ECHA
EUROPEAN CHEMICALS AGENCY

Technical Agreements for Biocides

Human Health (TOX)

August 2021

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Preface

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

The TAB is publicly available in the S-CIRCABC Interest Group[1].

Starting from August 2021[2], version numbers are assigned to single TAB entries and not the entire TAB document. The starting point ("version 1") for version numbering are entries in the TAB document published in November 2018. Changes to these entries are implemented as new entries with the same reference number but a higher version number. For entries where more than one version may be applicable, due to different applicability timelines for active substances and products, all applicable versions are provided.

The applicability of a TAB entry depends on the type of the entry and is shown separately for each entry. Publication date (i. e. reference date) and applicability dates are given as presented in Table 1 below. For more information on rules regarding applicability of guidance and TAB entries, see BPC-31 document "Applicability time of new guidance and guidance-related documents in active substance approval", CG document Doc. no. CG-33-2019-07 and CA document CA-July12-Doc.6.2d. Links to these documents are provided in footnotes to the table below.

For entries published more than two years before August 2021, the following text is included instead of publication dates: "*Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products*".

Table 1: Type of TAB entries and applicability dates

Type of entry in the TAB	**Applicability of the TAB entry**	
	(A) for active substance approval	**(B) for product authorisation**
a) Editorial changes of the existing guidance	As of the publication date, for all dossiers (independent of the submission date of the dossier)	As of the publication date, for all applications (independent of the submission date of the application)[3,4]
b) Clarification/interpretation of the existing guidance (clarification /explanation)		

[1] https://webgate.ec.europa.eu/s-circabc/w/browse/4047dcc1-ff35-45e1-894c-8647639f9ae8

[2] Date of change to a TAB databse system to manage the human health TAB entries.

[3] CG document CG-33-2019-07, "Date of applicability of: A) Technical Agreements of Biocides (TAB) entries and B) Conclusions of the Working Groups on the technical questions referred from CG" is available here: https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/00cafca0-81f6-44c2-8aaf-05cb1cbcff93/CG-33-2019-07%20AP%2014.3%20Date%20of%20applicability_TAB%20entries_CG%20quest_rev1.pdf; Please note that "publication date" in Table 1. equals to "reference date" in the CG-33-2019-07 document.

[4] In case the application is already at the peer review, applicability should be discussed on a case-by-case basis by the eCA and the applicant.

<table>
<tr><td>c) New guidance as new technical scientific advice is given which triggers new data requirements</td><td rowspan="2">Applicants: for dossiers submitted to the eCA 6 months after the publication of the TAB entry;
eCAs: for CARs submitted to ECHA 6 months after the publication of the TAB entry; with specified exceptions[5]</td><td rowspan="3">For applications submitted to the eCA 2 years after the publication of the TAB entry[6]</td></tr>
<tr><td>d) New guidance as new or updated technical scientific advice is given in order to have a harmonised approach on how the assessment should be done (without new data requirements)</td></tr>
<tr><td>e) New guidance not triggering new data requirements where:
no guidance was available at all for a certain issue
new guidance is correcting major mistakes of former guidance
new guidance is considerably more reliable than former guidance.</td><td>As of the publication date, for all dossiers (independent of the submission date of the dossier) [5]</td></tr>
</table>

Procedure

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

Updates on the document will be provided for a commenting period of 4 weeks for the WG members. After the commenting period, ECHA will revise the TAB if necessary, and publish it in S-CIRCABC.

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

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

[5] The document "Applicability time of new guidance and guidance-related documents in active substance approval" agreed at the BPC-13 meeting is available here: https://echa.europa.eu/documents/10162/4221979/applicability_guidance_jan_16_en.pdf/0b9c0634-eb54-4805-8b5e-b95f09a05632

[6] CA document CA-July12-Doc.6.2d, "Relevance of new guidance becoming available during the process of authorisation and mutual recognition of authorisations of biocidal products" is available here: https://echa.europa.eu/documents/10162/23036409/ca-july12-doc_6_2d_final_en.pdf

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 (e.g. sun lotions) be taken into account? Such products could enhance the dermal absorption of the biocidal product.

Version 2 (TM I 2009, WG-IV-2016, WG-I-2021)

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.

Type of entry:	b) Clarifications/existing guidance
Publication date:	09/08/2021
Date of applicability for active substances:	09/08/2021
Date of applicability for products:	09/08/2021

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.

Version 1 (TM I 2009)

Please note that this is not the most recent version of the entry – see the latest version above.

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.

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

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

TOX 2 Derivation of dermal absorption values.

Version 1 (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.

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

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

TOX 3 Dermal absorption value of dried dispersed residues

Version 1 (WG-III-2017)

The appropriate dermal absorption value of dried dispersed residues should be the higher of the values for the concentrate and the in-use dilution (EFSA Guidance on dermal absorption (2017)).
Note: The WG discussion referred to EFSA Guidance (2012) but the approach is identical in the guidance of 2017.

Type of entry:	b) Clarifications/existing guidance
Publication date:	09/11/2018
Date of applicability for active substances:	09/11/2018
Date of applicability for products:	09/11/2018

TOX 50 How is it decided whether a biocidal product is a concentrate or a dilution?

Version 1 (WG-II-2019)

The BPC has agreed [1] that the EFSA guidance on dermal absorption (Guidance on dermal absorption, EFSA Journal 2017; 15(6):4873) is applied for biocides.

For the purpose of the abovementioned guidance, a biocidal product is considered:

1. A "concentrate" when the active substance is present in the biocidal product at a concentration higher than 50 g/L (or 50 g/kg or 5%);
2. A "dilution" when the active substance is present in the biocidal product at a concentration lower than or equal to 50 g/L (or 50 g/kg or 5%).

This agreement is based on the agreement SANTE/2018/10591 rev.1[2].

[1] https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/4243a91f-af00-4aae-9ccd-581d318a91c8/Dermal absorption - applying EFSA Guidance.pdf

[2] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_tox_dermal-absorp-2018-paff.pdf

Type of entry:	b) Clarifications/existing guidance
Publication date:	09/08/2021
Date of applicability for active substances:	09/08/2021
Date of applicability for products:	09/08/2021

2 Reference values and assessment factors (AF)

TOX 4 How should reference values be rounded?

Version 1 (WG-IV-2017)

For the rounding of reference values (AEL, AEC, ADI, ARfD), the principles should be applied that are presented on pages 24-25 of the EFSA Opinion Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured Data; EFSA Journal 2012;10(3):2579 (https://www.efsa.europa.eu/en/efsajournal/pub/2579): "Derived values, such as health-based guidance values, should be rounded to a single significant figure if the impact of rounding is less than 10%, and to two significant figures if the impact of rounding to one significant figure exceeds that percentage. Rounding should happen as late as possible in the assessment process."
This agreement concerns reference values that are normally derived from NOAEL/NOAEC values by applying assessment factors. It does not concern measured values such as absorption values or NOAEC/LOAEC values used in e.g. local risk characterisation.

Type of entry:	b) Clarifications/existing guidance
Publication date:	09/11/2018
Date of applicability for active substances:	09/11/2018
Date of applicability for products:	09/11/2018

TOX 5 Is it acceptable to have different AELs for professionals and non-professionals?

Version 1 (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.

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

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

TOX 9 Which specific agreements are there for setting the AEL for anticoagulant rodenticides?

Version 2 (TM II 2007, WG-I-2021)

For acute effects, 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.

The AF will depend on the available data set. If an AF for duration extrapolation is concluded to be necessary from subchronic studies to chronic scenarios, a factor of 3 is considered sufficient to provide safe margins. 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 parts B+C).

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

Type of entry:	b) Clarifications/existing guidance
Publication date:	09/08/2021
Date of applicability for active substances:	09/08/2021
Date of applicability for products:	09/08/2021

TOX 9 PT 14: Which studies can be used in setting the acute AEL for anticoagulant rodenticides?

Version 1 (TM II 2007)

Please note that this is not the most recent version of the entry – see the latest version above.

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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 10 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?

Version 1 (TM II 2007)

Please note that this is not the most recent version of the entry – see the latest version of TOX 9 which replaced TOX 10 as of 9 August 2021.

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).

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 11 Is there an agreement on using an extra AF for anti-vitamin K (AVK) anticoagulants for the severity of the effect?

Version 1 (TM III 2006)

Please note that this is not the most recent version of the entry – see the latest version of TOX 9 which replaced TOX 10 as of 9 August 2021.

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

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 12 How should the systemic AELs be derived for pyrethroids, given that there is extensive first pass metabolism following oral administration?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

3 Local risk assessment

TOX 13 Is local risk assessment necessary for substances that are classified for local effects but are present at concentrations that do not trigger classification of the product?

(WG-II-2018)

This entry was erroneously missing in the TAB published on 9 August 2021 and was reintroduced on 25 May 2023.

According to ECHA Guidance Vol III Parts B+C, risk characterisation for local effects is triggered only when the biocidal product is classified for local effects. It is however considered that the assessment of local effects may be useful in several situations reflected below.

A qualitative local risk assessment (LRA) would not be required if classification is not triggered. However, if a relevant NOAEC/LOAEC is set for the active substance, a quantitative or semi-quantitative LRA may provide valuable information regarding the possible effects expected due to the use of a biocidal product. The following principles apply for each route of exposure, provided that the route is relevant for human exposure:

- For the inhalation route, a quantitative LRA should be performed whenever possible, i.e. whenever an inhalation AEC is derived for local effects.
- For the oral route, the possibility of performing a semi-quantitative or quantitative LRA should be considered for local effects on a case by case basis. The most relevant assessment would usually be expected to be either qualitative or semi-quantitative and not quantitative because the effects will depend on a number of parameters such as concentration, dosing system, exposure time and the frequency of exposure, and furthermore, the experimental design would most often not be corresponding to human oral exposure.
- For the dermal route, a semi-quantitative LRA should be performed. The assessment should include information regarding NOAEC/LOAEC for local effects and should also provide information regarding the expected dermal effects in the exposure situations, taking into account the amount and concentration to which exposure takes place, as well as the frequency and duration (descriptive approach). The nature of the expected effects should be considered together with exposure considerations in deciding whether PPE or RMMs are required to limit the effects.

In selecting the most relevant study results for setting the NOAEC/LOAEC for local effects, considerations should be given to the dosing that should optimally resemble the expected human exposure in terms of amount, concentration, frequency and duration. The identification of a NOAEC/LOAEC in a given study may not be relevant for the risk characterisation if the study setup is such that the information is not useful for the assessment of human exposure situations. This could be the case if the effects are only seen in conditions that are not relevant for human exposure, such as repeated exposure at high concentrations under occlusive dressing. The assessment should take into account the differences in the formulation tested (usually the active substance in a vehicle) and the formulation of the product. The NOAEC seen in testing should be considered relevant for the product unless there is information to the contrary.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB

document, i. e. currently applicable for both active substances and products.

TOX 14 Should dermal AEC values be derived based on local dermal effects?

Version 1 (WG-II-2018)

Local dermal effects seen in the studies and/or expected to take place in humans should be described and a NOAEC/LOAEC, usually expressed as a percentage concentration, should be provided. A dermal AEC should normally not be derived, as it is preferable not to set a defined limit for acceptable exposure due to local dermal effects. An AEC would express a concentration above which the use would become unacceptable, and setting this level below a NOAEC could be questionable. Furthermore, the usefulness of the information available from animal studies may be limited because the study setup would not necessarily reflect the human exposure situation. However, where appropriate information is available regarding cumulative dermal effects and this information is considered relevant for humans, an AEC could be derived. Normally the RC for dermal effects should be based on the NOAEC/LOAEC (usually expressed as a percentage concentration), and the acceptability of a scenario will be decided case by case using all the available information.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 15 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?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 51 Is a semi-quantitative or quantitative local risk assessment necessary for products that are classified for local effects due to a co-formulant for which a local NOAEC or a local AEC value is available?

Version 1 (WG-IV-2019)

A semi-quantitative or quantitative local risk assessment of a product classified for local effects (dermal or inhalation) due to a co-formulant is needed only in cases where local NOAEC or local AEC value for the co-formulant has been peer reviewed and agreed under the BPR and is considered relevant for that product. Expert judgment is required to conclude on the relevance of such NOAEC/AEC values for each product, considering among other things the compositions of the product and of the test substance, the role of pH in local effects, and the frequency, duration and route of exposure in the study used to derive these values.

Note also that a semi-quantitative or quantitative local risk assessment may need to be performed even if the product is not classified, if the co-formulant is a biocidal active substance. For these cases, TAB entry TOX 13 should be applied (Is local risk assessment necessary for substances that are classified for local effects but are present at concentrations that do not trigger classification of the product?).

Type of entry:	b) Clarifications/existing guidance
Publication date:	09/08/2021
Date of applicability for active substances:	09/08/2021
Date of applicability for products:	09/08/2021

4 Specific toxicological effects

TOX 16 How should unpalatability be considered when the NOAEL is set based on reduced body weight gain?

Version 2 (WG-II-2014, WG-I-2021)

Reduced body weight gain should usually be considered as an adverse effect and as a basis for setting the NOAEL, unless it can be 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.

Type of entry:	b) Clarifications/existing guidance
Publication date:	09/08/2021
Date of applicability for active substances:	09/08/2021
Date of applicability for products:	09/08/2021

TOX 16 How should unpalatability be considered when the NOAEL is set based on reduced body weight gain?

Version 1 (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.

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

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

TOX 17 Should emesis (e.g. in dogs) be considered as an adverse effect and used as a basis for setting the NOAEL?

Version 1 (WG-V-2014)

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

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

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

TOX 18 How should hepatocellular hypertrophy, enzyme induction and liver weight increases be interpreted in toxicological studies in rodents?

Version 1 (WG-IV-2018)

Liver cell hypertrophy and liver weight increase should be considered as potentially adverse effects. However, on a case-by-case basis, hepatocellular hypertrophy leading to ≤15% increased mean absolute or relative liver weight, should not be regarded as adverse, and should not be used for the purpose of defining the LOAEL for that specific study, in the demonstrated absence of all of the following changes: - other histopathological findings such as necrosis, inflammation, fibrosis, vacuolation, pigmentation, degeneration, hyperplasia, etc. but not limited to these, - other effects that are indicative of specific liver toxicity, such as adverse clinical chemistry changes. If relevant and comprehensive histopathological and clinical-chemistry investigations have not been performed or where there is insufficient information to determine whether the observed increase in liver weight is an adaptive or an adverse response, then the default is to assume that the effect is adverse. Mechanistic information such as enzyme induction can be used to support decision making. Further information was provided by UK in an annex that was not endorsed as such, but the Human Health WG generally agreed with the principles presented therein. This non-endorsed annex is available in S-CIRCABC: https://webgate.ec.europa.eu/scircabc/d/a/workspace/SpacesStore/3733c8dc-419c-4c58-ad1caf18c4f333af/Interpretation%20of%20liver%20effects_annex.pdf

Type of entry:	d) New guidance, no new data requirement(s)
Publication date:	
Date of applicability for active substances:	
Date of applicability for products:	

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

5 Corrosive substances

TOX 19 **For active substance approval, is systemic risk characterisation necessary for corrosive concentrations?**

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 21 How should dermal absorption values be derived for corrosive concentrations of the active substance?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

6 Exposure assessment

6.1 General issues

TOX 22 Can exposure assessment be performed by averaging the exposure e.g. over a year, if this information is needed?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 23 What is the most relevant exposure determinant in the spray application scenario?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 24 Should exposure assessment for non-professionals be performed with the use of gloves as Tier II?

Version 1 (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 (CAMarch14-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".

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 25 Which protection factor for coveralls should be used in low pressure (1-3 bar) spraying or wiping applications?

Version 1 (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 Technical Agreements for Biocides (TAB) – TOX v.2.0 Release date: 9 November 2018 12 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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

6.2 PT 1

TOX 26 PT 1: What retention factor value in hand wash should be used?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB

document, i. e. currently applicable for both active substances and products.

TOX 27 **PT 1: How is sufficient contact time determined for disinfection of hands?**

Version 1 (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.

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

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

TOX 28 **PT 1: How many facial tissues can be considered adequate for the estimation of acute and chronic exposure for non-professionals?**

Version 1 (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.

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

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

TOX 29 **PT 1: Which is the adequate transfer efficiency of an active substance from a facial tissue (PT 1) to hand?**

Version 1 (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 Methodology2 (2015).

This should be considered as a temporary agreement in the absence of appropriate guidance.

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

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

6.3 PT 2

TOX 30 PT 2, swimming pool: What exposure duration should be used for swimming in a pool?

Version 1 (WG-I-2015)

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

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

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

TOX 31 PT 2, swimming pool: What is the thickness of the product layer around the swimmer?

Version 1 (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 Methodology3 , 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.

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

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

TOX 32 PT 2, swimming pool: Which model should be used for inhalation exposure of consumers in swimming pools?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

6.4 PT 6

TOX 33 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?

Version 1 (WG-I-2015)

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

Type of entry: e) New guidance, immediately applicable

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 34 PT 6: Which work phases will be considered when performing the exposure assessment for an in-can preservative?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

6.5 PT 8

TOX 35 **PT 8: What wood density should be used? This will have an effect in the exposure assessment of cutting and sanding treated wood.**

Version 1 (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.

Type of entry: d) New guidance, no new data requirement(s)

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 36 **PT 8: Should secondary exposure of professionals handling treated dried wood be assessed?**

Version 1 (WG-V-2016)

Secondary exposure of professionals handling treated dried wood does not need to be assessed as it is covered by the exposure during the handling of wet wood after the application of the biocidal product. However, other types of secondary exposure to professionals (e.g. sanding treated wood) should still be assessed.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 37 PT 8: Does exposure for application and post-application need to be combined for professional uses?

Version 1 (WG-IV-2017)

The application tasks are daily tasks and are compared to the AELlong-term while some post-application tasks are not necessarily performed on a daily basis and can be considered as an acute exposure scenario. Therefore, exposure during application and post-application tasks should be assessed but not combined in those cases where the post-application scenario is not a long-term exposure scenario.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

6.6 PT 18

TOX 38 PT 18: Which models should be used to assess exposure of professional users (farmers) during watering/pouring application?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

Entry published more than 2 years before the publication date of this TAB

document, i. e. currently applicable for both active substances and products.

TOX 39 PT 18: Which model should be used to assess exposure of nonprofessional users during hand-held pump sprayer applications?

Version 1 (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).

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 40 PT 18: Does primary and secondary exposure for professional users need to be combined?

Version 1 (WG-II-2017)

A combined assessment should performed for the primary and secondary exposures, since the operator might be exposed to the same active substance at the workplace and at home. This applies to cases where both primary and secondary exposure are of the same time frame (e.g. short-term, mid-term or long-term).

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 41 PT 18: For general public exposure to active substance-releasing mats, how many mats should be considered per day in the exposure assessment as representative for a household scenario?

Version 1 (WG-III-2017)

A number of 2 mats per day and per household is considered appropriate, also for long-term scenarios, in the human exposure assessment.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

6.7 PT 21

TOX 43 **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?**

Version 1 (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".

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

TOX 44 **PT 21: Does exposure during cleaning of spray equipment for antifoulings (PT 21) need to be assessed?**

Version 1 (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)".

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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

7 Dietary risk assessment

TOX 45 **Should the transfer of biocidal active substance into food from food packaging be estimated?**

Version 2 (WG-III-2017,WG-I-2021)

The estimation of the transfer of biocidal active substance residues from paper used for food packaging (PT 12) into food should be assessed. The following approach was agreed:

- Biocidal residues in food packaging: it is proposed to estimate the biocidal active substance transfer from food packaging to food using data if available, and otherwise by a theoretical worst case scenario. This proposal should be seen as an interim approach until a more clear procedure is defined by the Commission.

Type of entry:	b) Clarifications/existing guidance
Publication date:	09/08/2021
Date of applicability for active substances:	09/08/2021
Date of applicability for products:	09/08/2021

TOX 45 **Should the transfer of biocidal active substance into food from food or feed packaging be estimated?**

Version 1 (WG-III-2017)

The estimation of the transfer of a biocidal active substance residues from paper used for food/feed packaging (PT 12) into food should be assessed. The following approaches were agreed:

- **Biocidal residues in food packaging**: it is proposed to estimate the biocidal active substance transfer from food packaging to food using data if available, and otherwise by a theoretical worst case scenario. This proposal should be seen as an interim approach until a more clear procedure is defined by the Commission.

- **Biocidal residues in feed packaging**: it is proposed to estimate the biocidal active substance transfer from packaging to feed using data if available, and otherwise by a theoretical worst case scenario.

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

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

8 Waiving

TOX 46 Can extra assessment factors be used to cover the lack of data in waiving cases?

Version 1 (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.

Type of entry: b) Clarifications/existing guidance

Publication date:

Date of applicability for active substances:

Date of applicability for products:

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