Minutes of the Working Group meeting I in 2022

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

(Meeting date: 29-30 March 2022 – WebEx meeting)

07 June 2022

1. Welcome and apologies

The meeting was a WebEx-meeting. The Chair welcomed the participants of the working group meeting. CEFIC was present at the meeting as an accredited stakeholder organisation (ASO) with two representatives. The following applicants registered to the meeting as observers for their agenda items:

- ERM Regulatory Services Limited
- CIDLINES NV
- European Lime Association aisbl
- SALVECO S.A.S.
- TROY CHEMICAL COMPANY BV
- BASF SE
- spectra Consult GmbH (on behalf of CVAS)
- Calvatis 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 clarified that the discussion table was switched from a word document to an excel table. This excel table keeps the history from the first comment to the discussion point, thus the development of an open issue. In addition, the working group discussion and the minutes will be added to this table. Thus, in the end the whole history will be compiled in one file. The working group members exchanged their views on the new format and expressed concerns on the editability of text in excel and the limitation for the amount of text that can be entered per cell. It was appreciated that the history of the case is kept in on document, thus the issue is easier traceable. The chair promised that ECHA will work on the improvement of the workability of the excel table so that it would facilitate the work of the member states (eCA and commenting members states) and ECHA. Therefore, ECHA will continue with using the excel table and gain more experience with the workability with this approach. In case, this approach will turn out as not workable, there should be the possibility to return to the work format.
- ECHA provided a presentation on the interact tool that must be used for commenting and cooperation. It was explained why the tool was introduced, how it should be used and what should be kept in mind when using it. ECHA recognised that improvement of the interact tool is still needed. Thus feedback from the member states is very welcome. However, the feedback should be consolidated by member state. Feedback from individuals of a member state, e.g. of one member of a working group, would not be appreciated and not be considered.
- ECHA informed further:
    - Nominations of new working group members will be only possible if existing members are leaving and in addition during the month of January.
    - Member states/ working group members should inform ECHA when they are leaving. Thus, they can be deleted form the list of working group members.
    - There will be a new tool for the declaration of interest that will be released in April.

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). It was noted that four items for AoB were already received:

1. Analytical methods for SoC
2. Shelf-life setting
3. Conditions for DSC to be used for explosives and self-reactive substances
4. Global composition for in situ generated active substances

The chair proposed to discuss these items in the beginning of the meeting as their conclusions might facilitate the discussions on active substances and Union Authorisations.

The agenda and the proposal to discuss AoB in the beginning were agreed.

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 IV 2021

The working group members provided comments on the draft minutes of WG IV 2021. These comments were included in the updated draft minutes and discussed. The draft minutes were modified accordingly and were agreed by the working group members.

6. Discussion of active substances

6.1 Formic acid

The open issues were discussed and agreed by the working group members.

7. Discussion of Union authorisations

7.1 UA for a product family containing L-(+)-lactic acid

The open issues were discussed and agreed by the working group members.

7.2 UA for a product family containing L-(+)-lactic acid

The open issues were discussed and agreed by the working group members.

7.3 UA for a product containing 3-iodo-2-propynyl butylcarbamate (IPBC)

The open issues were discussed and agreed by the working group members.

7.4 UA for a product family containing Peracetic acid

The open issues were discussed and agreed by the working group members.

7.5 UA for a product family containing Chlorocresol

The open issues were discussed and agreed by the working group members.

7.6 UA for a product family containing Hydrogen peroxide

The open issues were discussed and agreed by the working group members.

7.7 UA for a product family containing Hydrogen peroxide

The open issues were discussed and agreed by the working group members.

7.8 UA for a product containing active chlorine released from chlorine

The open issues were discussed and agreed by the working group members.

7.9 UA for a product containing calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime

The open issues were discussed and agreed by the working group members.

7.10 UA for a product containing calcium oxide/lime/burnt lime/quicklime

The open issues were discussed and agreed by the working group members.

8. Any other Business (AoB)

8.1 Analytical methods for SoC

The working group members discussed whether a modification of the current text in the Technical Agreements of Biocides (TAB) would be beneficial. Several members voiced the opinion that re-phrasing of the current text might open the door to new misunderstandings and that the current text can be considered sufficiently clear.

It was concluded that a change of the current TAB entry is not required. The current text is already sufficiently clear to conclude that analytical methods for SoCs are not required provided that that they are not generated during storage and/or their concentrations do not change during storage.

8.2 Shelf-life setting

The discussion was highlighting two inconsistencies between the published Coordination Group (CG) document "Post authorisation conditions for biocidal product authorisation:

harmonising practices" (GC 32-2018-16-AP-6.2) and the shelf-life decision tree included in the Technical Agreements for Biocides (TAB). The inconsistencies are

1. the term "mid-term […] storage stability data" in the CG document whereas the TAB entry uses the term "interim" and
2. the requirement to have (mid-term) results of the long-term storage test already available in order to be able to set post-authorisation conditions in the CG document whereas the TAB entry suggests that even without already available results of long-term storage test a shelf-life can be set due to an acceptable accelerated storage test.

It was stated that both documents must be aligned for avoiding confusion and clear guidance to member states and applicants.

Conclusion:
The CG will be consulted to clarify the intention of the CG document 'GC 32-2018-16-AP-6.2' regarding the term "mid-term" and the requirement of providing mid-term long-term storage analysis in order to set a shelf-life. The TAB entry and the CG document should be aligned.

8.3 Conditions for DSC to be used for explosives and self-reactive substances

A document was presented to the working group members highlighting that attention should be paid to the specific recording conditions for the differential scanning calorimetry (DSC). In particular, the need to use closed crucibles. Otherwise, the gained results might not be useful to conclude on the heat of decomposition. Working group members reported that they have started requesting DSC data but applicants were hesitant to provide this data as it is not an information requirement according to Annex II and III to the BPR. It was also mentioned that there are often problems in recording DSC scans, which can lead to non-acceptance of the data. It was explained that the concerns raised were the starting point for the development of the presented paper and it was recognised that applicants are reluctant to provide data on physical hazards. DSC is still seen as useful, with the correct parameters, to justify the waiving of explosives and self-reactive substances. It was highlighted that a DSC scan should be regarded as the pragmatic way for waiving otherwise the complete tests must be requested from the applicants. While acknowledging the possibility to perform DSC measurements for biocidal products with high water content, it was questioned whether this was always required. It was therefore suggested to include this aspect in the further discussions on the waiving of physical hazards where a definition of "high water content" and conditions when no test is required should be addressed.

Conclusion:

ECHA will launch an e-consultation for this document and included this item in the next working group agenda.

8.4 Global composition for *in situ* generated active substances

ECHA introduced this agenda item to the working group members. Clarification was provided with regard to non-marketable precursors that might be present in the active substance generated *in situ*. It was explained that in such cases, the biocidal product will be the active substance generated *in situ*. Thus, unreacted precursors that are present in the active substance generated *in situ* have to be taken into account in the global composition. The term "qualitative composition" refers to information on the (chemical) identity of the constituents of the active substance whereas the term "quantitative composition" refers to the individual amount of these constituents, which is usually expressed as concentration ranges. It was agreed that the definition of these terms should be included in the revised *in-*

situ recommendations that are under development. It was remarked that it should be made clear in the *in-situ* recommendations that the global composition is not supposed to be used to perform a technical equivalence assessment (TE) as TE is not expected to be conducted for *in situ* generated active substances.

Conclusion:

The working group members agreed with proposed definition of 'global composition' used for *in situ* generated active substances.

Annex 1 - List of attendees registered for the meeting

Working group member		**Member state**
Colson	Jerome	AT
Ghobrial	Michael	AT
Burmistova	Anastasia	BE
Fauconnier	Steven	BE
Herremans	Yannick	BE
Huerga Fernandez	Samuel	BE
Jarrety	Helene	BE
Lepage	Anne	BE
Aeschbacher	Michael	CH
Courdouan Merz	Amandine	CH
Vlasak	Martin	CZ
Mühle	Ulrike	DE
Domino	Katrine	DK
Vallikivi	Imre	EE
Escalada	Jesus	ES
Cano	David	ES
Vuorensola	Katariina	FI
Lutz	François	FR
Six	Therese	FR
Bujard	Thomas	FR
Boitier	Caroline	FR
Talhouët	Anne-Claire	FR
Cataldi	Lucilla	IT
Igaune	Ieva	LV
van Rijnsbergen	Peter	NL
Kruidhof	Sabine	NL
Blaga	Cornelia	NL
Bourke	Alena	NL

Huszał	Sylwester	PL
Horczyczak	Anna	PL
Zielińska	Klaudia	PL
Złotorowicz	Agnieszka	PL
Alpe	Mia	SE
Marsh	Göran	SE
Ryden	Andreas	SE
Velikonja Bolta	Špela	SI
Čebašek	Petra	SI
Porubiak	Michal	SK
Drabová Kušíková	Zuzana	SK

ECHA staff
Krebs Bernhard (Chair)
Uphoff Andreas
Marcon Eva
Vetelainen Kaisa
Van Galen Joost

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
CEFIC	Van Berlo Boris Bossert Jules
AISE	Darriet Marie

Applicant	**Agenda item**	**Observer**
spectra Consult GmbH	7.1	Wagner Silvia
Calvatis GmbH	7.1	Hamann Matthias
SALVECO S.A.S.	7.2	Hisiger Steve Revol Baptiste
Troy Chemical Company BV	7.3	Plössl Jonathan Stuelten Dele
ERM Regulatory Services Limited	7.4	Meritxell Guino Byravan Rama
CID LINES NV	7.5	Decroix Lies Guillemyn Karel
Evonik Operations GmbH	7.7	Imm Sebastian Khrenov Victor

European Lime Association aisbl	7.9, 7.10	Gryspeirt Celia Pelletier Marc

WG-I-2022

Final minutes

1 June 2022

Minutes of Efficacy WG-I-2022

28 and 30 March 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 days. The list of attendees is given in Annex 1.

2. Administrative issues

SECR gave brief information on the administrative issues. The Chair informed that the case discussions (AS, UA) will not be recorded anymore. As a consequence, the minutes may be somewhat shorter. There will be no effect on action points and conclusions, which is the most important part of the minutes. These principles concern all WGs (APCP, EFF, ENV and TOX).

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-IV-2021 and Ad hoc WG-2022 were agreed at the meeting.

6. Discussion of active substances

6.1 Formic Acid (eCA BE)

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 containing active chlorine released from chlorine (eCA SI)

There were two open points that were closed during the meeting. In addition, there were two provisionally closed points that remained closed. Please, refer to the confidential minutes in the form of the discussion tables for more details.

7.2 UA for a product containing calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime (eCA FR)

There were six open points in the discussion table that were closed during the meeting. In addition, there was one provisionally closed point that remained closed. Please, refer to the confidential minutes in the form of the discussion table for more details.

7.3 UA for a product containing calcium oxide/lime/burnt lime/quicklime (eCA FR)

There were three open points in the discussion table that were closed during the meeting. In addition, there was one provisionally closed point that remained closed. Please, refer to the confidential minutes in the form of the discussion table for more details.

7.4 UA for a product family containing Peracetic acid (eCA BE)

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

7.5 UA for a product family containing Hydrogen peroxide (eCA DE)

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

7.6 UA for a product family containing Hydrogen peroxide (eCA NL)

There was one open point in the discussion table that was closed during the meeting. Please, refer to the confidential minutes in the form of the discussion table for more details.

7.7 UA for a product family containing L-(+)-lactic acid (eCA SI)

There were two open points that were closed during the meeting. Please, refer to the confidential minutes in the form of the discussion table for more details.

7.8 UA for a product containing 3-iodo-2-propynylbutylcarbamate (IPBC) (eCA DK)

There was one provisionally closed point in the discussion table. The point remained closed. Please, refer to the confidential minutes in the form of the discussion table for more details.

7.9 UA for a product family containing L-(+)-lactic acid (eCA FR)

There was one provisionally closed point in the discussion table. The point was re-opened at the meeting. Please, refer to the confidential minutes in the form of the discussion table for more details.

7.10 UA for a product family containing Chlorocresol (eCA FR)

There were three provisionally closed points in the discussion table. The points remained closed. Please, refer to the confidential minutes in the form of the discussion table for more details.

8. Technical and guidance related issues

8.1 Efficacy testing for disinfectants at elevated use temperatures (DE)

The EFF WG agreed on the TAB proposal presented by DE. The agreed TAB entry is presented below:

How to assess the efficacy of disinfectants at elevated temperatures ≥40°C in case of organism groups where no standardised thermotolerant test organisms are available?

Note: This agreement is not intended to overrule existing or future agreements on testing strategies for specific uses, like e.g. aseptic filling or laundry disinfection.

The following agreement covers only organism groups for which no standardised thermotolerant organism is described in the guidance. Where such organisms already are described (e.g. *E. faecium* for bacteria), the relevant tests should be performed at the intended use temperature with these organisms as required by the guidance.

In cases where no standardised thermotolerant representative organism exists for the intended use temperature, the following tests should be performed in a first step:

- Use-specific tests (e.g. P2S1 and P2S2) with usual standard organisms of the claimed organism groups at claimed use temperature (e.g. test temperature of 60°C if this temperature is claimed for the use), with an additional water control (20°C or the highest temperature where water controls are valid; corresponding to control A in CEN P2S1 disinfection standards) to demonstrate cell vitality. In complex simulated use tests (e.g. dishwasher test), the temperature should be measured frequently over the duration of the test to ensure that the intended use temperature is reached and maintained.

Case A: In case all controls of the standard organisms are valid at the intended use temperature and all other test requirements are fulfilled, the test can be accepted without any further requirements and a claim against the tested organism group should be accepted.

Case B: In case all standard test organisms of a target organism group are killed by the intended use temperature in the relevant tests (P2S1 and P2S2), a chemical-biocidal effect cannot be established. If the respective group is mandatory for the use, the mandatory status is waived and the group is considered optional because the standard organisms are not relevant to a chemical-biocidal claim at the intended use temperature. This means that

there is no requirement to authorise these organisms, but they also cannot be named in the SPC as target organisms based on these data on standard organisms. This means, e.g. if *Candida albicans* is killed at 60°C there is no need to test any further; however yeast should not be listed anymore as target organisms in the SPC.

If however, the applicant intends to maintain the claim for case B, the following additional data can be used to support the claim for organisms groups for which no thermotolerant organism is described in the guidance:

- P2S1 tests with one thermotolerant representative of the respective organism group at the intended use temperature[1].

The applicant should justify why the chosen test organism is considered a representatively tolerant organism for the intended application. The following thermotolerant species are examples that may be used for tests at elevated temperatures:

Yeasts: *Ogataea polymorpha* (syn. *Candida thermophila*) [Shin et al., International Journal of Systematic and Evolutionary Microbiology 2001, 51, 2167-70; Lehnen et al., BMC Microbiology 2019, 19:100]

Fungi (spores): *Aspergillus fumigatus* [Araujo et al., Medical Mycology 2006, 44, 439-443; Hagiwara et al., PLoS ONE 2017, 12(5):e0177050; O'Gorman et al., Nature 2009, 457, 471-475]

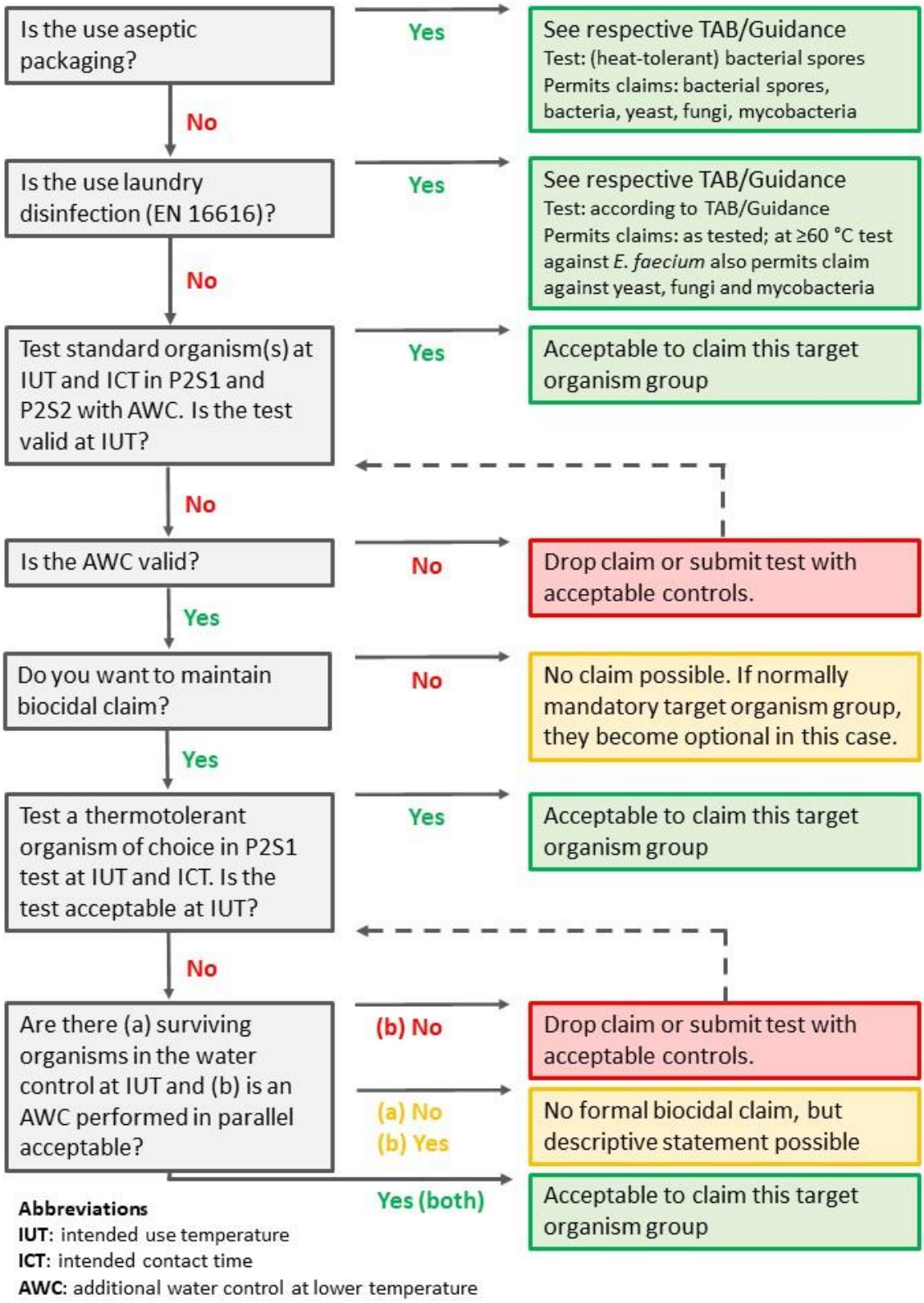
Mycobacteria: *Mycobacterium hassiacum* [Schröder et al., International Journal of Systematic Bacteriology 1997, 47, 86-91; Haas et al., BMC Research Notes 2020, 13:140]

[1] If in rare cases the water control at the intended use temperature does not contain enough surviving organisms to demonstrate the required log reduction, an additional water control at a lower temperature can be performed. As long as this control is valid and the other requirements are fulfilled there are two options:

a. If there still are survivors in the water control at the intended use temperature and a chemical biocidal effect can be demonstrated, the claim can be granted.
b. If there are no survivors in the water control at the intended use temperature, no chemical effect of the biocide can be demonstrated. If a chemical effect is demonstrated for at least one other group of target organisms, a descriptive sentence can be included for the thermally inactivated target organisms in section "Other information" of the SPC with clear reference to the affected uses: "A biocidal effect against [Group of target organisms] could not be demonstrated due to thermal inactivation of the test organisms at XX°C during YY min contact time."

This rule also applies in cases where standardised thermotolerant test organisms already are available (bacteria, viruses, bacterial spores).

Graphic depiction of proposed workflow for disinfectant testing at elevated temperatures for organism groups without thermotolerant standard organisms



9. AOB

9.1 Other information

Information about the provisional dates of the next WG meeting was given, which possibly can be a physical or hybrid meeting. The Chair kindly reminded members that as a principle, late registrations for WGs will not be handled. This concerns WG members, applicants and stakeholders. Some of the WG members expressed their preference to have a hybrid meeting instead of a physical meeting.

Short information was given about current guidance updates and foreseen future discussions. ECHA informed also about the ongoing revision of the UA working procedure, which will be available for comment by the MSs before the BPC meeting in June. The EFF WG members were encouraged to comment.

9.2 Interact tool

ECHA gave a presentation on the Interact Collaboration, the approaches taken in using this tool, explaining the reasons for some of the problems and the reactions to these. Feedback was requested to be provided per Member State, to be directed via the BPC member.

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)
   - PELMAN Natania (BE)
   - PIROTTE Jennifer (BE)
   - WANDELER Eliane (CH)
   - DONZE Gerard (CH)
   - MEIER Margrith (CH)
   - DOLEZELOVA Katsiaryna (CZ)
   - PECINKOVA Martina (CZ)
   - SCHOPS Ricardo (DE)
   - CLEYTON JØRGENSEN Charlotte (DK)
   - PLOOMPUU Grethe-Johanna (EE)
   - PEREIRO COUTO Natividad (ES)
   - NIEMINEN Timo (FI)
   - Brizard Mathias (FR)
   - HADDACHE Nabila (FR)
   - OWENS Aoife (IE)
   - Lynch Helen (IE)
   - RONCI Maria Beatrice (IT)
   - MEZULE Linda (LV)
   - SCHOEP Piet (NL)
   - ÅSLING Bengt (SE)
   - DANADAIOVA Emese (SK)
3. **Rapporteurs:**
   - BOITIER Caroline (FR)
   - TALHOUËT Anne-Claire (FR)
4. **Advisors:**
   - Jarrety Helene (BE)
   - Svejstil Roman (CZ)
   - KASPRZAK Karolina (PL)
   - BIELINSKI-BILINSKI Marin (PL)
   - POSLEDOVICH Diana (SE)
5. **ECHA Staff**
   - SZYMANKIEWICZ Katarzyna (Chair)
   - RAULIO Mari
   - HONKA Anni
   - HAMALAINEN Eva
6. **Stakeholders:**
   - VAN BERLO Boris (CEFIC)
   - BOSSERT Jules (CEFIC)
   - THEELEN Meredith (AISE)
   - DARRIET Marie (AISE)
   - CORNER Hannah (AISE)
   - RYCKEBOER Jaak (AQUA-EUROPA)
   - SIMOES Ines (EURO3ON)
7. **Applicants:**
   - European Lime Association aisbl

- Evonik Operations GmbH
- Spectra Consult GmbH (on behalf of CVAS)
- SALVECO S.A.S.
- CID LINES NV
- TROY CHEMICAL COMPANY BV

Environment WG-I-2022

Final minutes

14 July 2022

Minutes of Environment WG-I-2022

Including TAB entries for revision in Appendix I

4-5 April & 7– 8 April 2022

Additional dates: 21 March, 12 April

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 63 participants present, of which 10 were core members, 36 flexible members, 3 rapporteur and 8 advisers. Six representatives from accredited stakeholder organisation were present at some agenda items. Applicants were registered for their specific substance discussions.

Participants were further informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes.

2. Administrative issues

SECR reminded the MSCAs to inform when colleagues leave the CA. This is needed for revoking the accesses as relevant.

The (alternative) core members will receive an e-mail from a new Declaration of Interest tool in mid-April with a link to fill in the annual declaration.

SECR presented the approaches taken in using Interact, explaining also the reasons for some of the problems and the reactions to these. The presentation is available in Interact to the members. Feedback was requested to be provided per Member State, to be directed via the BPC member.

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-IV-2021

The minutes were agreed without further changes.

6. Discussion on active substances

6.1 Formic acid, PT 2-6 (eCA BE)

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

Action: A discussion and agreement on the temperature used for DT50 derivation from manure degradation studies is needed

AHEE to follow up, **DE** volunteered to prepare a thought starter together with **NL**.

6.2 ED assessment: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (former MBO), PT 2, 6, 11, 12, 13 (eCA AT)

6.3 ED assessment: Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (former HPT), PT 2, 6, 11, 13 (eCA AT)

These agenda items were discussed jointly.

The WG agreed not to perform additional testing for MBO and HPT to assess the ED properties for NTO.

7. Discussion of Union Authorisation cases

7.1 UA for a product containing active chlorine released from chlorine, PT 2, 5 (eCA SI)

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 a product containing calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime, PT 2, 3 (eCA FR)

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 a product containing calcium oxide/lime/burnt lime/quicklime, PT 2, 3 (eCA FR)

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

7.4 UA for a product family containing Peracetic acid, PT 2, 3, 4 (eCA BE)

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

7.5 UA for a product family containing Hydrogen peroxide, PT 2 (eCA DE)

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

7.6 UA for a product family containing Hydrogen peroxide, PT 2, 4 (eCA NL)

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

7.7 UA for a product family containing L-(+)-lactic acid, PT 3, 4 (eCA SI)

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

7.8 UA for a product family containing L-(+)-lactic acid, PT 2, 3, 4 (eCA FR)

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

Action: The **eCA** to provide a proposal for a background concentration in surface water, to be discussed and agreed via a TAB entry

TBD ECHA internally, if substance specific TAB entries should be added in the TAB or at a different place.

7.9 UA for a product containing 3-iodo-2-propynylbutylcarbamate (IPBC), PT 8 (eCA DK)

Please refer to the confidential minutes

The WG noted that a discussion on the efficacy of the proposed RMM (covering the ground during application of the product) on a general level for all preservatives and other relevant products (e.g. PT 18) would be needed, since it is questionable that in case of high PEC/PNEC values proposed RMMs would be 100% efficacious. Should e.g. a trigger value be provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: Point for consideration to be forwarded to the **BPC**: The WG noted that a discussion on the efficacy of the propose RMM on a general level for all preservatives and other relevant products (should e.g. a trigger value be discussed in the future?)

7.10 UA for a product family containing Chlorocresol, PT 2, 3 (eCA FR)

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

Action: FR and **DE** to provide the document for an AHEE consultation on the default values for the large-scale applications. SECR to initiate the consultation.

7.11 Early WG: UA for a product family containing Glutaral, PT 06, 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.

8. Technical and guidance related topics

8.1 In-situ generated active substances: Revision of recommendations – options for assessment of in-situ generated AS

Progress of the in situ ENV task group was presented and the conclusions from the recent e-consultation were discussed and the conclusions were agreed for two of five questions. Useful discussions took place regarding the new mixed approach proposed for ENV hazard assessment and the proposal by DE and AT to apply a so called reverse Toxic Unit method for identification of ecotoxicological endpoint for pure active substance. For the remaining open questions, a follow up e-consultation will be launched (reverse rel. TU approach) and/or they will be brought forward again to one of the next WG ENV meetings.

The two elements from the e-consultation for which an agreement was reached were:

1. The mixed/combined approach considers that depending on available data and technical limitations, a mixed approach can be applied for ecotox endpoints. It is, for instance, the case when it is not possible to generate the pure active substance conventionally to carry out the required tests. It may be also possible that only relevant data are available from tests which are performed with the same pure active substance which is either generated in situ in other physico-chemical conditions or with different precursor substances or different devices.

   In principle, the mixed/combined approach requires a way of working comparable to the mixtox assessment, however, the other way around.

   The WG agreed that it is not possible to consider synergism and inhibitory effects in this approach because the data is not available.

2. It is not possible to derive environmental fate data for the active substances generated in situ (i.e., consisting of pure AS and impurities), since target analytic of single constituent is always necessary for these endpoints (biodegradation, abiotic degradation, adsorption, bioaccumulation). Therefore, regarding e-fate studies, even if the entire active substance generated in situ will be used as the test material in the study, the results are, however, constituent specific.

   The WG agreed that such a case belongs to the mixed/combined approach.

Next steps:

- e-consultation on the reverse Toxic Unit method under the mixed approach (deadline 5.5.2022)
- ENV in-situ task group to continue with the revision of the WG recommendations.

8.2 Disinfection by-products environmental risk assessment

The document was presented to the WG and was generally well received. The method seems appropriate to identify those DBPs which are most relevant for the environment.

To the question "Is there other volunteers to assess the remaining groups?" Switzerland offered support.

To the question "Do you agree with the approach?" and "Are the proposed criteria enough to determine the relevant DBP to assess?": The WG generally agreed with the presented approach. It was recommended to add the DT50 when available.

In regard to the studies to assess the hazard: "Do you agree with this approach to assess studies?" the WG generally agreed. SECR recommended to use the Read-Across framework. Other members reflected on the fact that not all the data necessary may be available. In addition, the members noted that currently member states are doing the work while it may be the responsibility of applicants. In addition, asking applicants to generate studies may be challenging due to the number of applicants involved.

With regards to the preliminary discussion on risk assessment methodologies, several comments were collected:

- It was suggested that perhaps Environmental Quality Standards from the Water Framework Directive (WFD) could be used,
- A regulatory discussion is needed to understand what the consequences would be when identifying risk for one or several DPBs,
- It was highlighted that some DBPs are included in the WFD and some applicants are already applying risk mitigation measures.

8.3 Roadmap for PBT R.11 Guidance update

ECHA provided a presentation on the expected amendments that will be made to the R11 Guidance and the expected timelines. SECR invited experts to contribute and will inform on further developments.

8.4 Update on Chesar Platform developments

ECHA provided a presentation on the latest developments on the Chesar platform and the emission scenario repository under preparation.

8.5 Proposal for an emission scenario for PT 18

The emission scenarios for PT18 include combinations of "spot – surface" and "spot – crack and crevice". For both of these scenarios the default surface area is 2 m^2, with the difference being defined by the maximum % exposed to cleaning (3% for crack/crevice, 20% for surface). In both cases, the application rate is required as g product/m^2.

While this may be considered appropriate for situations where residual efficacy on treated surfaces is required, for the direct knockdown of a visible crawling insect where the label instructions specify a spray duration of e.g. 2 seconds this leads to a gross overestimation of the amount of product applied.

An alternative approach was presented by CEFIC to circumvent this issue.

No conclusion could be drawn at the WG meeting, only arguments where collected which will be forwarded to CEFIC together with the minutes.

Action: CEFIC should look at the comments raised and come up with a revised proposal at WG-II-2022/AHEE-7.

8.6 PEC/PNEC: concentration of AS as manufactured versus concentration of pure AS

Members generally agreed that further clarification is needed in order to be consistent among MSCAs. Biocides for Europe volunteered to prepare a TAB template to be included in the TAB (See Appendix 1).

EG meeting on fate and distribution models (12 April 2022)

In order to be able to harmonise the fate models across biocides scenarios with direct releases, these were extracted and grouped per environmental compartment and by similar release pathway as presented in a separate document.

As a follow up of the EG meeting on 12th April 2022, a written commenting phase was initiated to have a detailed look at the document and the generic model description as well as at the summary of the EG feedback, if this reflects the discussions that took place. The commenting phase ended on 13th May 2022.

The following summary on the EG feedback only shows the notes taken during discussion. It does not include the feedback provided during the commenting period and should not be considered as final.

The following questions were discussed regarding the scenarios:

GENERAL:

1. Is table 1 covering all relevant variations of equations deriving Clocal?

   EG feedback:

   SECR to cross check if the following items are missing in Table 1: equations for stormwater overflow (= flowing surface water) and degradation in the sewer system
   It was noted that the equations in PT 8 should be considered as a kind of "exception" and should not be used as standard to which other PTs should be adapted to.
   SECR to check if any equations covering direct release are missing for disinfectants (direct releases in PT 2, e.g. drip irrigation and pool water disinfection)

2. Does the "generic model description" describe well in what situations given equation is applicable?

   EG feedback:

   The generic model description is crucial and should be distributed to the EG for commenting before sending it to one of the next WG meetings. It is important that it is correct since it is the basis for choosing the correct fate-equations. SECR to move the description as first column in Table 1, since it is the key information, defining the generic model to be used for taking into account degradation.
   SECR to check wording "semi static", can/should it be replaced by flowing water? Alternative: use MAMPEC for the exceptional models in PT 8 (sheet piles in a water way, harbour wharf); can the PT 8 scenario be covered by another model (topic for the future…).

3. Are there any other discrepancies in the fate models than those identified by below specific questions that would require harmonisation?

   EG feedback:

   For soil: When should TWA be calculated after N events => solved by the software since the choice depends on the PNEC. However, the reasons for TWA not being used in some cases stemming from the release events pattern are worth to document (cf. PT18 manure/sludge application vs PT 8 vs PT 19 tent scenario).

   SOIL:

4. Is it justified to model service life from leaching where the leaching source is exchanged regularly (e.g. as in PT 8 storage of treated wood) differently from "standard" leaching where the leaching source does not change? Is the equation for steady state concentration relevant in other service life situations? For releases in cemeteries (PT 22) steady state concentration equation is also used, would concentration at time x also be relevant for that use?

   EG feedback:

   It is justified to use different equation for wood storage (steady state) and treated wood in service (conc. at the end of a period), since at a storage place there is a constant replacement of treated wood. A cemetery is comparable to storage place since a certain area is considered in which different corpses are exchanged over time. Therefore, for PT 22 it is acceptable to use the steady state equation. Also the time scale is different, i.e. longer than a service life of 10/20 years (can be any time for storage place/cemetery).

5. Is it necessary to calculate the concentration in soil with and without degradation?

   EG feedback:

   No need to calculate a risk assessment "without degradation" for service life, if information on degradation is available (for the application step, no degradation is assumed, concentration just after application is taken into account).

SURFACE WATER:
Flowing

6. Is plain dilution of releases appropriate for the respective scenarios? (e.g. NL PT 12 paper production excel uses equation 48 of Volume IV part B and C although the use is not referring to multiple point source releases as suggested by the guidance)

   EG feedback:

   Equation 48 calculates cdissolved from total concentration.

   To be cross checked: guidance does not refer to multiple points sources per se, it refers in first instance to a single point source.

   See reference in the Table 1 below.
   To be cross checked: EUSES 2.1.2/2.2.0 should be transferring concentration in surface water to the concentration dissolved. (ESDs are doing the transfer inconsistently)

Static

7. Is the TWA equation for releases during service life to static surface water (e.g. equation 3.16 of ESD PT 8) relevant (ref TAB ENV 186 and 209)? Should an equation calculating concentration at time x be relevant instead?

   EG feedback:

   In line with TAB 186, also for surface water TWA equations are not relevant, concentration at time x should be calculated. SECR to amend TAB 209 in that way, that the note on <u>not</u> using TWA also for surface water is clearer (move note at the beginning or highlight it at the end).

8. TAB ENV 209 provides equations for releases of very lipophilic substances to static water. Is the TWA equation for releases during service life to static surface water as provided by TAB ENV 209 relevant (ref TAB ENV 186)?

   EG feedback:

   Eq 3.18 and 3.19 as corrected by the TAB 209 (to calculation the concentration at the end of Time T) are the equations that should be used.

9. Can a trigger value for using the equations for "very lipophilic substances" be derived?

   EG feedback:

   Question is obsolete, see point 8.

Semi-static

10. Is the TWA equation for releases during service life to semi-static surface water (e.g. equation 3.22 of ESD PT 8) relevant (ref. TAB ENV 186 and 209)? Should an equation calculating concentration at time x be relevant instead?

    EG feedback:

Question to be added to the EG e-consultation: are the equations in the ESD PT 8, Table 3.8 correct (TWA situation) or should they be corrected as done for static water (TAB entry 209).

11. TAB ENV 209 provides equations for releases of very lipophilic substances to static water. Should analogous equations for semi-static water be corrected (i.e. equations 3.24 and 3.25 of ESD PT8)?

    EG feedback:

    Obsolete, see conclusions on point 8 and 10 above.

12. Are equations 3.24 and 3.25 of ESD PT 8 applicable to harbour wharf scenario?

    EG feedback:

    Not clear from the revised ESD. Due to the short residence time in the harbour wharf, taking into account degradation is less important. It is further noted that in the original ESD for PT 8, degradation was not considered relevant for the harbour wharf (and also not for sheet piles in the water way).
    To be checked in general, if the modelling of the semi-static scenarios in PT8 cannot be done in the same way as scenarios looking at a flowing water body!

AIR

13. Please propose appropriate general description for the equation identified

    EG feedback:

    SECR to cross check if there are additional scenarios where release to air is calculated in the ESD.

14. In which cases is it useful to derive a concentration in air?

    EG feedback:

    For PEC soil calculation (following wet and dry deposition). Check why PECair is proposed for shoe box scenarios and in PT 14 (at this point in time not to be included in CP?).

    SECR to cross-check how release to air is further used in EUSES.

9. AOB

9.1 Other information & lessons learned (SECR)

EFSA&ECHA drinking water project update

EFSA's contractor is drafting chapters on exposure assessment for PPP, transformation product formation in water treatment processes, hazard assessment and risk assessment. ECHA is drafting exposure chapter for Biocides, a consultation of the ENV WG will be launched after the WG meeting.

Next steps: first consolidated draft of the guidance to be ready by end of May – prepared by EFSA's contractor, EFSA will launch a public consultation by mid-Sept (open for 2 months).

Environmental ED assessment

Waiving of additional tests: Many dossiers do not contain sufficient information to conclude on ED properties, additional data is needed: additional time, costs and (animal) test

needed. Instances where the generation of additional data is not: possible, feasible, desirable, necessary, ….

Waiving based on Annex V: not scientifically necessary, not technically feasible. Usually there is more than one reason. No harmonized approach, no agreed reasons to waive, is ~~is~~ rather an ad hoc discussions.

Documents available

The revised ECHA Guidance Vol III Part A (human health information requirements) was published on 29 March 2022[1]. The PEG members from MSCAs (DE, EL, FI, NL, RO and SE) and Associated stakeholder organisations (PETA, HIS, ECETOC, IBMA and Cefic) were thanked for their contributions.

Recordings

SECR informed that the case discussions (AS, UA) will not be recorded anymore. As a consequence, the minutes may be somewhat shorter. There will be no effect on action points and conclusions, which is the most important part of the minutes. These principles concern all WGs: APCP, EFF, ENV, TOX.

Next WG meetings

SECR reminded the members that as a principle, late registrations for WGs will not be handled. This concerns both members and applicants. Once the draft agenda is available, there should be around two weeks to register.

The next WG is expected to be a physical meeting with the following provisional timing[2]:

- 30. May &, 8 – 10 June (physical meeting), one additional day TBC.

[1] Biocides guidance page: https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation; Direct link: https://echa.europa.eu/documents/10162/2324906/bpr_guidance_vol_iii_part_a_en.pdf

[2] This information was updated after the WG.

Appendices:

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

Biocides for Europe (Cefic) – Proposal of two TAB entries for PEC/PNEC

Chapter 1 Effect and Hazard Assessment

ENV x Setting PNECs when experimental data is available.

Version 1 (WG-II-2022)

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

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

Chapter 2.1 Exposure assessment - general items

ENV 12 Calculation of PEC values – Consistency with PNECs

Version 1 (WG-II-2022)

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

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

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

Appendix 2: List of participants

Core members and alternates:

- AT Lukas Kührer
- DE Daniel Frein
- DE Eleonora Petersohn
- FR Jerome Lozach
- FR Stéphanie Alexandre
- FR Anne Straczek
- IE Helena Joyce
- NL Barry Muijs
- SE Liselott Säll
- SI Petra Muri

Flexible members :

- AT Lea Breul
- AT Iris Buchner
- AT Christian Kantner
- BE Anne Brasseur
- BE Thomas Cougnon
- BE Bart Heulens
- BE Samuel Huerga Fernandez
- BE Helene Jarrety
- BE Wiet Raets
- CH Maria a Marca
- CH Tenzing Gyalpo
- CH Petra Kunz
- CZ Lucie Bielska
- DE Maren Ahting
- DE Julia Margaretha Anke
- DE Stefanie Jacob
- DE Katja Michaelis
- DK Henrik Wennermark
- EE Helen SULG
- ES Myriam Martin Vallejo
- ES Elena Fuensanta Ruiz Lopez
- FI Oskari Hänninen
- FI Sanna Kaukoniemi
- FI Jaana Pasanen
- FI Sari Penttinen
- IE Andrea Paskuliakova
- IT Alessandro Ubaldi
- NL Els Smit
- NL Peter van Vlaardingen
- NO Terje Haraldsen
- NO Karina Petersen
- PL Agnieszka Podlaska
- PL Helena Rzodeczko
- SE Rina Andersson
- SE Edda Hahlbeck
- SK Jana Molnarova

Rapporteur:

- AT Dominik Altmann
- FR Caroline Boitier
- FR Anne-Claire TALHOUËT

Advisors:

- AT Christine Hoelzl
- AT Simone Mühlegger
- DE Christiane Stark
- DK Jesper Johannessen
- FR Yannice Convert
- FR Arthur GILSON
- FR Fanny Herard
- NL Zhichao Dang
-

ASOs:

- Jules Bossert Cefic
- Boris VAN BERLO Cefic

For item 8.1 (in-situ):

- Alienor Poher
- Ines Simoes
- Jaak Ryckeboer
- Arnaud Massel

ECHA chairs and experts

Human Health WG-I-2022

Final minutes

31 May 2022

Minutes of Human Health WG-I-2022

31 March – 1 April 2022

6 – 8 April 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 70 members or advisers registered, of which 12 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 reminded the MSCAs to inform when colleagues leave the CA. This is needed for revoking the accesses as relevant.

The (alternative) core members will receive an e-mail from a new Declaration of Interest tool in mid-April with a link to fill in the annual declaration.

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-IV-2021

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Formic acid, PT 2-6 (eCA BE)

The genotoxicity endpoint was covered by a new study provided by the applicant, and the WG agreed that this study should be requested and evaluated. The negative results will still be confirmed by the eCA, supported by DE.

The reference values and absorption values were confirmed as proposed by the eCA.

6.2 Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 3:2) (former MBO), PT 2, 6, 11, 12, 13 (eCA AT)

6.3 Reaction products of paraformaldehyde and 2-hydroxypropylamine (ratio 1:1) (former HPT), PT 2, 6, 11, 13 (eCA AT)

These agenda items were discussed jointly.

The WG agreed that MBO and HPT do not meet the ED criteria for the T modality for human health. For EAS modalities, the WG agreed on scientific grounds not to perform additional testing.

7. Discussion of Union authorisation applications

7.1 UA for a product containing active chlorine released from chlorine, PT 2, 5 (eCA SI)

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 a product containing calcium dihydroxide/calcium hydroxide/caustic lime/hydrated lime/slaked lime, PT 2, 3 (eCA FR)

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 a product containing calcium oxide/lime/burnt lime/quicklime, PT 2, 3 (eCA FR)

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

7.4 UA for a product family containing Peracetic acid, PT 2, 3, 4 (eCA BE)

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

7.5 UA for a product family containing Hydrogen peroxide, PT 2 (eCA DE)

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

7.6 UA for a product family containing Hydrogen peroxide, PT 2, 4 (eCA NL)

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

7.7 UA for a product family containing L-(+)-lactic acid, PT 3, 4 (eCA SI)

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

7.8 UA for a product containing 3-iodo-2-propynylbutylcarbamate (IPBC), PT 8 (eCA DK)

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

7.9 UA for a product family containing L-(+)-lactic acid, PT 2, 3, 4 (eCA FR)

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

7.10 UA for a product family containing Chlorocresol, PT 2, 3 (eCA FR)

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

8. Technical and guidance related issues

8.1 Update on guidance development

SECR presented the current status of guidance documents. The document is available in Interact to members and in S-CIRCABC to associated stakeholder organisations.

8.2 Relevant groundwater metabolites

- Closed session -

Example case

A closed session took place to discuss one MSCA's proposal for risk assessment of a

metabolite meeting the criteria for Carc. Cat. 2 classification, aiming to clarify if the metabolite should be considered toxicologically relevant. This case study was discussed first to show an example before proceeding to discuss the principal questions. The members had different views regarding the possibility of concluding on the relevance of a metabolite based on risk assessment, as opposed to a purely hazard based approach. Some members supported the proposed approach, while others had reservations both regarding the sufficiency of the assessment and the overall acceptability of such an assessment. A revised assessment may be provided for an e-consultation, where some of the members asked to consider the following points:

- Other sources of the same metabolite, referring to Step 5 of Sanco/221/2000 – rev.11 (2021)
- Uncertainty analysis
- Validity of the TDI

The first point above was considered particularly difficult, since aggregate exposure should be included in the assessment, but it is not clear how this could be done for a biocide.

SECR clarified that while an e-consultation can be launched at the technical level, the acceptability of the approach (concluding on relevance based on risk assessment) has to be decided at the CA meeting and/or the BPC.

- End of closed session -

Carc. Cat. 2 metabolites

A discussion on metabolites meeting the classification criteria as Carc. Cat. 2 was held because the members have different interpretations on the SANCO Guidance.

A slight majority of the members supported an approach based purely on hazard, without a risk assessment. The members noted that there should not be a possibility of different interpretations of the guidance between the regulatory frameworks, i.e. for biocides and pesticides.

Some of the members that supported purely hazard based interpretation of the guidance had some sympathy towards the possibility of following also a risk based approach in a case where abundant information is available for the metabolite, noting an example of having mechanistic information on the carcinogenic effect. One member pointed out that a risk based approach could be supported in the future guidance revision, while maintaining the view that the current guidance should be considered as hazard based.

Other issues before discussing possible endorsement

The SANCO guidance concerns groundwater metabolites while noting that it may also be applicable for surface water intended for the abstraction of drinking water. It was noted that surface water might be more relevant for biocides, and this should be raised during the future revision of the guidance.

Endorsing the guidance for biocides

SECR reiterated that the WG is not intended to endorse the guidance, but this should be discussed and concluded either by the CA meeting or the BPC. The technical level input from the WG is however needed.

Many members considered that the guidance should be revised because it has many weaknesses and unclarities, nevertheless supporting the use of it in a flexible manner. With the expectation that the SANCO guidance will be revised, it would not be sensible to develop separate guidance for biocides. Rather, the members hoped that in the revision, both biocides and pesticides could be considered. One member noted that the use of the guidance could be supported only if the assessment is purely hazard based.

The following aspects were noted as needing better guidance:

- Information to be required for a metabolite under BPR, including the legal basis for this

- Clarity on hazard based approach vs. risk based approach, in particular regarding Carc. Cat. 2 metabolites
- Considerations on groundwater vs. surface water
- How should other sources of the metabolite be considered in groundwater
- How should human exposure from other sources be considered
- Implications of the drinking water Directive (EU) 2020/2184

The members apart from AT supported applying the guidance for biocides with flexibility and on a case-by-case basis.

Conclusion: The members supported endorsing the SANCO guidance with flexibility and on a case-by-case basis, noting the limitations and lack of clarity in some of the approaches in the guidance. In general, a full revision of the guidance was seen necessary to cover the shortcomings identified.

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

The discussion took place in a closed session.

SECR made a short explanatory note, highlighting that:

- the e-consultation on Part A of the draft recommendation "*In-situ* guidance on data requirements and risk assessment for active substances generated in-situ, their precursors and biocidal products", drafted by the human health task force (HH TF) members, was launched in mid-March and is ongoing until mid-April 2022,
- the members were requested to pose critical comments in the first two consultation weeks to discuss these at WG-I-2022,
- the current draft is presented for discussion and to collect suggestions for improvement,
- once the comments are addressed, the guidance will be shared with the interested ASOs for further consultation, provisionally by May 2022.

The HH TF members jointly presented the key aspects of the new draft guidance, two real case-based examples to demonstrate the practical application on selected guidance aspects and questions for consideration of the members.

The members shared their views on the questions raised, suggesting ways to better address some of the issues in the revised guidance document.

SECR reminded the members that they could still provide additional suggestions for improvement and/or examples to improve the guidance readability within the ongoing e-consultation by 14 April 2022.

9. Any other business

9.1 Other information & lessons learned

Chesar Platform

SECR informed that the invitation was sent in January 2022 to nominate experts for the Topic Expert Group (TEG) on workers assessment. This TEG has now been formed, consisting of 27 members. The members are from five authorities (3 with affiliation to biocides), six tools owners (ART, Stoffenmanager, Easy TRA ECETOC TRA, EMKG, Mease, Croplife Europe) and 16 industries/consultants.

In 2022, the TEG will concentrate on ART implementation in Chesar (considering the applicability to biocides assessments), reporting and criteria for measured data and information around workers' assessment tool needs, updates and new tools. A biocides

authority interested in actively participating in the discussion should contact chesarplatform@echa.europa.eu.

Documents abailable

The revised ECHA Guidance Vol III Part A (human health information requirements) was published on 29 March 2022[1]. The PEG members from MSCAs (DE, EL, FI, NL, RO and SE) and Associated stakeholder organisations (PETA, HIS, ECETOC, IBMA and Cefic) were thanked for their contributions.

The material from the mixture classification workshop of December 2021 is available to MSCAs in S-CIRCABC[2].

Recordings

SECR informed that the case discussions (AS, UA) will not be recorded anymore. As a consequence, the minutes may be somewhat shorter. There will be no effect on action points and conclusions, which is the most important part of the minutes. These principles concern all WGs: APCP, EFF, ENV, TOX.

Next WG meetings

SECR reminded the members that as a principle, late registrations for WGs will not be handled. This concerns both members and applicants. Once the draft agenda is available, there should be around two weeks to register.

The next WG is expected to be a physical meeting with the following provisional timing[3]:

- 31 May – 2 June (Tuesday to Thursday, physical meeting)
- 10 June (virtual meeting, to be held if necessary)

9.2 Interact tool

SECR presented the approaches taken in using Interact, explaining also the reasons for some of the problems and the reactions to these. The presentation is available in Interact to the members. Feedback was requested to be provided per Member State, to be directed via the BPC member.

[1] Biocides guidance page: https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation; Direct link: https://echa.europa.eu/documents/10162/2324906/bpr_guidance_vol_iii_part_a_en.pdf

[2] https://webgate.ec.europa.eu/s-circabc/w/browse/42249322-1764-4253-b7ec-471e4d419320

[3] This information was updated after the WG.

Annex 1

Human Health WG attendees

Core and alternative members

HOELZL Christine AT
MIKOLAS Jan CZ
GUENTHER Isabel DE
HERRMANN Kristin DE
HOLTHENRICH Dagmar DE
BOURNELE Despina EL
ARAPAKI Niki EL
NIKOLOPOULOU Dimitra EL
AUBIN Aurelie FR
LAUMONIER-MAXIMILIEN Elisabeth FR
LORI Julia FR
BREEN Alan IE
DEKOVI Edlira IT
WELTEN Angelique NL
LEŠER Vladka SI

Flexible members

DERLER Angelika AT
HAUZENBERGER Ingrid AT
HOCHEGGER Patrick AT
KINZL Maximilian AT
BRYS Kristel BE
HERREMANS Yannick BE
HOUAMED Anis BE
GOLDINGER Daniela CH
GRÜNIG David CH
RUSCONI Manuel CH
SANS-PICHÉ Frederic CH
GOTTLOB Kathrin DE
HOLZWARTH Andrea DE
KLUTZNY Saskia DE
RIME Soyub DE
SCHNEIDER Heiko DE

Flexible members

SEMISCH Annetta DE
HUNTER Douglas DK
JENSEN Stine DK
REPOUSKOU ANASTASIA EL
DE RIVAS Ana ES
SÁNCHEZ José María ES
HÄMÄLAINEN Anna-Maija FI
HYVARINEN Tuija FI
RYDMAN Elina FI
VÄLIMÄKI Elina FI
AMSALLEM Tiffany FR
BELLINGARD Valérie FR
COLLIN Elodie FR
KOSE Serif FR
REY Marion FR
ANDERSEN Hilde Mariken NO
GAUSTAD Astrid NO
MIDTHAUG Hilde Karin NO
DANIELSEN RONGVED Tonje NO
GÓRECKI Roman PL
UJMA-CZWAKIEL Monika PL
PETTERSSON Emma SE
ČEBAŠEK Petra SI
OLHA Roman SK
PILIŠIOVÁ Ružena SK

Rapporteurs

BOITIER Caroline FR
NDIAYE Lena FR
TALHOUËT Anne-Claire FR
VAILLANT Vincent FR

Advisors

MÜHLEGGER Simone AT
KRIEGL Isabel AT
JARRETY Helene BE
MAUL Katrin DE
ROITZSCH Michael DE
RUDZOK Susanne DE
KOENIG Jeannette DE
VAILLANT Vincent FR
BODERO Marcia NL
HENRIKSSON Rebecca SE

ECHA Staff

AIRAKSINEN Antero
DAMSTEN Micaela
ESTEVAN MARTINEZ Carmen
PAPADAKI Paschalina
VAN DER LINDEN Sander
LAITINEN Jaana
VASILEVA Katya
MULLER Gesine

Applicants

BASF SE
ERM Regulatory Services Limited
European Lime Association aisbl
Evonik Operations GmbH
Spectra Consult GmbH (on behalf of CVAS)
TROY CHEMICAL COMPANY BV
SALVECO S.A.S.
CID LINES NV

Stakeholders

VAN BERLO Boris (CEFIC)
BOSSERT Jules (CEFIC)