Minutes of the Working Group meeting II in 2022
Analytical methods and Physico-Chemical Properties
(Meeting date: 07-10 June 2022 – Hybrid meeting)

29 September 2022

1. Welcome and apologies

The meeting was a hybrid-meeting, thus a part of the working group members was physically present at the ECHA conference centre, the other part was following virtually the meeting. The Chair welcomed the participants of the working group meeting. CEFIC, AISE and Euro3zon registered for the meeting as accredited stakeholder organisations (ASO). The following applicants were registered for the meeting as observers for their agenda items:

Redebel Regulatory Affairs SCRL
The European Ozone Trade Association Limited
ARCHE Consortia
Bode Chemie GmbH
WESSO AG

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 explained the organisation of the hybrid meeting. In particular, the house rules of the conference centre were presented. In this context a guided tour through the new ECHA buildings were provided to the working group members present in Helsinki.

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 one item for AoB was received:

- Dust explosion hazard

The agenda was agreed with this 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 I 2022

The working group members provided comments on the draft minutes of WG I 2022. 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 Outcome of e-consultations

The results of the e-consultations were presented and discussed by the working group members as required.

7 Technical and guidance related items

7.1 Waiving justifications for physical hazards

This agenda item was a follow-up of the working group meeting III in 2021. The working group members discussed and agreed on the structure and the content that is required for scientific sound waiving justifications of physical hazards. In general, the burden of proof is always with the applicant. Therefore, general and generic waiving is not acceptable. The waiving justifications must always be case specific and address the specific composition of an active substance or biocidal product. The considerations and agreements made for the specific hazard classes are summarised in a separate document which will be distributed to the working group members. A TAB entry will also be drafted.

7.2 Unstable active substances

ECHA presented the document intended as thought starter for discussion.

Four options were presented to deal with substances, which are outside the reference specification at the time of formulation due to uncontrolled decomposition of the active substance received from a reference source during storage and transport.

1. Do not accept the substance as it does not correspond to the assessed composition of the active substance anymore
2. Do an assessment of additional data with the result of potentially adjusting the reference specification
3. Require an assessment of technical equivalence of the material used as active substance, where additional data would be assessed.
4. Require an assessment of additional data to prove safety and efficacy of the biocidal product

ECHA indicated that 1. is legally straight forward and 4. has been already applied in some cases, whereas 2. and 3. may be more difficult to establish.

ECHA elaborated on a possible implementation of 4. including a proposal to establish a maximum extent of decomposition according to the REACH conventions for substance identification.

Reservation was expressed to apply option 4. as the substance used corresponds to a different active substance that has not been assessed and as the composition after storage may again be out of specification.

ECHA proposed to follow the standard approach applied to degradation for long term storage tests, i.e. if the concentration of active substance degrades by more than 10%, an additional assessment of efficiency, degradation products and hazard is required as for other active substances, otherwise the shelf life will be set based on the time when the degradation of the active substance is < 10%.
Reservations expressed about option 3. (assessment of technical equivalence) and also questioned whether it is reasonable to change the reference specification after approval (option 2.).
Option 4. was considered as a feasible approach as it has already been applied.
In summary, only options 1. and 4. were supported during the discussion.
It was questioned whether the number of instable substances is sufficient to warrant such a general discussion or whether it should be a focused on specifically active chlorine only. However, there are other instable substances for which similar problems are expected, e.g. iodine.
It was noted that specifically for biocidal products containing active chlorine, it is possible to comply with the reference specification at the time of formulation as there were several biocidal products approved without this problem, which would support option 1. also for the reason of equal treatment of applicants.
It was highlighted that the union authorisation applicant has the responsibility for the biocidal product and not the manufacturer of the active substance, supporting option 1.

Following the proposed implementation of option 4., the threshold for not considering further degraded substances was discussed. There was some support for binding this threshold to a change in formal substance identity. Although this is an arbitrary cut-off, it is linked to the approach used under REACH assuring a level of alignment.
Furthermore, the possibility of defining unstable substances or their counterpart, stable substances, with or without reference to the reference specification was discussed, but without conclusion.

It was mentioned that active chlorine released from sodium hypochlorite has some unique characteristics as the reference specification is referring to a norm which specifies relative ratios of constituents and that the motivation for this approach may have been to avoid the request of a five batch analysis. The consequences for product authorisation were not considered at approval of the active substance.

Conclusion:
An e-consultation will be launched on this paper to collect all diverging views. Specifically:

- Should the discussion be focussed on specific substances with specific exceptional treatment or try to find a general approach?
- What is the consequence of applying option 1.? What problems are expected and in which order of magnitude?

7.3 Technical Agreements Biocides (TAB)

An update of the Technical Agreements on Biocides – APCP section was presented to the working group members. This update included decision made by the working group members during the working group meeting from 2017 to now. Each new or

modified entry was presented, discussed (if needed) and agreed by the working group members. The new version of the TAB will be published on the ECHA website as soon as possible.

7.4 Biocidal products – in situ active substances – case type 3

The eCA introduced this agenda item and explained that there are uncertainties with regard to the information requirements for case type 3 where the biocidal products could include not only a coating but also mixtures containing the catalyst(s) to be incorporated in coatings. These biocidal products are mixed by the user of the BP with other substances which form the final coating. Therefore, the authorisation holder of the BP might not know the final composition and conditions of use of the final coating. It was questioned whether the information on the final coating (e.g. service life, leaching of the catalyst) can be requested from the future authorisation holder. However, it was highlighted that efficacy has to be demonstrated also for a representative BP when the active substance (free radicals generated from ambient air and water) will be approved. Thus, in analogy to efficacy, APCP data, leaching and service life, can also be requested. It is in the responsibility of the applicant to provide these data.

8 Discussion on active substances

8.1 Mecetronium ethylsulphate (MES) PT01

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

8.2 Ozone generated from oxygen - PT02, 05, 11

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

9 Discussion on Union authorisations

9.1 UA for a product family containing peracetic acid PT02, 03, 04 (BC-QN034236-29) - WESSOCLEAN GOLD LINE

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

9.2 UA for a product family containing hydrogen peroxide PT02, 03, 04, 05 (BC-HC029658-43) - Oxy'Pharm H2O2

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

9.3 UA for a product family containing active chlorine released from sodium hypochlorite PT02, 03, 04, 05 (BC-HQ045419-21) - Sodium hypochlorite BPF - general & water disinfection

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

9.4 UA for a product family containing active chlorine released from sodium hypochlorite PT02, 03, 04, 05 (BC-LK045398-25) - Sodium hypochlorite BPF - general disinfection

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

10 Any other Business (AoB)

10.1 Dust explosion hazard

According to the Guidance on the Biocidal Products Regulation, Volume I, a dust explosion hazard is applicable to all powders and products containing, or able to produce, dust that can either ignite or explode when exposed to an ignition source when dispersed in air (relevant for particulates up to 1 mm in diameter). The question was raised whether testing on dust explosion hazard can be waived due to experience in use or based on chemical composition of the product in cases where a powder product consists of both non-combustible (e.g. inorganic salts/ silicate minerals) and combustible substances, with non-combustible components being in majority?

It was agreed that it is not sufficient to waive the testing based on a generic waiver justification as 'experience in use' and that the content of combustible is low. Therefore, a study on dust explosion hazard should be provided.

Annex 1 - List of attendees registered for the meeting

Working group member		Member state
Colson	Jerome	AT
Ghobrial	Michael	AT
Neuwirth	Erich	AT
Burmistova	Anastasia	BE
Fauconnier	Steven	BE
Herremans	Yannick	BE
Huerga Fernandez	Samuel	BE
Aeschbacher	Michael	CH
Courdouan Merz	Amandine	CH
Vlasak	Martin	CZ
Mühle	Ulrike	DE
Domino	Katrine	DK
Vallikivi	Imre	EE

Tzanetou	Evangelia	EL
Gatos	Panagiotis	EL
Cano	David	ES
Escalada	Jesus	ES
Fuertes	Pedro	ES
Vuorensola	Katariina	FI
Weber	Philippe	FR
Six	Therese	FR
Bujard	Thomas	FR
Lutz	François	FR
Cataldi	Lucilla	IT
van Rijnsbergen	Peter	NL
Kruidhof	Sabine	NL
Storm	Ingeborg	NL
Stave Sekkenes	Marianne	NO
Huszał	Sylwester	PL
Horczyczak	Anna	PL
Zielińska	Klaudia	PL
Alpe	Mia	SE
Österwall	Christoffer	SE
Marsh	Göran	SE
Ryden	Andreas	SE
Drabová Kušíková	Zuzana	SK
Porubiak	Michal	SK

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

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

	Bossert Jules
AISE	Darriet Marie Regnier Marie
EurO3zon	Ryckeboer Jaak

Applicant	Agenda item	Observer
Liney Peter	9.2	Redebel Regulatory Affairs SCRL
Rouessay Fabien	9.2	Redebel Regulatory Affairs SCRL
McGuire Alison	8.2	The European Ozone Trade Association Limited
Verdonck Frederik	9.3 9.4	ARCHE Consortia
Ngo Linh-Dan	9.3 9.4	ARCHE Consortia
May Martin	8.1	Bode Chemie GmbH
Hahn Stefan	8.1	Bode Chemie GmbH
Zoellner Ralph	9.1	WESSO AG
Breuer Franziska	9.1	WESSO AG

WG-II-2022

Final minutes

7 September 2022

Minutes of Efficacy WG-II-2022

31 May, 1 and 2 June 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) hybrid meeting and informed that this meeting is split into three separate days. The list of attendees is given in Annex 1.

2. Administrative issues

The Chair gave a brief introduction concerning the hybrid meeting rules.

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-I-2022 were agreed at the meeting.

6. Discussion of active substances

6.1 Ozone generated from oxygen (eCA NL)

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

6.2 Mecetronium ethyl sulphate (MES) (eCA PL)

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 hydrogen peroxide (eCA NL)

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

7.2 UA for a product family containing active chlorine released from sodium hypochlorite (eCA FR)

There were seven open points in the discussion table, five points were closed at the meeting. For the remaining two 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.

7.3 UA for a product family containing active chlorine released from sodium hypochlorite (eCA FR)

There were four open points in the discussion table, three points were 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 UA for a product family containing Peracetic acid (eCA DE)

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

8. Technical and guidance related issues

8.1 Antimicrobial resistance - draft guidance (FR)

FR presented the revised version of the draft guidance. The intention of this meeting was to discuss the tiered approach for resistance assessment, i.e. literature review, laboratory studies and monitoring/field test, its implementation (active substance (AS) approval, or product authorisation (PA) stage) and the requirements and pass criteria. Nevertheless, from the beginning, i.e. literature review the WG members shared different views concerning the possible approaches and it became quite difficult to conclude the discussion and to get an agreement. All WG members were of the opinion that a literature review should be performed during active substance approval, most probably not only for the representative target organisms but also for all potential target organisms. With reference to PA stage the opinions differed, some of the members indicated that information about resistance is quite limited and between the active substance approval and product authorisation stages it will be difficult to obtain any new reports/information. It was pointed out that only for some ASs giving a clear indication about possible resistance (criteria to be developed) this review may be continued at PA stage. The members noted that it would be good to have a list of all active substances with indications about potential resistance and a separate forum (resistance expert group) to discuss and assess the resistance aspects in a harmonised way. It was agreed that FR will send to ECHA the list of active substances used at the national level as an example of what kind of information concerning resistance is available there. With reference to the part of the draft guidance concerning literature review, DE proposed a significant amendment of the document, among others containing also checkpoint that will guide on how to proceed with the further assessment. As the revised version was sent just before the WG meeting the WG members will have a possibility to provide written feedback before the next discussion.

With reference to laboratory testing, FR indicated that the intention of the document is to conduct them only in specific cases, where there is a clear indication of resistance from the literature data. The WG members also here have quite different views, it was pointed out that it might be challenging to determine a proper microorganism to perform the laboratory test, it was also raised that in these tests a genetic modification can rarely occur and the evidence of resistance from the laboratory studies is rather doubtful (as there are many factors having an impact on it). Moreover, it was pointed out that, if the "clear indication of resistance" comes from the literature data that only describes the results of laboratory studies, such an approach would be somewhat biased towards active substances that are used more often for these kinds of experiments. If appropriate laboratory protocols are available to determine the potential of a given active substance to induce resistance, these should be applied to verify indications coming from the field and not from the other laboratory studies. On the other hand in the laboratory, there are well-controlled conditions, known microorganisms, and relevant parameters, and the outcome of such test can give a clear indication of what can happen in the field. There was no conclusion about the next steps after the literature review, the discussion about a real case (details to be agreed upon) will take place in December. There are also some aspects to be clarified (via e-consultation as suggested) concerning the new data, i.e. is the aim of new data to show that the biocide in question generates the development of resistance and how likely is that, or to find out what kind of resistance already exists to the biocides used (independently how it was generated) and how it will affect the efficacy.

8.2 Differentiation of virucidal claim in PT4 (hard surface disinfection) (FR)

FR presented a draft proposal concerning the acceptability of a claim against enveloped viruses in PT4. The proposed outcome was based on the e-consultation and the opinions received from the EFF WG members. In general, the majority of EFF WG supported the differentiation of virucidal claims, i.e. the possibility to claim virucidal activity and activity against enveloped viruses in PT4, for both, professional and non-professional users. Two WG members (AT and DK) disagreed with the proposal.

The proposed TAB entries (1 and 19) as they will appear in the updated version are presented below:

1. Virucidal activity against enveloped viruses

Version 3 (WGII2016, WGIII2022)

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

MVA representing enveloped poxviruses is a sufficient test organism to confirm efficacy against enveloped viruses for biocidal products used in PT 1: *Human hygiene* as hand disinfectants (hygienic and surgical), PT3: *Veterinary hygiene* as skin disinfectants, e.g. teat disinfection with a claim against enveloped viruses and also for biocidal products used as hard surface disinfectants in PT2: *Disinfectants and algaecides not intended for direct application to humans or animals* and PT4: *Food and feed area*.

Type of entry:	c) New guidance, as new technical scientific advice is given which triggers new data requirements
Publication date: XX/XX/2022	
Date of applicability for active substances:	XX/XX/2023
Date of applicability for products:	XX/XX/2024

Limited virucidal activity

Version 1 (WGII2016): Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

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

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

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

Regarding biocidal products used in PT 4: *Food and feed area* it is necessary to point out that for the time being a claim against enveloped viruses is not accepted. For biocidal products used in other PTs a virucidal activity within the meaning of full virucidal activity can only be claimed, i.e. against both enveloped and non-enveloped viruses.

19. Hard surface disinfection and differentiation of virucidal claims

Version 3 (WGI2020, WGIII2022)

Should different virucidal claims be allowed for hard surface disinfection in PT2 and in PT4?

1. For disinfectants used in healthcare and non-healthcare areas in PT2 (e.g. hotels, public sanitary, homeless shelters, public transport or clean rooms for production of pharmaceuticals) by professional users in addition to the currently accepted virucidal claim, also the limited spectrum virucidal activity and the activity against enveloped viruses can be claimed;
2. For disinfectants used in non-healthcare areas in PT2 by the general public only a virucidal activity and activity against enveloped viruses can be claimed;
3. For disinfectants used in PT4 (e.g. food industry, kitchens in restaurants or homes, shops like butchers and grocery shops where food is processed, etc.) by professional users and by the general public a virucidal activity and activity against enveloped viruses can be claimed.

Hard surface disinfection and differentiation of virucidal claims

Version 1 (WGI2020): Entry published more than 2 years before the publication date of this TAB document, i. e. currently applicable for both active substances and products.

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

Should different virucidal claims be allowed for hard surface disinfection in PT2?

1. For disinfectants used in healthcare and non-healthcare areas in PT2 (e.g. hotels, public sanitary, homeless shelters, public transport or clean rooms for production of pharmaceuticals) by professional users in addition to the currently accepted full

virucidal claim, also the limited spectrum virucidal activity and the activity against enveloped viruses can be claimed;

2. For disinfectants used in non-healthcare areas in PT2 by the general public only a full virucidal activity and activity against enveloped viruses can be claimed.

8.3 Influence of wipe/mop materials on the efficacy of surface disinfection products (DE)

The document addressed cases when the surface disinfectant is distributed by a wipe or a mop over the surface without mechanical action, and the wipe/mop material may react/interact with the active substance of the product.

The EFF WG members agreed that as an initial step justification from the applicant should be provided whether an adverse effect on efficacy can be excluded after contact of the biocidal product with the distribution material. It was also agreed that the active substance measurement should be taken out from the proposal and the determination of the potential impact of the wipe/mop material should be proven by performing the efficacy test according to EN16615. With reference to the alternative option (soaked liquid with the test without mechanical action), the opinions were different and it was not possible to conclude this. In addition, it was pointed out that the quantity of product claimed is not taken into account in this proposal, and this may have an impact on the test result. It was agreed that the proposed approach will be revised based on the outcome of this discussion and the WG discussion will continue.

9. AOB

9.1 Other information

Short information was given about the EFF WG-III-2022 meeting, the deadline for early WG discussion requests and working documents submission, the current status of the draft guidance, TAB publication, ongoing e-consultations and EFF team absence during the summer.

List of Attendees

1. **Core members:**
   - JANSEN Irina (DE)
   - KRÜGER Martin (DE) – Alternate
   - ATTIG Isabelle (FR)
   - MAXIMILIEN Yann (FR) – Alternate
   - GIATROPULOS Athanasios (EL)
   - WARMERDAM Sonja (NL)
   - MARCU Horatiu (RO)
   - DUH Darja (SI)
2. **Flexible members:**
   - WIDHALM Bernhard (AT)
   - BURGER Natascha (AT)
   - BURMISTROVA Anastasia (BE)
   - LEPAGE Anne (BE)
   - ABLA Anene (BE)
   - WANDELER Eliane (CH)
   - DONZE Gerard (CH)
   - SVEJSTIL Roman (CZ)
   - PECINKOVA Martina (CZ)
   - CLEYTON JØRGENSEN Charlotte (DK)
   - PEREIRO COUTO Natividad (ES)
   - PORTELA HENCHE Cristina (ES)
   - NIEMINEN Timo (FI)
   - HADDACHE Nabila (FR)
   - BRIZARD Mathias (FR)
   - LYNCH Helen (IE)
   - OWENS Aoife (IE)
   - RONCI Maria Beatrice (IT)
   - BALDASSARRI Lucilla (IT)
   - MEZULE Linda (LV)
   - BIELINSKI-BILINSKI Marin (PL)
   - ÅSLING Bengt (SE)
   - DANADAIOVA Emese (SK)
3. **Rapporteurs:**
   - TALHOUËT Anne-Claire (FR)
4. **Advisors:**
   - CHABOT Esther (FR)
   - BRIDIER Arnaud (FR)
   - SOUMET Christophe (FR)
   - DEKKER Bas (NL)
   - PETTERSSON Emma (SE)
5. **ECHA Staff**
   - SZYMANKIEWICZ Katarzyna (Chair)
   - RAULIO Mari
   - HAMALAINEN Eva
6. **Stakeholders:**
   - VAN BERLO Boris (CEFIC)
   - BOSSERT Jules (CEFIC)
   - DARRIET Marie (AISE)
   - CORNER Hannah (AISE)
   - PAHL Steffen (CEFIC)
   - RYCKEBOER Jaak (AQUA-EUROPA)
7. **Applicants:**
   - ARCHE Consortia
   - WESSOCLEAN GOLD LINE

Environment WG-II-2022

Final minutes

13 September 2022

Minutes of Environment WG-II-2022

Including TAB entries for revision in Appendix I

8–10 June 2022

Additional dates: 30 May, 16 June 2022

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 (partly physically), of which 11 were core members, 34 flexible members, 5 rapporteur and 4 advisers. Five representatives from accredited stakeholder organisation were present at some agenda items. Applicants were registered for their specific substance discussions.

2. Administrative issues

SECR informed that a cleaning exercise will be launched to ensure membership information is up to date.

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-I-2022

The minutes for most of the items were agreed without further changes. For the minutes of two cases, a written procedure will be launched after the WG meeting since additional comments were made.

6. Discussion on active substances

6.1 Ozone generated from oxygen, PT 2, 4, 5, 11 (eCA NL)

Two open points regarding PNECaquatic and direct release in PT 11 were discussed and two provisional closed points were presented. All points were closed and the CAR can proceed to the BPC.

Action: SECR to include the following conclusion in the substance specific section of the **TAB**: The WG agreed that for future product authorisations, a quantitative assessment for ozone would only be needed for direct release to surface water, indirect release via STP can be covered by a qualitative assessment.

6.2 Mecetronium ethyl sulphate (MES), PT 1 (eCA PL)

Seven open points regarding ED, PBT and exposure assessment were discussed and one provisional closed point regarding soil microorganisms was presented. Two points remained open.

Action: SECR to initiate an ad-hoc follow up.

6.3 Early review: Iodine, PVP-iodine - ED Assessment (eCA SE)

There is sufficient evidence to demonstrate population relevant effects and these are a consequence of an endocrine mode of action. Iodine and PVP-iodine meet the ED criteria for NTO for the T modality. The information available is however not sufficient to conclude on EAS modalities for NTO.

7. Discussion of Union Authorisation cases

7.1 UA for a product family containing hydrogen peroxide, PT 2, 3, 4 (eCA NL)

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

Action: SECR to add the following substance specific conclusions in the **TAB**: It was concluded that the exposure route via air during treatment with hydrogen peroxide indoors, does not need to be assessed for this and for similar future cases, deviating from the assessment as provided in the CAR for the active substance.

7.2 UA for a product family containing active chlorine released from sodium hypochlorite, PT 2, 3, 4, 5 (eCA FR) / 7.3 UA for a product family containing active chlorine released from sodium hypochlorite, 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.

Actions:

- **DE** will provide a proposal for an emission scenario for disinfection of tyres/wheels via disinfection basin in PT3, i.e. a list of proposed volumes (see case specific minutes for details); **SECR** to share the list with ENV WG and AHEE members.
- The general need to adjust the ENV TAB entry 198 and to further clarify Table 5 in the ESD for PT4 was raised, general need for clarifications as noted in the case-specific minutes to be discussed by the AHEE (**SECR** to schedule item for next AHEE meeting).
- A general discussion of one of the proposed scenarios in PT 4 was agreed. The scenario provided will be distributed via an Interact collaboration, to further discuss an appropriate default value for one parameter. **SECR** to initiate collaboration.
- **TAB** entry for RTUs to be extended: it was generally agreed that trigger sprays are only used for small scale applications, and it is independent on if the product is diluted or undiluted.

7.4 UA for a product family containing peracetic acid, PT 3, 4 (eCA DE)

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)

8. Technical and guidance related topics

8.1 Draft revision of in-situ ENV recommendations

The ENV Task Group for the revision of the in-situ recommendations presented the topic. The in-situ generated active substance part is under revision. A third option is being proposed, the so called “combined approach” for the assessment where test data are mixed (from the pure AS and on constituents or from the in-situ generated AS).

The task group presented the outcome of the e-consultation on the subject: „Reverse relative toxic units (TU) approach” – in the scope of in-situ generated active substances assessment.

The following items have been discussed:

Q1: Do MS agree to use the reverse TU approach in case no alternative for the determination of ecotoxicological endpoints for the pure active substance is available?

> **Discussion**: In theory seems a good approach, but in practice it could lead to underestimation of the toxicity of the AS. It is important to try the approach on example cases. The Tier 1 is very necessary but would need to be more elaborated.
>
> The approach is based on the availability of data, would there be an issue in lack of the data requirements? In this case only the whole in-situ generated active substance can be tested, not the pure AS. The data requirements for precursors are still under discussion. In the 2017 recommendation, there is already a decision tree, based on which certain data needs to be available.
>
> **WG conclusion:** The WG in principle agrees to the TU approach. However, when this approach shall be used, further example cases and clarification on the use of the Tier 1 method is needed.

Q2: Do MS agree that only data from the same type of trophic level (e.g. daphnia) should be used for the reverse TU calculation?

> **Discussion**: If data are available for different trophic levels, the calculation will be done for all (separately). It is important to not over- or underestimate the toxicity of the AS. To derive an endpoint for the AS, the lowest value would be chosen. If precursors are more toxic to other trophic levels than the AS, that data will be used to assess the precursors. In the revision of the recommendations, it needs to be specified what are the different percentages/proportions used in the calculation and how to do it in practice. Also how is the endpoint referred to (e.g. total substance).
>
> **WG conclusion:** The WG agreed that only data from the same type of trophic level (e.g. Daphnia) should be used for the reverse TU calculation. The quality of the data needs to be comparable.

Q3: Do MS agree that the impurities included in the reverse TU approach to derive the EC50 of pAS should not be limited only by their concentration in the isAS?

Discussion: Trigger value of 5% might not be appropriate as it is concentration-related but not effect-related. There are however some unclarities in what the trigger value shall be and the ENV task group will be proposing a solution later. The constituents of low concentration but high toxicity would need to be considered. Regarding workload indeed there needs to be a trigger value due to a lot of work. Both concentration and toxicity need to be considered.

WG conclusion: The WG agreed that the impurities included in the reverse TU approach to derive the EC50 of pure active substance should not be limited only by their concentration in the in-situ generated active substance.

The other open points coming from the e-consultation concerning the ecotoxicological relevance of impurities and respective trigger values will be discussed separately as a subsequent action (planned for WG III/2022 or later).

The ENV task group also presented a thought starter on a need to revise the Figure 2 from the Recommendations. Furthermore, it was asked whether and how the BPC-31 document on the identification of relevant impurities should be incorporated into the recommendation. It might be important to compare the SoC and Relevant impurities methods. From the real cases we see that there will always be unconsumed precursors.

Action: **SECR** to open an e-consultation for this topic, to last until 15 June 2022.

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

The WG agreed that the OECD cannot be considered as a chronic study when plants are the most sensitive species, as these studies do not cover chronic effects or effects on reproduction (i.e., seed set, flower formation, fruit maturation). That means that when the endpoint from plants is lower than the endpoint from microorganisms and/or earthworms by a factor 10 the AF can only be lowered to 50. In such cases the applicants could lower the AF by providing chronic studies or other lines of evidence.

Next step would be to define when can be ascertain that the plants are not more sensitive than microbes and earthworms. FR will revise the cases and bring up a revised table. The WG will rediscuss the proposal at the next WG meeting in September 2022.

8.3 Outcome EG meeting on fate and distribution models

SECR set up an Expert Group (EG) on fate and exposure models as a follow up of AHEE-6, with the aim of reviewing the fate models used in direct release routes and harmonising them. The EG (composed of AT, DE, FR, NL, CZ and ECHA) met in a virtual meeting on 12 April in the frame of WG-I-2022. The group discussed a document listing the fate models used in direct releases routes in biocides scenarios which was then followed by an e-consultation. The same document was provided also to the ENV WG. Annex 1 of this document presents the feedback received in the EG meeting for information and a revision of the initial list of key fate equations following the comments provided during the EG meeting and e-consultation. Annex 2 of this documents provides for information an overview on questions to be discussed next by the EG.

The following items have been identified needing further discussion and agreement by the Environment Working Group:

Q1: Is it necessary to calculate the concentration in soil with and without degradation?

Note: this question concerns also the specific release pattern during service life when the leaching source is regularly renewed such as in the scenario of PT 8 storage of treated wood prior to shipping.

The EG agreed that there is no need to calculate a risk assessment "without degradation" for service life – **does the WG confirm this agreement**?

WG conclusion: The WG confirmed the conclusion of the EG, there is no need to calculate risk assessment "without degradation" for service life in relevant PTs.

Q2: For some substances e.g. SoC, no degradation rates might be available. In this case a very low degradation rate could be applied in the model – ***does the WG confirm this agreement****?*

WG conclusion: The WG agreed to use a default value for any substances for which no degradation rate is available of 1.000.000d, corresponding to a degradation rate of 6.93E-7 d-1 independent of any temperature. In case the implementation in the Chesar Platform would need any link to a temperature, the implementation will be done in line with the current implementation in EUSES.

Q3: Currently, if no degradation of parent substance is considered an assessment of the metabolites is not needed for the environmental risk assessment. ***Question to WG****: How should this be handled in future if degradation will always be considered?*

WG conclusion: The WG agreed that this should be handled case specific. The only case where currently no degradation of the parent is applied is if the metabolites have the same toxicity profile, in that case the assessment of the parent also covers the assessment of metabolites.

Action: **SECR** to add the above conclusions in the TAB.

8.4 Follow up AHEE-6 Item 4.4: PT 18 -– Outdoor large-scale spraying

The document presented is a revision of the document AHEE-6_AP4-4, taking into account the comments and conclusions made during the AHEE-6 meeting. The revised document was agreed to be provided for a written procedure. SECR however considered that agreement at WG meeting level could be a more appropriate setting to reach an agreement. DE further provided a proposal for a drift values picklist in a separate document which was provided as a separate document. The picklist document would later be used as an annex to this scenario document.

The following items have been discussed and agreed by the WG:

Does WG agree with the exposure scenario for PT 18 Outdoor large scale spraying scenario as presented in this document?

WG conclusion: the WG agreed with the scenario as presented in the document, the changes in the Actions below should be incorporated before publication in the TAB

Actions:

- SECR to add a note in the document that time dependent factors provided in the document and equations are provided in the unit "days".
- The time values provided in the equations for periods and intervals should be replaced with symbols.
- SECR to add a note on mixing and loading (in line with other outdoor uses).
- **TAB** ENV 237 to be amended in line with the GW section in the document presented (initial PEC = first Tier)

Questions in relation to the proposal for the picklist of drift values:

Do the MS agree in principle with the proposal for the default and the picklist?

WG conclusion: The WG agreed in principle with the proposal for the default and the picklist. The drift values provided in the picklist are only relevant for single application for treatments against the oak processionary moth. However, in case of multiple applications per season/year, different drift values have to be considered in the emission scenario. DE will provide a proposal on the respective approach.

Action: DE to provide information on how to derive the correct drift values in case of multiple applications.

Post-meeting notes from DE: During discussions with our colleagues, unfortunately, it became obvious that the information in footnote 2 is not correct. At the moment, we are in contact with the Julius-Kühn-Institut, which is responsible for the derivation of drift values of PPP applications, to clarify how the values can be correctly derived for multiple applications. Thus, we decided to delete the footnote 2 in the document. The updated document will be made available in Interact under the folder for Working documents. Since the document is understood as living document, we will come back to members of AHEE/WG ENV with a correct approach as soon as possible.

Do the MS agree to the further chosen distances of 5, 10, 15, 20, 30 m and that only those fixed distances should be used in case that further refinements are needed?

WG conclusion: The WG agreed to the chosen distances of 5, 10, 15, 20, 30 m.

Do the MS agree that distances beyond 30 m are no longer reasonable for refinement and should therefore not be considered for the environmental exposure assessment of the aquatic compartment?

WG conclusion: The WG agreed that distances beyond 30 m should not be considered in the exposure assessment of the aquatic compartment.

Action: SECR to prepare a TAB entry.

8.5 PT 18 Emission scenario (CEFIC)

Item was postponed to a later WG meeting.

8.6 Manure and slurry storage – selection of European standard temperatures

The issue has been arising during the last WG ENV discussions (WG-I-2022) at which the consideration of manure degradation processes for an a.s. approval was discussed. It was realised that for biocidal a.s. approval / b.p. authorisation no agreement on a harmonised European standard manure storage temperature is available yet.

The following questions have been discussed and agreed by the WG:

Q1: For liquid manure (slurry) of cattle and pigs, do MS agree to use a default manure storage temperature of 12°C?

WG conclusion: The WG agreed with the proposed default manure storage temperature of 12°C for cattle and pigs.

Q2: For poultry litter (dry manure), do MS agree to use a default manure storage temperature of 25°C?

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

Action: **SECR** to include document and conclusions in the next TAB version.

9. AOB

9.1 Other information & lessons learned (SECR)

Next WG meetings
The provisional timing of coming WG meeting: 5-16 September 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.
Post WG meeting note: in addition, AHEE-7 will take place on 6th September 2022.

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.

Workshop waiving ED tests for NTOs
Selected date: 28 June 2022. The final timings depend on the number of cases. DE already agreed to present some example, please inform us if you are also willing to present previous or future cases.

EFSA & ECHA drinking water project update
Drafting still on-going (ECHA and EFSA's contractor): delay from previously announced timelines. Exposure chapter for Biocides: commented by ENV WG (8 April - 6 May), comments to be reflected in the draft to the extent possible (need to comply with the project deadlines) + RCOM will be shared in Collaboration (ENV WG will be informed)
EFSA will launch public consultation by mid-Sept (open for 2 months)
Background and previous info on the project: WGI2020, WGIII2021, WGI2022.

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

9.2 Update on Chesar platform developments – Repository examples

In the document presented at the WG meeting, emission scenarios harmonised in the

frame of setting up of the emission scenario repository, are presented in an **exemplary form** - for information and preliminary discussion to get feedback if SECR can proceed as suggested.

Parameter symbols and codes[1] were proposed in line with the ongoing analysis of core equation(s), also respecting the limitations of the Chesar Platform. Where symbols have changed, the old symbol nomenclature is provided in the last column.

Names of some of the parameters have been changed in view of harmonisation across different scenarios as well as units may have changed so that the equations could be presented without conversion factors in the repository.

The order of the parameters in the tables and the equations has been changed to respect the ongoing analysis. Note that further changes to the order may still apply since some level of harmonisation of presentation of parameters in the tool with REACH is sought.

Feedback on the scenarios was collected from WG members and it was agreed that the document will be distributed for a written commenting (the feedback received during the meeting will be incorporated before the written commenting).

Action: **SECR** to update the scenario proposals and distribute for commenting.

[1] While the symbol will appear in the equation and may be used across different scenarios as it is more generic, the code is a unique identifier for a specific parameter in the IT system (it will allow displaying the label of the parameter which is relevant in a given scenario).

Appendices:

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

Chapter 1 Effect and Hazard Assessment

ENV xxx Warning sentence for bees

Version 1 (WG-II-2022)

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

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

The already agreed upon warning sentence is:

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

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

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

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

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

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

Chapter 2.3 Groundwater

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

Version 2 (WG-I-2021, WG-II-2022)

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

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

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

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

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

Chapter Cross-PT items

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

Version 1 (WG-II-2022)

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

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

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

Background document: [link to the CIRCA space]

ENV xxx Use of trigger sprays

Version 1 (WG-II-2022)

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

ENV xxx Degradation during service-life for emission scenarios using the house scenario or similar emission scenarios from PT 8 or other PTs

Version 1 (WG-II-2022)

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

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

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

Chapter 3.17 PT 18

3.17.1 Household and professional use

Outdoor application

ENV xxx Outdoor large scale spraying scenario

Version 1 (WG-II-2022)

The emission scenario for the use of insecticides in outdoor large-scale spraying agreed at WG-II-2022 is provided in the CIRCA TAB repository (entry "ENVxxx…")

[Emission scenario: link to the CIRCA space where the full scenario is provided]

New TAB chapter on substance specific WG conclusions

ENV xxx Lactic acid

Version 1 (WG-II-202?, WG-I-2022)

Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and

urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L-(+) lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (tier 1).

For all these reasons, it can be stated that lactic acid does not cause unacceptable risk for soil, groundwater and also the indirect release to surface water (via STP and via manure). Thus, no further quantitative assessment for soil, groundwater and the indirect release to surface water (via STP and via manure) are needed.

For direct release to surface water a quantitative assessment is however still needed. As in the case for other natural occurring substances, a comparison of the PEC with the natural background concentration instead of the PNEC is acceptable.

ENV xxx Ozone

Version 1 (WG-II-2022)

The WG agreed that for future product authorisations, a quantitative assessment for Ozone would only be needed for direct release to surface water, indirect release via STP can be covered by a qualitative assessment.

ENV xxx Hydrogene peroxide

Version 1 (WG-II-2022)

The WG agreed, that the exposure route via air during treatment with hydrogen peroxide indoors, does not need to be assessed for any products containing hydrogen peroxide, deviating from the assessment as provided in the CAR for the active substance.

Appendix 2: List of participants

Core members and alternates:

- AT Lukas Kuehrer
- DE Daniel Frein
- DE Eleonora Petersohn
- DE Sascha Setzer
- FR Stéphanie Alexandre
- FR Jerome Lozach
- FR Anne Straczek
- IE Mike Broderick
- IE Helena Joyce
- NL Barry Muijs
- SI Petra Muri

Flexible members:

- AT Dominik Altmann
- AT Christian Kantner
- BE Anne Brasseur
- BE Bart Heulens
- BE Samuel Huerga Fernandez
- BE Wiet Raets
- CH Tenzing Gyalpo
- CH Petra Kunz
- CH Maria a Marca
- CZ Lucie Bielska
- DE Julia Margaretha Anke
- DE Stefanie Jacob
- DE Katja Michaelis
- DE Torsten Schwanemann
- DE Christoph Stang
- DK Henrik Wennermark
- EE Helen SULG
- ES Myriam Martin Vallejo
- ES Elena Fuensanta Ruiz Lopez
- ES Ángeles Jiménez
- FI Oskari Hänninen
- FI Sanna Kaukoniemi
- FI Timo Nieminen
- FI Jaana Pasanen
- FI Sari Penttinen
- 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
- SE Johan Persson
- SK Jana Molnarova

Rapporteur:

- DE Daniel FREIN – Peracetic Acid
- FR Esther CHABOUT – Sodium hypochlorite
- NL Barry MUIJS – Ozone generated from oxygen
- PL Helena RZODECZKO - MES
- SE Edda HAHLBECK – Iodine and PVP iodine

Advisors:

- DK Jesper Johannessen
- FR Valérie Larno
- NL Zhichao Dang
- SE Ifthekhar Ali Mohammed

ASOs:

- Jules Bossert - Cefic
- Boris VAN BERLO -Cefic
- Ellen Thom - Cefic
- Yuhua Wu - Cefic
- Jaak Ryckeboer - ISG

ECHA chairs and experts

Human Health WG-II-2022

Final minutes

13 September 2022

Minutes of Human Health WG-II-2022

31 May – 2 June; 10 June 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 71 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 informed that a cleaning exercise will be launched to ensure membership information is up to date.

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-I-2022

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Ozone generated from oxygen, PT 2, 4, 5, 11 (eCA NL)

The same active substance had been discussed already earlier in an assessment from another eCA. No changes were required in the assessment already performed and agreed.

6.2 Mecetronium ethyl sulphate (MES), PT 1 (eCA PL)

Due to missing reference specification, it had not been possible to assess whether the batches used in toxicity studies cover the reference specification. This would be needed before concluding on the human health assessment.

Based on the information available, it was not possible to conclude whether the ED criteria are met.

6.3 Early review: Iodine, PVP-iodine - ED Assessment (eCA SE)

There is sufficient evidence for adverse effects in humans, and these are a consequence of an endocrine mode of action. Iodine and PVP-iodine meet the ED criteria for T modality with respect to humans.

It was not possible to conclude on EAS modalities for human health based on the available information. No further testing was considered necessary, as the ED criteria for the T modality are met.

6.4 Early WG: Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide, PT 18 (eCA DE)

Based on the information provided it was not possible to conclude on developmental toxicity. The proposed read-across approach was in general supported for fertility and carcinogenicity, while more details and weight of evidence was requested.

6.5 Early WG: In situ generated monochloramines (eCAs AT, ES, FR, SE)

To provide the necessary information on ED properties and fertility, the WG supported performing the extended one-generation reproductive toxicity study, unless it could still be justified that testing might not be technically feasible and/or scientifically justified.

6.6 Sorbic acid, PT 6 (eCA DE)

Based on the available information, sorbic acid was considered to give rise to concern regarding skin sensitisation, and on this basis it would not be eligible for inclusion into BPR Annex I. Read-across between sorbic acid and sorbate salts was not supported, and there is a data gap for in vitro genotoxicity.

6.7 Sulphur dioxide generated from sulphur by combustion, PT 4 (eCA DE)

6.8 Sulfur dioxide released from sodium metabisulfite, PT 9 (eCA DE)

These agenda items were discussed jointly. The wording concerning genotoxicity will be better aligned with the RAC opinion. No changes were made in the already agreed NOAEL values and reference values. The discussion will be reflected in the revised CAR.

7. Discussion of Union authorisation applications

7.1 UA for a product family containing hydrogen peroxide, PT 2, 3, 4 (eCA NL)

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

7.2 UA for a product family containing active chlorine released from sodium hypochlorite, PT 2, 3, 4, 5 (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 family containing active chlorine released from sodium hypochlorite, 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.

7.4 UA for a product family containing peracetic acid, PT 3, 4 (eCA DE)

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

8. Any other business

8.1 Other information & lessons learned

Chesar Platform

SECR reported of the latest developments and the next steps in the Topic Expert Group (TEG) on workers assessment. The TEG is working on ART implementation in Chesar, where the identified open issues were reported. HEAdhoc will be kept informed of the minutes and documentation from the TEG meetings.

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 will be a virtual meeting with the following provisional timing:

- 5-16 September 2022

Annex 1

Human Health WG attendees

Core members
HOELZL Christine (AT)
MIKOLAS Jan (CZ)
HERRMANN Kristin (DE)
HOLTHENRICH Dagmar (DE)
REPOUSKOU Anastasia (EL)
LORI Julia (FR)
LAUMONIER-MAXIMILIEN Elisabeth (FR)
BOS Carina (NL)
MIDTHAUG Hilde Karin (NO)
Flexible members
DERLER Angelika (AT)
AZZOPARDI Charline (BE)
TORDOIR Charlotte (BE)
BRYS Kristel (BE)
RUSCONI Manuel (CH)
SANS-PICHÉ Frederic (CH)
DONZE Gerard (CH)
GOLDINGER Daniela (CH)
GRÜNIG David (CH)
ROSSIER Nadine (CH)
SEDLAK Petr (CZ)
HOLZWARTH Andrea (DE)
KLUTZNY Saskia (DE)
ROITZSCH Michael (DE)
SCHNEIDER Heiko (DE)
SEMISCH Annetta (DE)
JENSEN Stine (DK)
KÄOSAAR Sandra (EE)
DE RIVAS Ana (ES)
SÁNCHEZ José María (ES)
HÄMÄLAINEN Anna-Maija (FI)
RYDMAN Elina (FI)
VÄLIMÄKI Elina (FI)
HYVARINEN Tuija (FI)

AUBIN Aurelie (FR)
BELLINGARD Valérie (FR)
AMSALLEM Tiffany (FR)
CAPDEVILLE Perrine (FR)
COLLIN Elodie (FR)
REY Marion (FR)
DEKOVI Edlira (IT)
FRYDENLUND Jorid (NO)
GÓRECKI Roman (PL)
UJMA-CZWAKIEL Monika (PL)
BLODÖRN Krister (SE)
MALMGREN Birgitta (SE)
PERSSON Johan (SE)
ČEBAŠEK Petra (SI)
OLHA Roman (SK)
PILIŠIOVÁ Ružena (SK)

Alternate members	ARCHE Consulting
GUENTHER Isabel (DE)	EDF
BREEN Alan (IE)	API Additives GmbH
Advisors	f_OXYDE GmbH
RIME Soyub (DE)	Knoell
WILLENBOCKEL Christian Tobias (DE)	Canal de Isabel II
HANSEN Max (DK)	ERM
KIRKEGAARD Maja (DK)	Buckman
CHABOT Esther (FR)	TS Consulting
VAN DEN BERG Suzanne (NL)	EDF
HENRIKSSON Rebecca (SE)	SANIPUR S.p.A.
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