 and phase 2, step 2 tests are not required;
2. A negative control should be performed (with e.g. water) to demonstrate that the high temperature alone is insufficient to achieve sufficient control of microorganisms;
3. Products are efficacious under certain conditions, e.g. temperature, concentration, contact time, etc. Products can be tested in aseptic filling machines that meet/use the (worst-case) conditions for the product to be efficacious. The conditions to be taken into account:
    - surface temperature;
    - concentration;
    - amount of product applied;
    - contact time;
    - relative humidity;
    - dose;
    - inner surface properties of the packaging.
4. All target organisms claimed should be tested in the negative control to demonstrate which target organisms are killed by the use conditions and which need the addition of a disinfectant. In general, only bacterial spores survive these conditions, while vegetative bacteria and yeasts will be killed in the negative control. Therefore, demonstrating efficacy against bacterial spores (e.g. *Geobacillus stearothermophilus*) is sufficient for an efficacy claim against other groups of microorganisms for aseptic filling applications. However, when the negative control shows survival of any other target organisms (e.g. fungal spores) these should also be tested by validation of the product in the disinfection process.

2. Devices generating the active substances by electrolysis (WGV2016)

Should the devices generating the active substances by electrolysis be taken into account when authorising biocidal products?

If the active ions are produced *in situ* by electrolysis the device can affect the efficacy. Therefore, at product authorisation stage the efficacy tests should always be done with the electrodes in a specified device or devices with a defined output range. Information on how the device is protected for under- and overdosing should also be given. However, it shall be noted that the device itself is not subject to product authorisation.

3. Co-formulant(s) being a potential active substance in disinfectant products (WGII2017)

How to exclude or confirm that a co-formulant in a disinfectant product is a potential active substance?

In case during evaluation phase of biocidal product containing one or more co-formulant(s) the evaluating Competent Authority regards one or more of the co-formulant(s) to be an additional active substance the applicant should provide a justification on its function in the formulation and how this will not influence efficacy of the product. Only in cases where a justification is not conclusive tests should be provided to demonstrate the 'non-activity' of the co-formulant(s). The following strategy has been developed[7].

A) Three kinds of tests have been identified. The eCA may request one, two or all of them – as necessary and appropriate.

Test 1: The biocidal product without active substance is tested.

The active substance(s) are replaced by water or, when justified, any other suitable substance(s). The test should be performed at the recommended concentration of the product[8].

If the active substance(s) cannot be replaced for whatever reason, the concentration of the product without active substance has to be decreased accordingly.

[7] The conclusions of the test performed according to this strategy are only valid when at least one active substance is identified.

[8] Example: Amount of the active substances is 30g/100g in the biocidal product. Concentration used for claiming bactericidal activity is 2.0 %. Concentration in Test 1 should be 2% of 70.0g = 1.4 %.

In cases where in this test a high lg reduction is seen, further tests 2 with each co-formulant under question would be required to verify which co-formulant is causing this effect.

Test 2: Each co-formulant under question is tested alone.

The concentration (of the co-formulant) in the test has to be adapted to the relative amount of the co-formulant in the biocidal product[9].

Test 3: The biocidal product without the co-formulant is tested.

Two products are tested in parallel: the biocidal product and the same product, but without the co-formulant that should be replaced by water or, when justified, any other suitable substance(s). Separate testing may be performed for each co-formulant under question removing only one co-formulant at a time. The test should be performed at the recommended concentration of the product.

Any deviation from a test method above must be clearly described and a justification for any deviations provided.

B) Each test should be performed as a (modified) Phase 2, step 1 test. For all tests it is requested to show a definite lg reduction considering the detection limits of the respective tests, i.e. within the detection limits precise lg reduction values need to be given such as 2.68 lg instead of <5.00 lg. The EN tests may be adapted accordingly, if necessary. For instance, extra dilution steps will be needed for these tests to show lg reductions around 3.00 and 3.50.

C) Generally, these tests should be performed with bacteria.

D) Test 3 should be performed under the test conditions (interfering substance/soiling, contact time) used for a product claim, demonstrating that the product without the co-formulant is still efficacious under use conditions.

Since both tests, 1 and 2 are tests without active substance the conditions should not be as severe as under use conditions. These Phase 2 step 1 tests should be performed with proportionate amount of interfering substance and with the longest contact time claimed for the product.

E) In all tests the pH of the test solution should be adjusted to the pH of the biocidal product.

F) To demonstrate in tests 1 and 2, that the co-formulants under question are not active substances the lg reduction should be at least 2 lg lower than the required lg reduction in the EN Phase 2 step 1 test performed. For test 3, the lg reduction of the two products should be similar, i.e. show no more than 1.50 lg difference.

[9] Example: Amount of the co-formulant is 3.0g/100g in the biocidal product, concentration used for claiming bactericidal activity is 3.0 %, concentration of the co-formulant in Test 2 should be 3% of 3.0g=0.09 %.

G) Schematic overview of possible test results and conclusions

Test	Test product*	Result (lg reduction)	Conclusion
Test 1	BP without AS	<3**	all CFs are not active substances in this product
		≥3**	one or more or the combination of the CF might have biocidal activity in the product
Test 2	Only CF	<3**	this CF is not an active substance in this product
		≥3**	this CF might be acting as an active substance in this product
Test 3	BP without CF	≥3.5**	this CF is not an active substance in this product
		<3.5**	this CF might be acting as active substance

* BP = biocidal product; AS = active substances; CF = co-formulant.
** lg reduction in an EN phase 2 step 1 tests for bacteria (EN1276; EN13727; EN1656).

4. Insecticide against crawling and flying insects intended to be used in aircrafts (WGI2017)

In the context of the authorisation of an insecticide (against crawling and flying insects) intended to be used in aircrafts, shall a field test (i.e. in the specific environment of aircraft in realistic settings) be submitted?

There is currently no guideline available that describes a possible set-up for semi-field trials in a laboratory. For biocidal products authorised as insecticides for aircraft disinsection semi-field tests in line with the WHO guidelines (specific to mosquitoes) simulating realistic conditions of use, using cabin crew training sites or decommissioned aircrafts shall be submitted.

5. Limited virucidal activity (WGII2016)

Is modified Vaccinia Virus Ankara (MVA) acceptable test organism to prove virucidal activity of biocidal products used as disinfectants in PT1, 2, 3 and 4?

MVA representing enveloped poxviruses is a sufficient test organism to confirm efficacy against enveloped viruses for biocidal products used in PT 1: *Human hygiene* as hand disinfectants (hygienic and surgical) and PT3: *Veterinary hygiene* as skin disinfectants, e.g. teat disinfection with a claim against enveloped viruses.

Regarding biocidal products used in PT 2: Disinfectants and algaecides not intended for direct application to humans or animals and in PT 4: Food and feed area it is necessary to point out that for the time being a claim against enveloped viruses is not accepted. For biocidal products used in other PTs a virucidal activity within the

meaning of full virucidal activity can only be claimed, i.e. against both enveloped and non-enveloped viruses.

6. PT14: Applications for major changes with lower concentration of an active substance (WGIV2016)

What kind of efficacy data are requested as a part of application for major change of PT14 biocidal products with lower concentration of an active substance?

Based on current experience the following approach applies:

- laboratory tests

  palatability - in choice tests it should absolutely be validated (criteria of 20 % should be met without exceptions) and the same amount of bait as well as challenge diet should be provided.

  Proposal for laboratory tests:

  - systematic comparison between laboratory tests with old and new formulation to check the increase of palatability (valid if active substance is the only change);
  - longer exposure time accepted only if palatability > 20 % and no signs of animal suffering.

- field tests*: efficacy must be demonstrated according to the claims for two reasons:

  - environmental risk assessment takes into account the application rate per surface unit, then quantities applied in the field tests has to be considered;
  - in case of high infestation, bait stations should be checked and refilled more often than every 2/3 days or once a week;

  Proposal for field tests:

  - quantities in bait stations must follow the label claims, particularly in case of an active substance decrease.

In case a complete efficacy data package for the ‘old’ formulation has been submitted including at least 20% of palatability in the laboratory tests and the product composition remains unaltered except lower concentration (≥25 ppm) of an active substance only new field tests are required.

In case the palatability in the ‘old’ formulation is lower that 20%, choice and field tests are required.

For products with active substance concentration <25 ppm, choice and field tests are required.

For any other change in product composition other than lower concentration of an active substance, efficacy and palatability have to be demonstrated in choice and field tests.

** Only for roof rat (Rattus rattus) it is acceptable to demonstrate efficacy:*

- *in two or more well-conducted semi-field trials, in regions where infestations of roof rats are quite rare, or*
- *two (or more) well-conducted field trial(s) in regions with infestations of roof rats.*

7. Shelf life of PT18 bait products (WGV2016)

Could 'a long period storage' agreed for PT14 products be accepted with reference to the requirements on palatability studies corresponding to more than 24 months also for PT18 biocidal products?

The palatability testing defined for PT14 products can also be applied to PT18 biocidal products. Therefore, efficacy testing should only be provided for the following cases:

- bait products with preservatives that claim a shelf life longer than 24 months;
- bait products without preservatives that claim a shelf life longer than 12 months;
- bait products for which the degradation of the active content is >10% and assessment of the degradation on the efficacy is needed to substantiate the shelf life claim.

For bait products with a shorter shelf life claim than stated above, no efficacy tests of aged bait (i.e. product at the end of maximum storage) have to be provided. For these products it is sufficient to provide tests on fresh bait (i.e. newly produced product).