Final public minutes of the Working Group meeting III in 2022

Analytical methods and Physico-Chemical properties and Physical hazards (APCP)

(Meeting date: 06-07 September 2022 – virtual meeting)

7 December 2022

1. Welcome and apologies

The meeting was a virtual meeting. The Chair welcomed the participants of the working group meeting. CEFIC registered for the meeting as accredited stakeholder organisations (ASO). The following applicants were registered for the meeting as observers for their agenda items:

Meulepas	Ralph	7.1	Lonza Cologne GmbH
Freemantle	Mike	7.1	Lonza Cologne GmbH
Lubura	Borjana	9.1	Jesmond Bioscience GmbH
Gimeno	Miguel	9.1	Jesmond Bioscience GmbH

Participants of the working group meeting were informed that the ECHA code of conduct applies to this meeting and that the meeting is not recorded and any recording is not allowed.

2. Administrative issues

The chair reminded about the security rule for connecting to the meeting.

ECHA informed about security requirements for the access to the interact portal for praticipants in committees.

(see https://echa.europa.eu/documents/10162/17086/interact_rules_en.pdf/3548c383-8f35-84c3-0f41-19a395624329)

The opinion poll procedure was clarified informing that each member state represented in the working group is allowed to express their opinion in the opinion poll by raising their hand. Invited experts can express their opinion if this function is delegated to them by the inviting member state. This information is used to propose an acceptable compromise for the discussion at hand.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the working group members to include any additional items under any other business (AoB).

The agenda was agreed without modification.

4. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all working group members to declare any potential conflicts of interest in relation to the agenda. None was declared by the working group members.

5. Agreement of the draft minutes from WG II 2022

The working group members reviewed the comments on the draft minutes of WG II 2022. The draft minutes were modified accordingly and were agreed by the working group members.

6. Technical and guidance related items

6.1. Treatment of unstable substances

From the received comments in the related e-consultation, ECHA had distilled a proposal that has been shared with the working group as a discussion starter.

The discussion was broadly speaking divided into two positions. One position arguing that the reference specification has to be fulfilled at the time of the formulation in order for the substance to be used in the biocidal product. The other position arguing that especially for the example of active chlorine generated from sodium hypochlorite it is impossible to ensure that the reference specification is met at the time of formulation and that the socioeconomic consequences of insisting on the reference specification would be unproportionally big.

It was remarked that there are product authorisations on national level for which the reference specification were fulfilled so it is not completely impossible to comply.

Regarding the socioeconomic impact, there were no concrete facts reported during the e-consultation but a general concern was raised that a multitude of product may not be marketable anymore. The accredited stakeholder was requested to provide additional insight into this possible problem. However, this consideration falls outside the responsibility of the APCP working group.

There was a concern from several members regarding the additional work required to do the assessment of additional data provided during the biocidal product evaluation and also regarding the fact that the assessment needs to be repeated for each new biocidal product. On the other hand, this way has already been followed for some products.

It was pointed out that there is the possibility to prove with additional data that stored product in which the active substance concentration has changed more than 10 percent is still efficient and safe (see APCP TABv2 "4.2.1.3. Shelf life decision tree"). This assessment is of the same nature as proposed for active substances not within reference specification at the time of formulation. Additionally a positive assessment after long term storage necessarily implies that the active substance at the time of formulation was still effective and safe. This was the situation also e.g. in BC-HQ045419-21.

Some members remarked that the provided information in the long term storage test is not always sufficient to assess the accordance with the reference specification. It was therefore proposed to ask additional analytical proof of the composition of the active substance at the time of formulation. It was argued that this request can be based on Art 19.1(c) of the biocidal product regulation (Regulation (EU) 528/2012) but it was also remarked that this additional analytical proof may only be required in cases where the identity of the active substance is justifiably doubtful e.g. for "Active chlorine released from sodium hypochlorite". It was discussed that potentially data on the biocidal product (together with information on the formulation) would be acceptable instead of data on the active substance and the analytical information could be limited to specific constituents known to be of concern.

A question was raised whether the reference specification as specified in the respective implementing regulation is meant to describe the active substance only at the time of manufacture or during its full lifecycle including the time of formulation of the product. This question should be addressed with the commission.

Regarding the possibility to broaden the reference specification at the time of renewal, it was questioned whether this removes the problem or just extends the limits of what is allowable which will then be broken again. In response it was suggested, once the reference specification has been extended, not to allow deviations anymore.

Conclusions and action points

The working group agreed on the principle that any deviation from the approved reference specification, if considered allowable, would need to be supported by data on efficacy, on degradation byproduct(s) of the active substance and on the toxicity and ecotoxicity of these byproduct(s). The working group did not conclude whether deviations are allowable. ECHA should raise this question to the commission.

In the meantime a case-by-case assessment is proposed with additional focus on the conformity with the reference specification and a specific discussion in the working group in case of doubt.

6.2. Guidance for analytical methods in air

Please refer to the specific minutes of this agenda item.

6.3. Exchange on problems during evaluation

Please refer to the specific minutes of this agenda item.

7. Active Substances

7.1. Poly(oxy-1,2-ethanediyl), .alpha.-[2-(died-cylmethylammonio)ethyl]- .omega.- hydroxy-, propanoate (salt) (Bardap 26)

Please refer to the specific minutes of this agenda item.

8. Union Authorisations

8.1. UA for Glutaral (Glutaraldehyde)

Please refer to the specific minutes of this agenda item.

8.2. UA for Hydrochloric acid

Please refer to the specific minutes of this agenda item.

8.3. UA for L-(+)-lactic acid

Please refer to the specific minutes of this agenda item.

9. Mutual recognition

9.1. Request for ECHA opinion pursuant to Articles 36(2) and 38 of the BPR - biocidal product containing permethrin (PT 18)

The chair invited the applicant of the underlying biocidal product and/or its representative to the meeting. He informed them that the ECHA code of conduct has to be followed, hence they are invited to the meeting as an observer only who might respond to questions raised by the working group members. The applicant was informed that the meeting is not recorded. Furthermore, recording of the meeting is not allowed. The applicant and/or its representative confirmed that no unauthorised persons are participating in the WebEx meeting and that the ECHA code of conduct was read and understood.

ECHA shortly presented the background and summary of the proposed draft decision.

The applicant gave an overview of their comments on the draft opinion. The applicant offered to generate more analytical data if this was requested but considered the analytical method should be provided.

ECHA pointed out that the applicant i) introduced new claims that were not available during the drafting of the opinion and ii) these claims are not substantiated with experimental data. These have not been considered for drafting the opinion and should have been provided earlier.

The working group was not considering the read-across from aliphatic amines offered by the applicant to be convincing to conclude on the presence or level of free aromatic amines.

The working group agreed without further discussion on the results of question 1 concluding that the presence of free aromatic isocyanates is not expected.

The chair requested the working group to consider whether the presence of free aromatic amines, that are formed in an intermediate state of the polymerisation reaction, can be excluded with the information available. The applicant stated that the presence of free amines in the biocidal product can be excluded but was admitting that no supporting evidence was available. The working group agreed that the presence of aromatic amine cannot be excluded.

The remainder of the discussion was considering the reliability of the provided estimation of a worst case free amine concentration as a basis for the assessment whether Art 19.1.(b)(iii) and (iv) are fulfilled.

Conclusions and action points

The working group agreed that the presence of the free isocyanates is not expected in the products (question 1).

The working group agreed that the presence of free aromatic amines cannot be excluded based on the information available (question 2).

The working group also agreed on the estimation method of the worst case estimate which can be used for HH and ENV assessment.

10. AoB

10.1. Comment on physical hazard waiving discussion WG II 2022

The working group member from Germany gave additional feedback on the physical hazard waiving discussion in working group II 2022. There was a reference to low boiling components and whether there is a concentration threshold for the flash point. DE experts confirmed that there is no threshold for low boiling components. Formic acid, propionic acid, isopropanol are given as examples as low boiling components. These may affect the flash point also in low concentrations.

10.2. Feedback on the meeting

The chair asked the members of the working group for feedback and suggestions for improvement for future meetings. While the general feedback was quite positive, members mentioned a few points of improvement.

- Distribution of discussion relevant documents, esp. reference specifications

  For this WG meeting the distributed documents did not contain the proposed reference specification. The chair explained that while the reference specification was available to all working group members, it is the intention to continue distributing all relevant documents also specifically for the working group meeting and announce via email when they have been distributed.

- Sharing of more precise timings of agenda items

  Members requested to get access to more exact timings of agenda items for future meetings. The chair indicated to be willing to share more exact timing for future meetings but cautioning that it is possible that the timing is adjusted still during the meeting to accommodate for unforeseen developments.

The accredited stakeholder was inquiring whether stakeholders will get access to agenda items where they were present. The chair expressed the intention to follow current procedures.

Annex 1 - List of attendees registered for the meeting

Member state participants		Member state
Ghobrial	Michael	AT
Burmistova	Anastasia	BE
Fauconnier	Steven	BE
Dang Thy	Minh-Dung	BE
Fauconnier	Steven	BE
Huerga Fernandez	Samuel	BE

Swennen	Kim	BE
Aeschbacher	Michael	CH
Vlasak	Martin	CZ
Dragan	Constantin-George	DE
Holthenrich	Dagmar	DE
Krug	Monica	DE
Mühle	Ulrike	DE
Hansen	Cecilie Felicia	DK
Jespersen	Cindy	DK
Triantafillopoulos	Maria	DK
Vallikivi	Imre	EE
Batistatou	Stavroula	EL
Tzanetou	Evangelia	EL
Cano	David	ES
Escalada	Jesus	ES
Fuertes	Pedro	ES
Vuorensola	Katariina	FI
Weber	Philippe	FR
Six	Therese	FR
Lutz	François	FR
Cataldi	Lucilla	IT
Igaune	Ieva	LV
Blaga	Cornelia	NL
van Rijnsbergen	Peter	NL
Kruidhof	Sabine	NL

Stave Sekkenes	Marianne	NO
Huszał	Sylwester	PL
Horczyczak	Anna	PL
Marsh	Göran	SE
Cebasek	Petra	SI
Zirngast	Klavdija	SI
Drabová Kušíková	Zuzana	SK
Porubiak	Michal	SK

ECHA staff
Uphoff Andreas (chair)
Marcon Eva
Vetelainen Kaisa (6 September only)
Jochen Matthes (item 7.1)
Hämäläinen Eva (7 September only)

Accredited Stakeholder Organisations (ASOs)	
Organisation	Observer
CEFIC	Van Berlo Boris Bossert Jules

Applicants
Lonza Cologne GmbH
You Solutions Germany (an Arxada Company)
Jesmond Bioscience GmbH

Environment WG-III-2022

Final general minutes

16 September 2022

Final minutes of Environment WG-III-2022

Including TAB entries for revision in Appendix I

13, 15 and 16 September2022

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 54 participants present (virtual meeting), of which 14 were core or alternate members, 40 flexible members, 3 rapporteur and 7 advisers. Four representatives from accredited stakeholder organisation were present at some agenda items. Applicants were registered for their specific substance discussions. SECR informed on the leave of Heike, Speranza and Simon from ECHA and the addition of Amaia Rodriguez-Ruiz to the environmental team. SECR informed that Sander will take over from Simon as chair.

2. Administrative issues

SECR informed on several administrative issues.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The agenda was agreed without changes.

4. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None was declared.

5. Agreement of the draft minutes from WG-II-2022

The minutes for most of the items were agreed with some changes.

6. Discussion on active substances

6.1 Poly(oxy-1,2-ethanediyl), .alpha.-[2-(dide- cylmethylammonio)ethyl]-.omega.- hydroxy-, propanoate (salt) (Bardap 26), PT 2, 4 (eCA IT)

Six points were discussed and there was one provisionally closed item. Most of the points were closed but there were two points left open for which the eCA need to make some revisions and agree with other Members through an Ad-Hoc follow up. The WG agreed that the new STP simulation study can be used in the risk assessment to refine the degradation of the parent compound, nevertheless no degradation half-life could be derived for the main metabolites. The WG agreed that the metabolites need a risk assessment.
Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action:

- The eCA will revise the assessment for all the uses for the WG to review

- The eCA will include a Tier I assessment for all the uses for the WG to review. Further information in relation to the metabolites (e.g. SMILES codes or screen shots of QSARs) should be included.

6.2 Outcome e-consultation on ED assessment of the active substances Alkyl(C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC) and didecyldimethylammonium chloride (DDAC), PT 1, 2, 3, 4 (eCA IT)

IT informed the WG on the outcome of the e-consultation, on the testing strategy for assessing the ED properties for non-target organisms. The members that responded to the e-consultation, together with the eCA, agreed with the testing proposal from the applicant.

Action: None

7. Discussion of Union Authorisation cases

7.1 UA for Glutaral (Glutaraldehyde) PT 6, 11-12 (eCA NL)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

18 open points were discussed, of which 17 were closed at the meeting. Point 18 in the DT was agreed to be clarified by the eCA and SECR bilaterally.

Action: SECR and the eCA will clarify the applicability of a TAB entry and agree on the way forward.

7.2 UA for Hydrochloric acid, PT 2 (eCA NL)

The WG agreed that the study submitted by the applicant can be accepted. A Fwater of 1% can be derived from the study However, based on the study, the distribution in the STP and specifically the fraction released to the sludge (Fsludge) needs to be recalculated using SimpleTreat 4, in line with what was agreed at WG-II-2020.

Action: The eCA to derive the distribution to sludge using SimpleTreat 4 and update the calculations.

7.3 UA for L-(+)-lactic acid, PT 3 (eCA LV)

No open points.

Action: None

8. Mutual Recognition

8.1 Request for ECHA opinion pursuant to Articles 36(2) and 38 of the BPR - biocidal product containing permethrin (PT 18)

SECR informed the members on the mandate received. SECR explained that since the concern is on the potential presence of genotoxic carcinogens, the proposed conclusion is that no additional environmental assessment is foreseen. The members asked if they could provide written feedback after the meeting. SECR confirmed this was possible (via e-mail).

Action: Members to provide written feedback (email). SECR to collect input and check the need to revise the proposed conclusion.

9. Technical and guidance related topics

9.1 Infobox 12, choice of the assessment factor when plants are as sensitive as other organisms

As a follow-up to the ENV WGII2022, the revised proposal by FR on the Vol IV Part B+C Infobox 12 (*Clarifications on the assessment factor to derive PNEC$_{soil}$*) was discussed by the WG. The WG was asked to reply to two questions:

Q1: should the OECD 208 test be considered as a long-term study in the Biocidal Product Regulation?

The issue of considering the OECD208 either as a long-term or a short-term test was revisited due to new information received after ENVWGII2022. A published study, written by ECHA and EFSA, shows that due to a higher number of tested plant species (up to 6 for the OECD 208 and two for the ISO 22030), the endpoints from the OECD 208 study are often in the same range or lower than in the ISO 22030 study. Therefore, the number of species tested is crucial for deciding which study is the more sensitive one. Different views were expressed by the WG members on how the mode of action (MoA) of the active substance is taken into account, specifically if the AS has a herbicidal or a non-herbicidal MoA.

The WG agreed that the OECD208 test using 6 species can be considered as a chronic study and the NOEC can be taken for the PNEC derivation. When less than 6 species are tested, the Infobox 12 should apply.

Q2: Do you agree with the new proposal for the Infobox 12?

FR presented a new proposal for the revised Infobox 12 with a simplified scheme. Three different situations were identified for the selection of the appropriate assessment factor (AF); 1) plants are significantly less sensitive than other taxonomic groups, 2) plants are the most sensitive compared to other taxonomic groups, 3) all other cases.

The WG agreed with the text proposal and made some editorial changes during the meeting. The proposal will be incorporated as a TAB entry and incorporated in the minutes of WGIII2022.

The proposed TAB entry can be found in Appendix I of this document.

9.2 New test requirements for active substances in PT 21 - follow up WG-IV-2020

As a follow-up to the ENV WG-IV-2020 regarding data requirements for PT 21 active substances, CEPE provided feedback that the suppliers of organic PT 21 antifouling active substances have jointly evaluated new test requirements and concluded that the requirements for Koc data generation are substance-specific. Four AS suppliers provided their feedback to ECHA and an e-consultation was initiated to collect feedback from the WG members. The WG was asked to reply to three questions:

Q1: Do you agree with the feedback provided?

The WG members noted that the AS supplier provided valuable information that could be used to refine the assessment for each substance. There were no further comments during

the WG meeting regarding the content of the feedback, and one MS asked whether the document should be shared with the applicants and if a public version should be prepared.

The WG would agree to share the document and the outcome with the applicants. SECR will ask CEPE if the information can be shared openly with applicants.

Q2: Should any new test requirement for active substances in PT 21 be agreed substance-specific?

It was noted that the some test adaptations could be substance-specific given that ASs can behave differently. Test environments should be substance-specific, and this issue may be especially relevant for metals. Several MSs noted that there are not so many metallic ASs for PT 21. It was noted that MAMPEC shows linear PEC/logKoc correlation, which could be used as a starting point to evaluate whether further data is needed. Some MS commented that harmonized test adaptation or a new test protocol would be needed to obtain Koc values that are more representative of realistic conditions and more relevant for environmental risk assessment. It was also mentioned that the need for a new test protocol was already identified during ENV WG-IV-2020 discussion.

The WG agreed that the requirement should not be substance specific and if a new method is agreed, all substances should follow the same test protocol.

Q3: Which further follow up actions should be undertaken?

Currently there are no harmonized and agreed protocols for assessing Koc at low concentrations in marine sediment. Several options were discussed on how to proceed. No MSCA has volunteered to lead the continuation of the work. It was mentioned that Cu CAR already contains an adapted method for the estimation of Kd (Koc) which can perhaps be used as starting point.

It was discussed that from a Risk Assessment perspective in most of the cases the RA fails for certain compartments and refinements of Koc values would not significantly change the outcome of the RA.

Action:

- SECR has agreed to contact CEPE to explore whether they could come up with a harmonized protocol. The protocol used for Cu or presented by SE (Option 1) could be a starting point.
- SECR/MSCAs has agreed to discussed internally whether there would be resources to initiate a contract with an external contractor to come up with a method or to take the lead.
- DK/NO/SE to bring the issue to the Nordic Biocides Group and see if there would be any option for the group to take the lead on this project.

9.3 *In situ* generated active substances – revision of recommendations

The *in situ* task group has informed the members of the WG on the progress of the revision of the recommendations for *in situ* active substances.

The decision tree for “Identification of precursors subject to risk assessment” has been updated based on the feedback received from the members in June 2022. A concentration threshold for when is the precursor “fully consumed” is not yet set. The members of the ENV WG expressed that it may not possible to define it, as the *in situ* generations differ. The recommendation could set the basic principle on how to approach this question during evaluation.

A second decision tree for by-products and other impurities was suggested.

In general, the working group agreed with the structure of these two decision trees.

The task group also informed that a comparison of the Toxic Unit (SoC) approach and BPC 31 document on relevant impurities was done. The BPC 31 document was agreed only after the initial recommendations were published in 2017, therefore the task group checked if it shall be included into the revised recommendations. The outcome is that the Toxic unit approach is more adapted to define which remaining precursors (impurities) require an environmental risk assessment. The human health task group however is considering to make use of the BPC 31 document in their revision. A joint discussion is needed, whether the approach can be different for the two areas.

The exercise raised an issue in the BPC 31 approach even for conventional substances, therefore a revision of this document is recommended.

The revised chapter for the in-situ active substances will be send for written consultation to the ENV WG in October 2022.

10. AOB

9.1 Other information & lessons learned (SECR)

Next WG meetings
The provisional timing of coming WG meeting: 5-16 December 2022. The meeting takes place as virtual meeting, exact days to be established. It is foreseen to have one physical meeting per year in the future.

Reminder: open/closed points in the RCOM table
In the RCOM, please ensure that each point is marked as open or closed. This is the only (adequate) way to ensure that the members are able to discuss the points they consider open. The other (inadequate) way to ensure this is to include each non-marked point in the discussion table, which means extra work, if “provisionally closed” by SECR, the members may be unprepared, possibility of discussion that could have been avoided.
Closing or opening the point is the eCA proposal.

Reminder: registrations for the WG
Baseline: late registrations will not be handled! This concerns both applicants and MSCA participants. Please take note of the deadline and check the draft agenda.

Chrysanthemum extracts PT18 – PNECsediment
The opinions are on hold (discussed at BPC-41) to address the potential risk to sediment. There will be an e-consultation (Interact Collaboration) on the new studies and re-assessment of the PNECsediment 15-28 September 2022. The outcome will be discussed in a virtual dedicated ENV WG meeting 13 October 2022, to ensure that the active substance can be discussed again at BPC-45.

IUCLID Annotations
Several MSCAs shared a concern related to the loss of annotations in the IUCLID file when a new version is created by the applicant. The IUCLID team is working on a solution. As a temporary workaround, MSCAs can see other dossiers (and relevant annotations) by clicking on the button ‘View Dossiers’ in the right top corner. The list containing all the dossiers created from the same dataset is displayed there. Then, the dossier annotated previously can be open and annotations can be checked.

Workshop waiving ED tests for NTOs
The workshop on waving (additional) data requirements was held on 28 June 2022. A dedicated folder has been created in CircaBC, under the space of the ENV WG (01_Training). All presentations from the workshop are saved in that folder. SECR will check if the recording can also be added as a downloadable file.

Coordination on bromide releasers
At the request of NL and SE, ECHA has started coordinating a more harmonized approach in the assessment of bromide releasing substances. The starting point is the conclusion on DBNPA, for which the *endocrine disrupting effects of DBNPA is attributed to the bromide ion (…)*. The goal is to clarity on how to handle the DBNPA conclusion to other substances that also release and/or contain bromide, including their CLH conclusion. So far, ECHA has identified substances from NL, SE, DK and PT.

Agreements AHEE-7 (6th September 2022)
A new TAB entry has been agreed for indoor disinfection of non-domestic veterinary healthcare scenarios in PT 3. Default values have been agreed for spray/foam disinfection of outer surfaces of animal transport vehicles in PT 3 as well as for an emission scenario for disinfection of wheels of vehicles for animal transport via drive-through basin in PT 3. ENV TAB 198: Splitting of releases of disinfectants used in entire plants was extended from breweries also to e.g. dairies and other beverage processing plants. ENV TAB 11 on porewater entering surface water was deleted, as the sorption to suspended matter was considered twice. The CEFIC proposal emission scenario for direct spray application on crawling insects in PT 18 was not accepted, as the use can be covered by spot treatment. If adjustments are needed, this can be done case-by-case (ENV TAB 204 provides this possibility). New SimpleTreat version 4.1.0 is available, correcting bugs, which triggers amendment of ENV TAB 9. As a follow up of the PT 7 - CEPE study on leaching from outdoor coatings, a Leaching Expert Group (EG) was created. Other ENV WG members were requested to join, but none volunteered. SECR noted that release of next TAB version was delayed to second half of September, in order to include also the conclusions/corrections agreed at AHEE-7.

EG on fate and distribution models
On 7th September 2022, there was a meeting as follow up on remaining open EG items reported at WG-I-2022 (Annex 2 of the ENV WG-I-2022 meeting document). At the meeting, generalised fate models for soil, water (and air) were discussed. The EG conclusions will be forwarded to the ENV WG-IV-2022 for confirmation.

EFSA & ECHA drinking water project update
The Public consultation on the draft Guidance Document on impact of drinking water treatment processes will start on 1 September 2022 until 27 October 2022. ENV WG members are kindly requested to also advertise the consultation in their own networks. The consultation will be hosted by EFSA at the below webpage:
https://connect.efsa.europa.eu/RM/s/publicconsultation
Background and previous info on the project: WGI2020, WGIII2021, WGI2022

Pollinators - Non-bee pollinators
The report “European arthropods and their role in pollination: scientific report of their biodiversity, ecology and sensitivity to biocides” is now public (https://echa.europa.eu/it/technical-scientific-reports). It is a standalone scientific report to support the development of the appropriate risk assessment methodologies to protect arthropod pollinators from the use of biocides in the future. The report also highlights the current knowledge gaps and potential research needs in the future.

Pollinators - Guidance developments

The work on the pollinators guidance will continue under the coordination of ECHA but with strong support from MSCAs experts. The EFSA guidance (Bees and pesticides: draft guidance update for public consultation), is now under consultation. DL 3 October 2022: https://www.efsa.europa.eu/en/news/bees-and-pesticides-draft-guidance-update-public-consultation. A strong alignment to EFSA principles and methods is foreseen. The deadline for the ECHA guidance is 6 months after the publication of EFSA guidance.

Pollinators. Warning sentence for products

As a temporary solution until the guidance is ready. Instructions will be included in TAB. See TAB entry in the WGII2022 General Minutes.

Integrated assessment strategy for the assessment of aquatic and terrestrial bioaccumulation

DE presented their project to develop and Integrated Assessment and Testing Approach to assess bioaccumulation, one for aquatic organisms and one for terrestrial and air-breathing organisms. Both IATA's are foreseen to also include data from new methods (in vitro, in silico, H, Azteca) and toxicokinetic data. The project started in August 2022 and will run for 3 years.

DBP project: State of progress and future steps

FR reported on the state of the DBP project, where the focus is now on the assessment of three groups of DBPs: the THM (trihalomethane), the HAA (halogenated acetic acid) and the HAN (halogenated acetonitrile). Currently, the group is working on the finalisation of the reports, addressing each of the group and the relevant DBPs within the groups. The reports are expected to be sent to the WG member by the end of 2022, to be discussed at WG-I-2023. Later in 2023, an additional report will address the three remaining groups of DBPs: Haloaldehydes, Halophenols and Bromate/chlorate/chlorite. The complete risk assessment strategy is expected to be discussed in 2023.

Mandatory early WG meeting

In the following cases, the ENV WG should ALWAYS be consulted first via an early WG:

- New emission scenarios are used
- Changes in existing emission scenarios
- Use of existing emission scenarios in another PT

Appendices:

Appendix 1: List of TAB entries for confirmation by WG members

Chapter 1 Effect and Hazard Assessment

ENV xxx

The WG agreed to further clarify Info-box 12 in the Vol IV part B. Therefore, the following text should be used instead. Since this is a clarification of available guidance, the new text should be applicable immediately after publication of the TAB.

Info-box 12: Clarifications on the assessment factor to derive $PNEC_{soil}$

Test with plants described in OECD TG 208 or OECD TG 227: Can this test be considered as a short or long term test and how does this influence the assessment factor to derive the $PNEC_{soil}$?

Different interpretations exist on whether these tests can be considered as a short or a long term studies. These studies are in principle short-term studies as they do not cover chronic effects or effects on reproduction. Nevertheless, Tarazona et al. (2013) showed that, when carried with 6 plant species, the OECD TG 208 often provided as sensitive of more sensitive endpoints than the chronic ISO 22030 test. Therefore, it was decided that the OECD TG 208 test can be considered a long term test when performed with 6 or more species of plants. Besides, when less plants species have been tested in the OECD TG 208 or with a OECD TG 227, it also can be considered a long-term study under certain circumstances, provided that in addition to the EC_{50} also a $NOEC/EC_{10}$ was derived from this test. Depending on the sensitivity of plants compared to other taxonomic groups when comparing $L(E)C_{50}$ values, different assessment factors to derive the $PNEC_{soil}$ must be chosen (for details see “Choice of AF for $PNEC_{soil}$ derivation”, below).

Possibility to lower the assessment factor for the derivation of the $PNEC_{soil}$ from 1000 to 100 when the most sensitive species is unknown (e.g. data for micro-organisms and acute data for earthworms are available, but no data for plants).

Application of an assessment factor of 100 instead of 1000 is only possible when effect data for three different species (i.e. micro-organisms, earthworms and plants) are available and therefore the potentially most sensitive species can be established (for details see “Choice of AF for $PNEC_{soil}$ derivation”, below).

In specific situations, and on a case by case basis, when the necessary data to establish the most sensitive species is available from a very similar compound as the active substance under consideration, and can be extrapolated, than these data can be used to lower the assessment factor to 100.

Choice of AF for $PNEC_{soil}$ derivation

If test results are available for:

- Microorganisms (28 days EC_{50} and $NOEC/EC_{10}$)

- Plants (EC_{50} and $NOEC/EC_{10}$ according to e.g OECD 208)

- Earthworms (14 days LC_{50} and 56 days $NOEC/EC_{10}$),

three different situations can be distinguished with respect to PNEC derivation and the choice of the AF:

1- Acutely plants are significantly less sensitive (EC_{50} ≥ 10 times higher than $L(E)C_{50}$ for microorganisms and/or earthworms) and moreover, the NOECs/EC_{10} of plants are higher than NOEC/EC_{10} for microorganisms and earthworms. An AF of 10 is applied to the lowest NOEC/EC_{10} for organisms other than plants.
2- Acutely, plants are the most sensitive species and the plant EC_{50} is significantly* lower than the NOECs/EC_{10} from the microorganism and the long-term earthworm study. Therefore the EC_{50} from the OECD 208 test are used to derive the PNEC, however it is considered that only two long-term data are available. An AF of 100 is applied to the lowest $L(E)C_{50}$ (in analogy to the note c for the PNEC derivation for the aquatic compartment). Besides, an AF of 50 is applied to the lowest plant NOEC/EC_{10}, (to cover the lack of a true long-term NOEC/EC_{10} for plants). The worst case derived PNEC is then selected for the risk assessment.
3- In other cases, an assessment factor of 50 is applied to the lowest NOEC/EC_{10} when long-term data are available for two trophic levels.

When additional to the plant study, only the microorganism or only the long-term earthworm study is available, the above AF should be increased to the next level (e.g. 100 instead of 50, or 50 instead of 10). However, in order to be consistent with the water compartment, when the LC_{50} of plants is used to derive the PNEC, an assessment factor of 100 is applied.

These assessment factors can be reduced if further testing on chronic toxicity to plants, e.g. according to ISO standard 22030:2005 on determining the inhibition of the growth and reproductive capabilities of higher plants, are available.

* Endpoints are considered not to be significantly different when the sensitivity difference is within a factor of less than 10.

Tarazona J.V., Cesnaitis R., Herranz-Montes F.J., Versonnen B. 2013. Identification of chemical hazards for terrestrial plants in the regulatory context: Comparison of OECD and ISO guidelines. Chemosphere, 93, 2013, 2578-2584

Appendix 2: List of participants

Core members and alternates:

- AT Lukas Kuehrer
- DE Daniel Frein
- DE Eleonora Petersohn
- DE Sascha Setzer
- FI Jaana Pasanen
- FR Stéphanie Alexandre
- FR Jerome Lozach
- FR Anne Straczek
- FR Séléné Verstraet
- IE Helena Joyce
- NL Barry Muijs
- SE Johan Persson
- SE Liselott Säll
- DK Jesper Johannessen

Flexible members:

- AT Dominik Altmann
- AT Lea Breul
- BE Anne Brasseur
- BE Bart Heulens
- BE Wiet Raets
- BE Samuel Huerga-Fernandez
- CH Tenzing Gyalpo
- CH Petra Kunz
- CH Maria a Marca
- CZ Lucie Bielska
- DE Katja MICHAELIS
- DE Maren Ahting
- DE Julia Margaretha Anke
- DE Stefanie Jacob
- DK Henrik Wennermark
- EE Helen Sulg
- ES Elena Ruiz
- ES Ángeles Jiménez
- FI Oskari Hanninen
- FI Timo Nieminen
- FI Sanna Kaukoniemi
- FI Sari Penttinen
- NL Els Smit
- NO Karina Petersen
- NO Terje Haraldsen
- PL Agnieszka Podlaska
- PL Helena Rzodeczko
- SI Bert van der Geest
- SK Jana Molnarova

Rapporteur:

- NL Barry MUIJS – Glutaraldehyde; Hydrochloric acid
- IT Lucilla Baldassarri - Bardap 26; Outcome e-consultation on ED assessment of ADBAC/BKC and DDAC

- LV Ieva Igaune - L-(+)-lactic acid
-

Advisors:

- SK Katarina Chuda
- NL ZhiChao Dang
- DK Jesper Johannessen
- FR Fanny Herard
- FR Gilson Arthur
- IT Maria Antonietta Orrù
- FR Séléné Verstraet

ASOs:

- Jules Bossert – Cefic
- Raf Leyman - Cefic
- Boris van Berlo -Cefic
- Roman Gyssels

ECHA chairs and experts

Human Health WG-III-2022

Final minutes

8 December 2022

Final minutes of Human Health WG-III-2022

13-14 September 2022

Meeting of the Human Health Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 60 members or advisers registered, of which 11 were (alternate) core members. Several stakeholder representatives were registered. Applicants were registered for their specific substance discussions.

The list of attendees is given in Annex 1.

2. Administrative issues

SECR informed that new security rules are in place for access to Interact by individual experts. This is similar to the practice and requirements regarding S-CIRCABC. Individual experts must sign the declaration of confidentiality that refers to rules related to S-CIRCABC Interest Groups and Interact.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The agenda was agreed without changes.

4. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflicts of interest in relation to the agreed agenda. None were declared.

5. Agreement of draft minutes from WG-II-2022

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Poly(oxy-1,2-ethanediyl), .alpha.-[2-(dide- cylmethylammonio)ethyl]- .omega.-hydroxy-, propanoate (salt) (Bardap 26), PT 2, 4 (eCA IT)

The WG agreed on the assessment without revisions.

7. Discussion of Union authorisation applications

7.1 UA for Glutaral (Glutaraldehyde), PT 6, 11-12 (eCA NL)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

7.2 UA for Hydrochloric acid, PT 2 (eCA NL)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

7.3 UA for L-(+)-lactic acid, PT 3 (eCA LV)

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

8. Mutual recognition

8.1 Request for ECHA opinion pursuant to Articles 36(2) and 38 of the BPR - biocidal product containing permethrin (PT 18)

9. Technical and guidance related items

9.1 Worst case and best case concentrations in a product family (DE)

DE provided a document that was commented in two e-consultations during 2022. The WG agreed on the proposed methodology to define the worst case and best case concentrations for the human health risk assessment of a biocidal product family. The document was agreed with minor changes and by clarifying the scope of the document - it is not in the remit of the document to address possible outcomes of the risk assessment and e.g. the need to split uses or to remove a use from a meta-SPC. The document and the accompanying Excel sheet are now publicly available[1].

9.2 *In situ* generated active substances – revision of recommendations

Two members of the *in-situ* Human health Task Force (HH TF) presented the main aspects and challenges in authorisation of biocidal products for generation of an *in situ* generated active substance, as addressed in Part B of the draft *In-situ* guidance for human health. It was further noted that the work on the specific considerations for different product case types is ongoing, but the HH TF is expected to complete the drafting and the review of 1st draft of Products part by the end of September or early October 2022.

SECR informed the WG members and ASO observers of the forthcoming e-consultation focused on Part B of the *in-situ* HH draft guidance, with a 4-week commenting period (October-November 2022) for both WG members and ASOs.

Following the e-consultation, the foreseen actions are:

- preparation of the revised HH draft guidance by the HH TF (mid-November to mid-December 2022), based on the comments received,
- additional e-consultation on compiled (APCP, EFF, HH and ENV) draft *in-situ* guidance for all WGs and ASOs in February-March 2023,
- endorsement of revised final draft *in-situ* guidance envisaged in June WG meetings.

10. Any other business

10.1 Other information

Documents published

CA-June22-Doc.4.6 was agreed at the CA meeting in June 2022 and provides principles for P statements. The WG will need to peer review the proposals by the eCA.

Coordination of bromide releasers

A new coordination activity has been launched for bromide releasers, noting the BPC opinion on DBNPA: "*The endocrine disrupting effects of DBNPA is attributed to the bromide ion* (…)". The main questions identified are:

- How to handle the DBNPA conclusion on ED properties for other active substances that may also release bromide?

[1] https://webgate.ec.europa.eu/s-circabc/w/browse/85748090-25b8-4c7a-9184-2c7b7c0a645b

- How to handle CLH for active substances releasing bromide and for in situ generated active substances where the "soup" contains bromide?

Guidance consultation

Public consultation of the guidance *Impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water* has been launched and is open until 27 October 2022[2]. The guidance outlines which environmental water residues have to be assessed, the identification of water treatment transformation products that are formed and how to complete a risk assessment that includes intakes from consuming treated water.

Next WG meetings

The next WGs will likely be virtual with the following provisional timing:

- 5-16 December 2022
- 13-24 March 2023

[2] https://connect.efsa.europa.eu/RM/s/publicconsultation (PC-0234)

Annex 1

Human Health WG attendees

Core and alternate members
HOELZL Christine (AT)
MIKOLAS Jan (CZ)
HERRMANN Kristin (DE)
HOLTHENRICH Dagmar (DE)
ARAPAKI Niki (EL)
LORI Julia (FR)
AUBIN Aurelie (FR)
LAUMONIER-MAXIMILIEN Elisabeth (FR)
BREEN Alan (IE)
BOS Carina (NL)
LESER Vladka (SI)
Flexible members
DERLER Angelika (AT)
HOCHEGGER Patrick (AT)
HOUAMED Anis (BE)
YUKSEL Aysel (BE)
GOLDINGER Daniela (CH)
GRUNIG David (CH)
ROSSIER Nadine (CH)
RUSCONI Manuel (CH)
SANS-PICHÉ Frederic (CH)
SEDLAK Petr (CZ)
KLUTZNY Saskia (DE)
ROITZSCH Michael (DE)
SCHNEIDER Heiko (DE)
SEMISCH Annetta (DE)
JENSEN Stine (DK)
KÄOSAAR Sandra (EE)
HI ROMAN Anastasia (EL)
SANCHEZ Jose Maria (ES)
HYVÄRINEN Tuija (FI)
RYDMAN Elina (FI)
VÄLIMÄKI Elina (FI)

AMSALLEM Tiffany (FR)
COLLIN Elodie (FR)
REY Marion (FR)
MIDTHAUG Hilde Karin (NO)
FRYDENLUND Jorid (NO)
GÓRECKI Roman (PL)
PETTERSON Emma (SE)
CEBASEK Petra (SI)
OLHA Roman (SK)
PILISIOVA Ruzena(SK)

Advisors
KRIEGL Isabel (AT)
RIME Soyub (DE)
MATTHES Susan (DE)
BELLINGARD Valerie (FR)
KERGUELEN Mathieu (FR)
NDIAYE Lena (FR)
VARET Julia (FR)
BODERO Marcia (NL)
ÅSLING Bengt (SE)
HENRIKSSON Rebecca (SE)
PETROVIČ Natasa (SI)
DRAB David (SK)
HORSKÁ Alexandra (SK)
Rapporteurs
DEKOVI Edlira (IT)
IGAUNE Ieva (LV)
Stakeholders
VAN BERLO Boris (BE)
GYSSELS Roman (BE)
LEYMAN Raf (BE)
STOERCHEL Peter (DE)
Applicants
SC Johnson
Arxada
Arrow Regulatory
Langxess
Jesmond Bioscience GmbH

WG-III-2022
Final minutes
7 December 2022

Final minutes of Efficacy WG-III-2022

7 and 9 September 2022

Meeting of the Efficacy Working Group of the Biocidal Products Committee

Efficacy Working Group

1. Welcome and apologies

The Chair welcomed all participants to the Efficacy Working Group (EFF WG) meeting and informed that this meeting is split into two separate, non-consecutive days. The list of attendees is given in Annex 1.

2. Administrative issues

The ECHA gave a brief introduction concerning security rules related to access to Interact and the declaration of confidentiality that refers to rules related to S-CIRCABC Interest Groups and Interact.

3. Agreement of the agenda

The Chair introduced the agenda items. The EFF WG agreed on the proposed agenda.

4. Declarations of potential conflicts of interest in relation to the agenda

The Chair invited all members to declare any potential conflict of interest to the agenda items. None was declared.

5. Minutes

The revised draft minutes of WG-II-2022 were agreed at the meeting.

6. Discussion of active substances

6.1 Poly(oxy-1,2-ethanediyl), .alpha.-[2-(dide-cylmethylammonio)ethyl]-.omega.-hydroxy-, propanoate (salt) (Bardap 26) (eCA IT)

There were no open points for discussion. The EFF WG agreed with the evaluation of the eCA.

7. Discussion of Union Authorisations

7.1 UA for a product family containing glutaraldehyde (eCA NL)

There was one open point in the discussion table. This open point remains open and an ad hoc follow-up will be launched.

7.2 UA for a product family containing hydrochloric acid (eCA NL)

There were no open points for discussion. The EFF WG agreed with the evaluation of the eCA.

7.3 UA for a product family containing L-(+)-lactic acid (eCA LV)

There were two open points in the discussion table and one provisionally closed point. One point was closed during the meeting. For the remaining open point an ad hoc follow-up will be launched. Please, refer to the confidential minutes in the form of the discussion table for more details.

7.4 Early WG on UA-APP containing peracetic acid (eCA DE)

Please, refer to the confidential minutes in the form of the discussion table for more details.

7.5 Early WG on UA-APP containing active chlorine released from hypochlorous acid (eCA SI)

Please, refer to the confidential minutes in the form of the discussion table for more details.

8. Technical and guidance related issues

8.1 *In situ* generated active substances – revision of recommendations (ECHA)

ECHA introduced the topic and informed the WG that the sections of the WG recommendation that has been finalised are Terminology and definitions, APCP active substance part, APCP biocidal product part and HH active substance part. ENV active substance part has been drafted, but not yet discussed at the WG.

Commenting for the EFF sections was launched in June. Three comments were received for the active substance part and the draft was amended according to these comments. For the products part, 37 comments were received, and 7 comments were discussed at the WG.

The EFF WG agreed that the sentence *"For the authorisation of the biocidal product the efficacy against claimed target organisms has to be demonstrated for the output of the in situ generation system (IGS) under defined in-use conditions for each of the intended uses."* will be amended as: *"For the authorisation of the biocidal product the efficacy against claimed target organisms has to be demonstrated for the output of the in situ generation system (IGS) under in-use conditions applied by the applicant for each of the intended uses."*

The paragraph about on-site validation in case the concentration of the active substance generated *in situ* cannot be measured was agreed to be amended as:

"*In such cases, as the assessment of efficacy is challenging, it is the responsibility of the end-user to perform on-site validation of the systems and devices to ensure that the system is efficacious under the use conditions. In cases, where on-site validation is not feasible a sound justification should be provided by the applicant and efficacy test strategies should be expanded to incorporate a set of realistic worst-case conditions concerning the generation of the active substance to ensure sufficient in-use efficacy."*

For case-type II it was decided to amend the paragraph concerning on-site validation as:

"Due to the complex nature of IGS including devices in addition to the regular test requirements according to the guidance (e.g. laboratory/simulated-use tests) efficacy data generated at a representative site with a representative device is required for biocidal product authorisation.

An on-site validation or on-site monitoring is usually required (see section 1.2).

The applicant, distributor, or end-user should at least be required in the SPC to adjust the device to the respective location to comply with the authorised specification of the output to ensure on-site efficacy of the system."

WG agreed that Figure 1 should not be amended.

The paragraph in section 2.3 about the mixing ration of precursors was agreed to be amended as: *"Different mixing ratios of the precursors are considered as use-specific application rates and are therefore not taken into account for the choice of the worst-case product."*

Testing requirements to substantiate storage stability and shelf life in case-type III were discussed. The requirement comes from the APCP part, where it is stated for the case-type III:

- "*…Instead, the storage stability and the associated shelf life should be demonstrated by efficacy tests of the aged BP.*
- *The efficacy tests should be conducted with a freshly applied coating and with an aged coating. The results should demonstrate that the level of efficacy remains acceptable.*
- *Information about leaching of the catalyst form the coating should be provided.*
- *Information about the service life of the coating should be provided and confirmed by efficacy tests."*

This point was left open, as agreement was not reached. An internal discussion will be initiated to clarify this issue with the APCP colleagues.

Requirements for the worst-case test product for the case-type III was discussed. It was decided not to amend the current text as defining all possible parameters affecting efficacy of coatings is not possible and should be addressed on a case-by-case basis for the time being.

Two points were opened during the discussion. It was proposed that more information should be added to the section 1.1 about requirement for 3 replicates in field trials. It was agreed that FR will send a proposal to ECHA. Also, it was agreed that the definitions for holding time and hydraulic cycle time will be harmonised with the PT 11 – PT 12 draft guidance.

8.2 Surface disinfection by products distributed without mechanical action (wiping/mopping) (DE)

DE presented an update of the TAB entry 15 dedicated to the disinfection of hard surfaces by products sprayed or poured on the surface and distributed without mechanical action. Initially, a distinction was made whether the wiping/mopping was intended to distribute the product evenly or whether wiping/mopping was intended to 'support' disinfection by mechanical action. Due to this distinction, currently, different EN standards have to be used to generate efficacy data, which, in fact, makes the approach a bit confusing and non-pragmatic. The EFF WG unanimously agreed with the proposed amendment, (see the working document WGIII2022_EFF_8-2), which will be implemented directly in Vol. II, Parts B+C draft efficacy guidance foreseen for publication in QIV 2022.

8.3 Handrub disinfectants used in PT 4 areas (DE)

DE presented a draft proposal concerning dirty conditions claimed for hygienic handrub products (PT1) used in food and feed areas (PT4). One of the EFF WG members commented that this solution should apply to professional users, the other one pointed out that it should apply also to other (surgical) handrub disinfectants. In general, the EFF WG agreed that such products should only be used on visibly clean hands and dirty conditions are not possible for hygienic handrub products used in PT4.

The proposed TAB entry is presented below:

XX. Dirty conditions claimed for hygienic handrub products (PT1) used in food and feed areas (PT4).

Is it possible to claim dirty conditions for a handrub product (PT1) that is used in food and feed areas (PT4)?

In line with EN 14885 standard and in addition to the fact that no appropriate phase 2 step 2 test with relevant soiling is available, hygienic handrub products (PT1) for uses in food and feed areas (PT4) always have to be applied on visibly clean hands. Therefore, for such products, it is not possible to claim dirty conditions.

Type of entry:	e) New guidance not triggering new data requirements where new guidance is considerably more reliable than former guidance
Publication date: XX/XX/2023	
Date of applicability for active substances:	XX/XX/2023
Date of applicability for products:	XX/XX/2025

8.4 Implementation of the EN 17272 – position paper (CEFIC/AISE)

CEFIC/AISE expressed their concern about the implementation of the EN 17272 standard, especially with reference to tests performed in very large volume-premisses (>150m3) by specifying the requirements and test conditions for which clarification is needed. As indicated by the WG members there are a few cases related to disinfection of large volume premises at the EU or national level, for some of them discussion already took place (UA-APP), or e-consultation was launched (BE - 2021). It was concluded that BE will share the outcome of the e-consultation with the EFF WG members. In general, the WG is open for any case-specific discussion for non-standard application in the future, based on the outcome a TAB entry may be developed as well.

8.5 Efficacy testing of disinfectants for treatment of aquarium water (DE)

DE presented a proposal for the disinfection of aquarium water. Following the approach taken for swimming pool disinfection it was agreed on the following data requirements:

Test methods

1. an (adapted) quantitative suspension test (phase 2 step 1 test), and
2. a quantitative simulated-use test.

For viruses an adapted phase 2 step 1 test or a simulates-use test should be provided.

One of the WG members pointed out that it would be sufficient to request only a simulated-use test as the phase 2 step 1 test was developed for surface disinfection and should not be adapted for water disinfection. Nevertheless, the other WG members indicated the importance of this test as supporting the tiered approach taken for disinfectants and as the only standardised test method for such an application. It was pointed out that in case of difficulties with the pass criteria, like lg reduction, it may be subject to further discussion.

Test organisms

Aquarium water disinfectants should at least be sufficiently effective against bacteria. Efficacy tests with the reference test organisms for non-medical areas in PT 2 or for PT 3 according to Appendix 3 of the efficacy guidance (Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts B+C)) should always be provided.

For all other groups of organisms, data with the standard test organisms for PT 2 non-medical areas or for PT 3 as per Appendix 3 only have to be provided when activity against those organisms is claimed.

It was left up to the applicant to choose between PT 2 or PT 3 test organisms, based on the experience gained it may be specified in more detail in the future.

Soiling

In general, dirty conditions in PT 5 (15 mg/L DOC) are considered appropriate for efficacy testing. Higher soiling (e.g. 0.3/3 g/L BSA) is acceptable as well but is not mandatory. Alternatively, the level of soiling can be based on an analysis of several real aquariums' water under in-use conditions. This approach could be applied e.g. in cases, where lower soiling is expected due to the presence of a filtration system. The applicant should provide a justification for why the chosen test conditions can be seen as representative/worst-case for the intended use. The MSCA will evaluate any justifications on a case-by-case basis, consulting the other MSCAs as necessary, and will decide whether it is acceptable or not.

Claim

As different aquarium types (tropical freshwater, cold freshwater, brackish water and saltwater aquariums) exist, properties of the intended water matrix (e.g. pH, mineral (salt) composition) can differ significantly and should be taken into account in the simulated-use test. Therefore, for a general claim of aquarium water disinfection, simulated-use tests should at least be performed under representative worst-case conditions for freshwater and saltwater. In case only one type of water matrix is claimed simulated-use tests should be performed under representative worst-case conditions for this water matrix. For the (adapted) quantitative suspension test (phase 2, step 1 tests), standard water according to EN is considered acceptable.

The EFF WG decided to develop a TAB entry in the future when more experience is gained.

9. AOB

9.1 Other information

Short information was given about the EFF WG-IV-2022 meeting, the deadline for early WG discussion requests and working document submission, the current status of the draft guidance, annotations in IUCLID and ongoing e-consultations.

List of Attendees

1. **Core members:**
   - JANSEN Irina (DE)
   - KRÜGER Martin (DE) – Alternate
   - ATTIG Isabelle (FR)
   - MAXIMILIEN Yann (FR) – Alternate
   - WARMERDAM Sonja (NL)
   - DUH Darja (SI)
2. **Flexible members:**
   - WIDHALM Bernhard (AT)
   - BURGER Natascha (AT)
   - BURMISTROVA Anastasia (BE)
   - LEPAGE Anne (BE)
   - ABLA Anene (BE)
   - DANG ThyMinh-Dung
   - PIROTTE Jennifer
   - WANDELER Eliane (CH)
   - DONZE Gerard (CH)
   - MEIER Margrith (CH)
   - RUSCONI Manuel (CH)
   - SANS-PICHÉ Frederic (CH)
   - SVEJSTIL Roman (CZ)
   - PECINKOVA Martina (CZ)
   - DOLEŽELOVÁ Katsiaryna (CZ)
   - CLEYTON JØRGENSEN Charlotte (DK)
   - KÄOSAAR Sandra (EE)
   - PLOOMPUU Grethe-Johanna (EE)
   - PEREIRO COUTO Natividad (ES)
   - PORTELA HENCHE Cristina (ES)
   - NIEMINEN Timo (FI)
   - Billault Catherine (FR)
   - HADDACHE Nabila (FR)
   - BRIZARD Mathias (FR)
   - OWENS Aoife (IE)
   - RONCI Maria Beatrice (IT)
   - BALDASSARRI Lucilla (IT)
   - MEZULE Linda (LV)
   - BIELINSKI-BILINSKI Marin (PL)
   - KASPRZAK Karolina (PL)
   - ÅSLING Bengt (SE)
   - MAGNER Jörgen (SE)
   - DANADAIOVA Emese (SK)
3. **Rapporteurs:**
   - Igaune Ieva (LV)
4. **Advisors:**
   - REY Juliana (DE)
   - DEKKER Bas (NL)
   - Jongerius Aniek (NL)
5. **ECHA Staff**
   - SZYMANKIEWICZ Katarzyna (Chair)
   - RAULIO Mari
   - HAMALAINEN Eva
   - VETELAINEN Kaisa
6. **Stakeholders:**
   - VAN BERLO Boris (CEFIC)
   - Theelen Meredith (CEFIC)
   - DARRIET Marie (AISE)
   - CORNER Hannah (AISE)

- CALDWELL Stuart (CEFIC)
- LEYMAN Raf (CEFIC)

7. Applicants:

- MC (Netherlands) 1 B.V.
- Arrow Regulatory (Ireland) on behalf of Quatchem