Final minutes of the Working Group meeting I in 2023

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

(Meeting date: 13 to 15 March 2023 – virtual meeting)

30 June 2023

1. Welcome and apologies

The meeting was a virtual meeting. The Chair welcomed the participants of the working group meeting. Two participants registered for the meeting as accredited stakeholder organisations (ASO). The list of registered participants and observers can be found in annex I to the minutes.

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

2. Administrative issues

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

The chair shared some reflections on the purpose and goal of the working group meetings.

The chair requested feedback on the need for training on the use of phys-chem properties in the further assessment. There was in general positive reaction. ECHA will see if such a training can be organised.

The chair informed the working group about some feedback received as part of the peer review regarding the functioning of the peer review procedure and indicated the intention to have this as a discussion item in a following working group meeting.

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).

No modifications to the agenda were proposed.

The agenda was agreed without modifications.

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 III 2022

Three comments on the minutes of WG IV 2022 were received in the commenting period. The working group members reviewed and accepted the proposed changes of the draft minutes. The draft minutes were modified accordingly and were agreed by the working group members.

6. Active Substances

6.1. Garlic extract PT19

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

6.2. Pentapotassium bis(peroxymonosulphate) bis(sulphate) PT2, PT3, PT4, PT5

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

6.3. Early WG discussion – Alphachloralose

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

6.4. Early WG discussion – TMAD identification

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

7. Union Authorisations

7.1. UA for a product family containing L-(+)-lactic acid PT3

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

7.2. UA for a product containing Hydrogen peroxide and L-(+)-lactic acid PT 2, PT3, PT4

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

8. Technical and guidance related issues

8.1. Update of the APCP TAB

The working group received a report from the sub group reviewing the TAB and discussed the principles how the APCP TAB should be updated in the future.

8.2. Exchange on problems during evaluation

Member states discussed general topics of interest observed during evaluation.

8.3. Waiving of oxidising properties for simple oxides

The working group reviewed a proposal how certain metal oxide compounds could be confirmed as not having oxidising properties. The approach and a concrete list of compounds will be refined and discussed in a future working group meeting.

8.4. Read-across possibilities for SADT

The working group reviewed a proposal how read-across for SADT and organic peroxide classification could be treated. The approach will be refined and discussed in a future working group meeting.

8.5. Global composition for in situ generated active substance

The working group considered the requirements for describing the composition of an in-situ generated active substance. The issue will be submitted again for decision.

9. AoB

There were no items for discussion under this agend point.

Annex 1 - List of attendees registered for the meeting

Member state	Member state participant		
DE	**Ulrike**	**MUHLE**	Core Member
FR	**Therese**	**SIX**	Core Member
NL	**Sabine**	**KRUIDHOF**	Core Member
PL	**Sylwester**	**HUSZAŁ**	Core Member
SI	**Špela**	**VELIKONJA BOLTA**	Core Member
FR	**François**	**LUTZ**	Alternate Member
NL	**Peter**	**VAN RIJNSBERGEN**	Alternate Member
AT	**Michael**	**GHOBRIAL**	Flexible Member
AT	**Erich**	**NEUWIRTH**	Flexible Member
BE	**Anastasia**	**BURMISTOVA**	Flexible Member
BE	**Minh-Dung**	**DANG THY**	Flexible Member
BE	**Steven**	**FAUCONNIER**	Flexible Member
BE	**Yannick**	**HERREMANS**	Flexible Member
BE	**Samuel**	**HUERGA FERNANDEZ**	Flexible Member
BE	**Kim**	**SWENNEN**	Flexible Member
CH	**Michael**	**AESCHBACHER**	Flexible Member
CH	**Amandine**	**COURDOUAN MERZ**	Flexible Member
CZ	**Martin**	**VLASAK**	Flexible Member
DE	**Tobias**	**DEDEN**	Flexible Member
EE	**Imre**	**VALLIKIVI**	Flexible Member
ES	**David**	**CANO**	Flexible Member
ES	**Jesus**	**ESCALADA**	Flexible Member
FI	**Katariina**	**VUORENSOLA**	Flexible Member
IT	**Lucilla**	**CATALDI**	Flexible Member
LV	**Ieva**	**IGAUNE**	Flexible Member
NL	**Cornelia**	**BLAGA**	Flexible Member
NL	**Alena**	**BOURKE**	Flexible Member
NL	**Marianne**	**POUWELS**	Flexible Member
NL	**Ingeborg**	**STORM**	Flexible Member
NO	**Marianne**	**STAVE SEKKENES**	Flexible Member
NO	**Ingrid**	**UR GJERDE**	Flexible Member
PL	**Anna**	**HORCZYCZAK**	Flexible Member
SI	**Petra**	**ČEBAŠEK**	Flexible Member

SI	**Klavdija**	**ZIRNGAST**	Flexible Member
SK	**Zuzana**	**DRABOVÁ KUŠÍKOVÁ**	Flexible Member
SK	**Michal**	**PORUBIAK**	Flexible Member
AT	**Dominik**	**ALTMANN**	Member's Advisor
FR	**Clement**	**LEBEE**	Member's Advisor
SE	**Anh**	**JOHANSSON**	Member's Advisor
SE	**Göran**	**MARSH**	Member's Advisor
SK	**Denisa**	**MIKOLASKOVA**	Member's Advisor
AT	**Jerome**	**COLSON**	Member's Advisor

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
CEFIF	Jules Bossert
EUROZON	Roman Gyssels

Applicant
Ecospray Limited
Exponent
United Initiators GmbH
SCC GmbH
CEHTRA
Thor
Huvepharma
Kersia Group
SPECTRA

ECHA staff
Uphoff Andreas
Marcon Eva
Veteläinen Kaisa
Costea Ion
Demattio Silvia
Lisboa Marto Susana

Final minutes of Efficacy WG-I-2023

14, 16 and 21 March 2023

Meeting of the Efficacy Working Group of the Biocidal Products Committee

20 June 2023

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 three separate days. The list of attendees is given in Annex 1.

2. Administrative issues

SECR gave brief information on the administrative issues.

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

DE and FR had sent comments on the EFF WG-IV-2023 draft minutes. The revised draft minutes of WG-IV-2023 were agreed at the meeting.

6. Discussion of active substances

6.1 Garlic extract (eCA AT)

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

6.2 Pentapotassium bis(peroxymonosulphate) bis(sulphate) (eCA AT)

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 L-(+)-lactic acid (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 Hydrogen peroxide and L-(+)-lactic acid (eCA FR)

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

7.3 Early WG on UA-APP containing C(M)IT/MIT (eCA NL)

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

7.4 Early WG discussion on UA-APPs containing active chlorine generated from sodium chloride by electrolysis (eCA NL)

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

7.5 Early WG discussion on UA-APPs containing active chlorine generated from sodium chloride by electrolysis (eCA NL)

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

7.6 Early WG discussion on UA-APP containing active chlorine released from calcium hypochlorite (eCA AT)

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

7.7 Early WG discussion on UA-APP containing active chlorine released from calcium hypochlorite (eCA DE)

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

8. Mutual recognition

8.1 COM request for ECHA opinion pursuant to Articles 36(2) and 38 of the BPR (closed session)

ECHA has received a COM's request in accordance with Art. 38 of the BPR about unresolved objections during the mutual recognition procedure for a biocidal product family that is intended for disinfecting drinking water for animals. To prepare a draft BPC opinion, ECHA asked EFF WG members several questions about the efficacy data package. The draft BPC opinion will be prepared based on the feedback received and presented to the BPC for endorsement.

9. Technical and guidance related issues

9.1 Antimicrobial resistance - draft guidance (DE/FR)

The discussion focused on two chapters of the draft guidance, i.e. Introduction and Literature review.

Introduction

Three points were discussed with reference to the revised Introduction part. The first point referred to the objective of the guidance, and question 1 (the main objective) was proposed to be rephrased by DK, FI and SI. After a short discussion on how to make it more formal the following question was agreed: *What information on resistance (or cross-resistance) is reported from the field and how does it affect efficacy?*

The second point referred to the objective of the guidance, and question 2, DE and NL proposed to rephrase the current text. After a short discussion the following text was agreed: *The question whether the biocide in question (i.e. the active substance(s) in it) could cause the development of resistance (or cross-resistance) and the likelihood of that happening is not the primary focus of the assessment of resistance (or cross-resistance) and no new data needs to be generated to answer this question. Nevertheless, if relevant information addressing this question is already available (e.g. in the scientific literature such as mode of action, mechanism of resistance), it should be addressed.*

The third item discussed concerned the term 'antibiotics'. It was decided to remove it from the Introduction.

Literature review

Regarding the Literature review part the discussion was not finished during previous meeting (EFF WG-IV-2022) due to time constraints and two issues remained open. The first one pertained to the inclusion of data on resistance from other areas, such as plant protection products, medicinal products, cosmetics, etc. The WG agreed to amend the current text with the following addition: *'Likewise, published information on resistance to the active substance in question from other areas of use outside the BPR, e.g. plant protection products, medicinal products, cosmetics, or experience of users (in case the AS was already on the market), should usually be taken into account'*.

The second issue referred to proposed checkpoints after the literature review. In order to make an informed decision about how to proceed with the information gathered and analysed in the literature review, four checkpoints have been proposed. They will help to establish clear criteria for addressing the collected information, ensuring that the assessment will be thorough and conclusive. Based on the outcome of the checkpoints, it will be determined if resistance is considered a potential concern and whether RMM are necessary or if there is no cause for concern. In cases where a conclusion cannot be drawn, additional information will be required at the later steps.

The WG accepted the proposal to adhere to the following tiered approach: '*For existing AS, Q1 (literature) is done first. If there is relevant literature showing no resistance or risk thereof, skip Q3 (MoA) and 4 (PC properties). If there is no relevant literature, follow with Q3 and 4 before deciding the next steps.'* In addition, it was proposed to draw a decision tree. It would show the sequence of decisions and their corresponding outcomes, making it easier to understand and interpret the decision-making process.

With reference to new active substances it was decided to remove question 2 and in case the answer to question 3 will lead to an unknown mode of action the possible implications on further requirements will be discussed at a later stage.

The discussion concerning question 4 was deferred due to a lack of clarity on the subsequent steps of the assessment and of some important information at the active substance approval stage which holds significance for the potentially authorised products, e.g. the frequency of applications, all intended uses, etc. The proposed rephrasing of question 4 is presently withheld and contingent upon the outcomes of forthcoming discussions on laboratory tests and field trials.

Following the conclusions of this discussion, the draft guidance will be revised accordingly.

9.2 PT19 topical repellents for human skin against mosquitoes – simulated-use test requiring landing rate (DE)

The WG was not in favour to place the current text concerning the minimum landing rate and already included in the room test section of PT 19 chapter of Vol. II, Parts B+C efficacy guidance to AIC and ATC sections. The main concern was related to the mean landing rate that in fact is achieved but individual landing measurements at certain checkpoints might be extremely low. There were some questions concerning the correct interpretation of the current text and the discussion focused again on the proposed amendments, which would lead to the revision of the text agreed upon during the PT19 guidance development within the ECHA consultation procedure. The WG members had different views on what should be added to make this text clearer without impacting its content. It was concluded to leave the current text as it is and not to add it to AIC and ATC sections.

9.3 TAB proposal - how to determine the duration of efficacy of the disinfection bath (NL)

Q1: The EFF WG agreed that the TAB entry should concern all five identified uses involving disinfection in baths in three product types, e.g. "Equipment disinfection by immersion" for PT2, "disinfectants for hard surfaces", "animal feet disinfection" and "disinfection of hatching-eggs" for PT3 and "equipment disinfection by soaking" for PT4. Moreover, it was agreed that the TAB should in addition concern all similar uses as well even if they are not yet explicitly mentioned in the EFF guidance.

Q2: The EFF WG agreed that for determining the duration of efficacy of the bath both time and the number of boots, eggs, animals, etc. passing through are relevant. The information on these restrictions should be included in the SPC. It was also mentioned that in the field trial when the active substance content is measured the other parameters as soiling and volume of the product might be addressed. A proposal was made to add the text that the number of disinfected items should not exceed the number of items used in the field trial. Otherwise, if the number of items will be too high the soiling will increase automatically and the disinfection will not be efficacious anymore.

Q3: The EFF WG agreed that it is allowed to set initially the concentration of the active substance in the disinfection bath higher than the efficacious concentration (as long as the dose is within the limit of safe use) to ensure that the bath can be used for a longer period and/or multiple times.

Q4: In the Vol II Parts B+C efficacy guidance two strategies are proposed for determining the duration of efficacy, i.e., capacity test (section 5.4.0.4.1) and measurement of the concentration of the active substance in a field trial. In the introduced capacity test, the efficacy of the bath is determined based on efficacy against microbial contamination in suspension rather than on a surface. This approach was not considered as appropriate and relevant for surface disinfection. The NL will prepare the updated draft proposal based on the discussion and it will be presented to the WG in June. The WG members and ASOs'

representatives may send proposals on how to amend section 5.4.0.4.1 on capacity testing to ECHA by the end of April.

9.4 Guidance needs and its prioritisation

Owing to time limitations, the guidance needs were briefly presented to the WG, including ECHA's initial perspective on the proposed suggestions. The subsequent phase will involve eliciting the ASOs' needs and resuming discussion shortly.

10. AOB

10.1 Other information

A brief update on the upcoming EFF WG-II-2023 meeting (planned as a hybrid meeting) was provided to the WG members including the deadlines for the early WG discussion requests and working documents submission. In addition, ECHA shared several updates, such as:

- the draft guidance status and recently finalised e-consultations;
- updated templates for the EFF WG discussions and their availability on S-CIRCABC;
- new document concerning new information in active substance and Union authorisation opinion-forming processes and its availability on the ECHA webpage;
- upcoming splitting of Volume II, Parts B+C into four separate documents in accordance with the Main Groups of the BPR;
- upcoming formal voting at the CEN level on some of the prEN standards.

Finally, ECHA reminded that the column 'Remaining question which has to be discussed at the WG (if the point is still open)' in the RCOM table should be filled in by the eCA in cooperation with the commenting MS.

List of Attendees

1. **Core members:**
   - JANSEN Irina (DE)
   - KRÜGER Martin (DE) – Alternate
   - AMPATZI Argyro (EL) – Alternate
   - GIATROPOULOS Athanasios (EL)
   - ATTIG Isabelle (FR)
   - MAXIMILIEN Yann (FR) – Alternate
   - WARMERDAM Sonja (NL)
   - DUH Darja (SI)
2. **Flexible members:**
   - WIDHALM Bernhard (AT)
   - BURGER Natascha (AT)
   - LEPAGE Anne (BE)
   - PEELMAN Natania (BE)
   - PIROTTE Jennifer (BE)
   - DANG THY Minh-Dung (BE)
   - BURMISTOVA Anastasia (BE)
   - WANDELER Eliane (CH)
   - DONZE Gerard (CH)
   - MEIER Margrith (CH)
   - RUSCONI Manuel (CH)
   - SANS-PICHÉ Frederic (CH)
   - SVEJSTIL Roman (CZ)
   - DOLEŽELOVÁ Katsiaryna (CZ)
   - CLEYTON JØRGENSEN Charlotte (DK)
   - TRAUER-KIZILELMA Ute (DE)
   - PLOOMPUU Grethe-Johanna (EE)
   - KÄOSAAR Sandra (EE)
   - PORTELA HENCHE Cristina (ES)
   - LANDA COLOMINA Blanca (ES)
   - NIEMINEN Timo (FI)
   - RYDMAN Elina (FI)
   - HADDACHE Nabila (FR)
   - BRIZARD Mathias (FR)
   - BILLAULT Catherine (FR)
   - DRMIC Zrinka (HR)
   - OWENS Aoife (IE)
   - Lynch Helen (IE)
   - RONCI Maria Beatrice (IT)
   - BALDASSARRI Lucilla (IT)
   - MEŽULE Linda (LV)
   - WIGGERS Hanneke (NL)
   - SCHOEP Piet (NL)
   - Stave Sekkenes Marianne (NO)
   - KASPRZAK Karolina (PL)
   - ÅSLING Bengt (SE)
   - DANADAIOVA Emese (SK)
   - JASSOVA Juliana (SK)
3. **Advisors:**
   - KULMA Martin (CZ)
   - DEKKER Bas (NL)
   - Jongerius Aniek (NL)
   - JURASZEK Magdalena (PL)
4. **ECHA Staff**
   - SZYMANKIEWICZ Katarzyna (Chair)
   - RAULIO Mari
   - HONKA anni

- HAMALAINEN Eva

5. **Stakeholders:**
   - Bossert Jules (CEFIC)
   - DARRIET Marie (AISE)
   - CORNER Hannah (AISE)
   - GYSSELS Roman (EurO3zon)
   - BRILL Florian
   - Schreiber Frank
   - Burney Carolyn
   - Steinhauer Katrin
   - Bernard Jennifer (CEFIC)
   - Black Elaine (CEFIC)
   - Schumacher Verona (CEFIC)
   - Moreno Mara (AISE)
   - Razzaboni Martina
6. **Applicants:**
   - HYPRED SAS
   - HUVEPHARMA SA
   - Arche Consortia
   - SCC GmbH (on behalf of WTR Europe GmbH)
   - SCC GmbH (on behalf of TOSOH EUROPE B.V.)

Final minutes of Environment WG-I-2023

21, 23 and 24 March 2023

Meetings of the Environmental Working Group of the Biocidal Products Committee

21-24 March 2023

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 57 participants present (virtual meeting), of which 10 were core or alternate members. The Chair also welcomed the new members to the ENV WG. Four representatives from accredited stakeholder organisation were present at some agenda items. Applicants were registered for their specific substance discussions.

The Chair gave a brief presentation on the mandate and tasks for the WG, and the roles of the members, secretariat, applicants and Accredited Stakeholder Organisations (ASOs).

2. Administrative issues

SECR informed on several administrative issues.

3. Agreement of the agenda

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

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

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

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

The minutes for all items were agreed with some small changes.

6. Discussion on active substances

6.1. Garlic extract, PT19 (eCA AT)

There were no open points.

Action: None

6.2. Pentapotassium bis(peroxymonosulphate) bis(sulphate), PT2, 3, 4, 5 (eCA SI)

All open points were closed at the meeting. Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: FR to draft two TAB entries.

6.3. Early WG discussion – Alphachloralose, PT14 (PL)

All open points were closed at the meeting. Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3. It is now up to the eCA to request the necessary studies.

Action: None

6.4. Early WG discussion - dissipation of OIT in two open recirculating liquid cooling systems, PT11 (FR)

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

No points were closed in the discussion, as in the discussion it became clear that a better definition of the system is required. Importantly, while the e-consultation focused on open systems, the system might actually be better described as a closed system (with periodic discharge). The applicant will rediscuss with the eCA to clarify the outstanding questions raised in the discussion.

Action: the eCA to follow-up with DE, NL and APP.

6.5. Early WG discussion: refinement of environmental risk assessment of copper powder, PT21 (FR)

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

No clear way forward was identified in the discussion, and additional clarification is needed on the role of DOC in the modelling of Cu-concentrations in the environmental risk assessment.

Action: None

7. Discussion of Union Authorisation cases

7.1. UA for a product family containing L-(+)-lactic acid, PT3 (NL)

There were no open points.

Action: None

7.2. UA for a product containing Hydrogen peroxide and L-(+)-lactic acid, PT2, PT3, PT4 (FR)

There were no open points.

Action: None

8. Article 75(1)(g) requests

8.1. Article 75(1)(g) mandate: Comparative assessment of anticoagulant rodenticides

The WG generally agreed with the content of the report, and with its current conclusion that at group level the environmental profile of SGARs tend to be worse in comparison to FGARs. However, the WG also agreed that a more detailed ranking of the individual substances is not scientifically justified. The current ranking in the report will be removed, and substances will be sorted alphabetically to avoid the suggestion of ranking.

8.2. Article 75(1)(g) mandate: Re-assessing the risk on the environment (soil compartment) posed by ADBAC/BKC from use in biocidal products of PT2

The WG agreed with the revised assessment for the environment (soil compartment).

9. Mutual recognition

9.1. COM request for ECHA opinion pursuant to Articles 36(2) and 38 of the BPR for a PT 5 biocidal product family intended for disinfection of drinking water for animals

Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3. The WG agreed with the draft BPC opinion provided by the SECR.

10. Technical and guidance related topics

10.1. Worst case and best case concentrations in a product family

The ENV WG agreed with the approach in general, but preferred specific examples in the document for the environment. A ENV specific version of the document will be drafted, together with a TAB entry.

Action: DE to draft a TAB entry.

10.2. Pollinator guidance update

The ENV WG was informed on the Status of guidance development and the tentative timelines. Also, an illustrative example was provided on the risk assessment of honey bees. It is expected to discuss the guidance at the ENV WG in June, followed by a CA and BPC consultation in September and October respectively.

After the presentation, ECHA replied on a number of questions made by the WG members. Further clarification was provided on the information requirements on bees and on the applied methodology in the effect assessment, which for bees follows a different approach than for other organisms covered in the biocide risk assessment.

In addition, it was explained that the selection of the specific PT18 uses which warrant development of exposure scenarios, is a result of a thorough screening of exposure scenarios and expert judgement. Although the focus of the first version of the guidance is

on certain PT18 uses, it doesn't exclude that scope is extended to other future uses that may be relevant for bee exposure.

10.3. Risk assessment of DBPs

FR presented the state of progress and future steps in the assessment of Disinfection By Products (DBPs), a project with the ultimate aim to develop a harmonized methodology for the risk assessment and update the volume V guidance. The current document focuses on four groups of active substances: active chlorine, active bromine, chloramine and chlorine dioxide. FR also informed the ENV WG that they will no longer lead the project. DE will coordinate the next meeting to discuss a recent report from UBA on the topic and the methodology of the exposure assessment.

10.4. CLP revision

SECR presented an update on the upcoming CLP revision, focusing on the additions: EDs, PBT, vPvB, PMT, vPvM. SECR explained the criteria for ED HH, ED ENV, PBT, vPvB, PMT, vPvM and that generic concentration limits (or specific concentration limits) will be set. New hazard statements (EUH) will be introduced for these, but there will be no symbol/pictogram yet for the new hazard classes as they are currently not accepted under UN-GHS (Globally Harmonised System of classification and labelling of chemicals). The CLP revision is divided into two parts: change of CLP "body" text by Ordinary Legislative Procedure (OLP) and changing Annex I by Delegated Act/Regulation (DA). The OLP will go via co-decision via Parliament and Council (Entry into force earliest June 2024), while the DA is agreed via Commission decision via CARACAL consultations (Entry into force 20 April 2023/Publication in Official Journal 31 March 2023). A transitional period will be in place for substances (24 months) and mixtures (36 months). The transitional period for reclassification for substances already on the market is 42 months, while for mixture this is 60 months. BPR and PPP active substances already under assessment for ED and PBT properties will be routed via CLH procedure to CLP Annex VI. The new hazard classes will no longer be subject to the peer review during the opinion forming phase of active substance under BPR. BPC with its working groups will no longer have the task to discuss and conclude on the hazard identification, but BPC will consider the risk. However, a CLH dossier needs to include these hazard classes (can already be applied when DA comes into force i.e. during transitional periods). If the CLH needs to be confirmed for PBT/vPvB and ED before starting the BPC opinion forming process, a CLH proposal has to be submitted some years before the CAR submission! ED EG and PBT EG can still be consulted e.g. on further testing needs, completeness of the data and initial scientific advice on these properties before submitting the CLH dossier for ECHA. However, it is currently unclear how to consider Known or Presumed EDs (Cat 1) vs. Suspected EDs (Cat 2) and Mobility (PMT, vPvM) under the BPR; this needs to be clarified by COM. ECHA will submit an information package and a revised CLH template on its website by 20 April 2023, and a CLP guidance on the new hazard classes on Q2/2024.

In addition to the CLP revision, SECR also presented the update on Guidance on IR&CSA Chapter R.11 and specific sections of Chapters R.7b and R.7c. SECR informed the ENV WG members that the BPC members will be consulted, to inform BPC committee on the elements update and to ensure that the guidance is acceptable to all interested parties by providing the basis for ECHA's final draft version. The outcome of the committee's consultation (MSC/BPC) serve as the basis for the next draft version of the guidance text for further consultation steps.

11. Other information & lessons learned

Next WG meetings

The provisional timing of coming WG meeting: 19-22 June 2023. The meeting takes place as a physical meeting, exact days to be established. Webex participation would be still possible. It is foreseen to have one physical meeting per year. After the physical meeting, there will be a 1-2 day extra virtual meeting, dedicated to the pollinator guidance.

Providing new information during opinion forming

Reminder that a combined document for AS and UA was endorsed at BPC-45. Main message of the document is that instead of "new information has the potential to change the outcome of the evaluation of the eCA", the focus is now on whether the new information would change an approval in a non-approval or vice versa (and similarly, change an authorisation into a non-authorisation). The WG was reminded that there always needs to be an AHF if new information is requested.

Info session for CAs on data requests

On 20 April 2023, 14:00-16:30 Helsinki time, there is a virtual information session on identifying data gaps and/or taking a decision to request additional information. The info session is aimed at Dossier managers, AS evaluators, process coordinators, regulatory coordinators, BPC/WG members and decision makers. The registration deadline is 12 April.

Webinar: Analysis of alternatives and tools to support substitution of biocides

On 26 April 2023, 15:00-16:30 Helsinki time, ECHA will organise a webinar on the analysis of alternative and tools and initiative that might support stakeholders into moving to safer alternatives. There is no need to register upfront.

Chesar Platform update

SECR provided the ENV WG with an update on the Chesar platform development. No new discussions are foreseen until the launch of the revised R.16 guidance consultation, expected to be launched Q2-2023. The goal is to finalise the R.16 update by the end of 2023. Drafting of TAB entries for remaining scientific topics is still ongoing, and a consultation for the ENV WG is foreseen in parallel with the R.16 consultation. First version is currently foreseen by spring 2024. An information session for the stakeholders is planned for 26 April 2023.

AOB

DE informed the WG they will launch a consultation soon for the draft revised ESD PT18 for insecticides, acaricides and products to control other arthropods for household and professional uses. The revised ESD will contain new emission scenarios and revise the existing ones based on the previous WG agreements and relevant TAB entries.

Lessons learned

- 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.
- E-consultations: Please consider reporting back the outcome of an e-consultation to inform the ENV WG members.
- When considering using new emission scenarios or changing existing ones, the ENV WG should always be consulted
- Please implement the agreements from the ENV WG as much as possible to avoid lengthy discussions at the BPC on points that were closed at the WG
- Only submit dossiers with a clear ED conclusion. Consult the ENV WG when considering waiving the need for (additional) studies.
- For the agreement of the minutes of the previous WG, SECR proposed to only go through the minutes at the WG where a MS has indicated they disagree with the minutes and/or want to discuss. The remaining minutes are then agreed by default, without showing them at the WG. This procedure will be tried for the next WG (in June).

Appendix 1: List of participants

Core members and alternates:

- AT Lukas Kührer
- DE Daniel Frein
- FR Stéphanie Alexandre
- FR Anne Straczek
- IE Helena Joyce
- DE Anja KEHRER-BERGER
- DE Sascha Setzer
- FR Jerome Lozach
- NL Karlijn Holthaus

Flexible members:

- AT Dominik Altmann
- AT Iris Buchner
- AT Lea Breul
- BE Anne Brasseur
- BE Bart Heulens
- BE Samuel Huerga Fernandez
- BE Helene Jarrety
- BE Wiet Raets
- BE Sofie Tijskens
- CH Maria a Marca
- CH Tenzing Gyalpo
- CH Petra Kunz
- CZ Pavla Lakdawala
- 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 Koivisto
- FI Jaana Pasanen
- FI Sari Penttinen
- IE Oscar McAuley
- NL Els Smit
- NO Terje Haraldsen
- NO Sanne Helene Kristensen
- NO Karina Petersen
- PL Agnieszka Podlaska
- PL Helena Rzodeczko
- SE Rina Andersson
- SE Edda Hahlbeck
- SE Johan Persson
- SI Bert Van Der Geest
- SK Simona Liskova
- SK Jana Molnarova

Advisors:

- DK Jesper Johannessen
- FR Yannice Convert
- FR Marina FERNANDEZ DECLERCK
- FR Arthur GILSON
- FR Fanny Herard
- FR Jeanne Raynert
- FR Séléné Verstraet
- NL Zhichao Dang
- SE Diana Posledovich
- SK Katarina Barlova
- IT Lucilla Baldassarri
- SE Säll Liselott
- SE Holmerin

ASOs:

- Roman Gyssels
- Boris VAN BERLO
- Jules Bossert
- Genevieve Faherty

ECHA chairs and experts

Final minutes of Human Health WG-I-2023

14, 15, 16, 21 March 2023

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

20 June 2023

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 70 members or advisers registered, of which 15 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.

The Chair gave a brief presentation on the mandate and tasks for the WG, and the roles of the members, secretariat, applicants and Associated Stakeholder Organisations.

2. Administrative issues

The renewal of the declaration of interest for core and alternative members will be launched in April 2023.

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-2022

The minutes were agreed without further changes.

6. Active substances

6.1 Garlic extract, PT 19 (eCA AT)

No reference values or absorption values are set for garlic extract, as adequate data was not available nor required for this.

6.2 Pentapotassium bis(peroxymonosulphate) bis(sulphate), PT 2, 3, 4, 5 (eCA SI)

The $AEC_{inhalation}$ is 0.175 mg/m³. No other reference values were considered necessary.

The WG agreed that KMPS should not be considered a skin or respiratory sensitiser, pending the RAC opinion.

6.2 Early WG discussion – Alphachloralose, PT 14 (eCA PL)

The read-across approach for several endpoints will be further elaborated, but also further studies on the active substance are needed.

7. Union authorisation applications

7.1 UA for a product family containing L-(+)-lactic acid, PT 3 (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 containing Hydrogen peroxide and 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.

8. Article 75(1)(g) requests

8.1 Article 75(1)(g) mandate: Comparative assessment of anticoagulant rodenticides

The draft document prepared by SECR was discussed. The principles were agreed on, and only relatively minor revisions will be needed. The toxicity rankings between substances will be removed as the differences are relatively small and with uncertainties in the reference values due to e.g. data sets and the study setups, including dose setting and dose spacing.

9. Technical and guidance related items

9.1 CLP revision

SECR informed of the status of the CLP revision. Annex I including the new hazard classes (ED, PBT, vPvB, PMT, vPvM) will follow the delegated act and will be published soon. Changes in the CLP body will be adopted following the ordinary legislative procedure (OLP). These changes include clarification on applying mixture rules on multi-constituent substances. The guidance on applying the CLP criteria will be published in 2024.

The presentation is available to members in Interact and to Associated Stakeholder Organisations in S-CIRCABC.

9.2 ARTFood: ADI and ARfD derivation for biocidal active substances

The discussion was started regarding the need to revise the earlier agreement[1] in situations where the effects are local.

The possible options were discussed for situations where ADI and/or ARfD are not derived for biocides, but these would be needed in product authorisation. In such cases, applying the values that may be available from EFSA will be considered.

9.3 ARTFood: Transfer coefficient for dislodgeable residues and systemic availability

An inconclusive discussion took place regarding the possibility to use default transfer coefficients for dislodgeable residues for the refinement of livestock exposure calculations. Further follow-up is expected.

9.4 ARTFood: Assessment of residue transfer to food from PT 3 and 4 uses for biocidal substances with MRLs

In dietary assessment for active substances in PT 3 and 4, it is necessary to request data on the efficiency of the rinsing step for substances that persist on surfaces and for which MRLs exist.

The draft ARTFood guidance on professional uses was recommended to be used in assessing residue levels. Other methodologies can be proposed. In any case, an assessment on the residues in food has to be performed.

[1] https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/95e13ba4-4da1-4f5e-b58c-c725a3b8487a/ADI and ARfD derivation.pdf

10. Any other business

10.1 Other information

Revision of ECHA Guidance Vol III Parts B+C

The drafting of the guidance has been started. An e-consultation will be launched to the members to collect feedback on the needs identified regarding the chapter on local risk assessment. Depending on the suggestions made in this context, a discussion is expected to take place in WG-II-2023.

According to provisional planning, publication of the revised guidance is expected in December 2024, pending the progress also in the revision of the CLP Regulation, CLP guidance and REACH guidance.

E-consultations

The members were asked to consider reporting to the WG on the outcome of e-consultations, as this was considered helpful for the other members.

Forthcoming events

An information session for CAs will take place on 20 April 2023 to share and discuss experience and best practices in requesting data from applicants during active substance evaluation. The registration deadline is 12 April.

A webinar "Analysis of alternatives and tools to support substitution of biocides" takes place on 26 April 2023. No registration is required. The webinar can be accessed in https://echa.europa.eu/webinars.

Next WG meetings

The next WG in June will be physical/hybrid and the remaining ones during 2023 will be virtual. The provisional timing is as follows:

- 20-22 June (physical)
- 18-29 September (virtual)
- 4-15 December (virtual)

Annex 1

Human Health WG attendees

Member state participants			
AT	Christine	HOELZL	Core Member
AT	Patrick	HOCHEGGER	Flexible Member
AT	Maximilian	KINZL	Flexible Member
AT	Angelika	DERLER	Flexible Member
AT	Ingrid	HAUZENBERGER	Rapporteur
BE	Margot	VAN CAUWENBERGHE	Flexible Member
BE	Glenn	BUVENS	Flexible Member
BE	Anis	HOUAMED	Flexible Member
CH	David	GRÜNIG	Flexible Member
CH	Daniela	GOLDINGER	Flexible Member
CH	Nadine	ROSSIER	Flexible Member
CZ	Jan	MIKOLAS	Alternate Member
CZ	Petr	SEDLAK	Flexible Member
DE	Isabel	GUENTHER	Alternate Member
DE	Kristin	HERRMANN	Core Member
DE	Dagmar	HOLTHENRICH	Core Member
DE	Annetta	SEMISCH	Flexible Member
DE	Saskia	KLUTZNY	Flexible Member
DE	Heiko	SCHNEIDER	Flexible Member
DE	Kathrin	GOTTLOB	Flexible Member
DE	Susann	MATTHES	Member's Advisor
DE	Anna	SONNENBURG	Member's Advisor
DK	Stine	JENSEN	Flexible Member
DK	Max	HANSEN	Flexible Member
DK	Maja	KIRKEGAARD	Member's Advisor
EE	Sandra	KÄOSAAR	Flexible Member
EL	Dimitra	NIKOLOPOULOU	Core Member
EL	Niki	ARAPAKI	Core Member
EL	ANASTASIA	REPOUSKOU	Flexible Member
ES	Eduardo	DE LA USADA MOLINERO	Flexible Member
ES	Ana	DE RIVAS	Flexible Member
ES	José María	SÁNCHEZ	Flexible Member
FI	Elina	RYDMAN	Flexible Member
FI	Tuija	HYVARINEN	Flexible Member
FI	Janne	ATOSUO	Flexible Member
FR	Aurelie	AUBIN	Alternate Member, Rapporteur
FR	Elisabeth	LAUMONIER-MAXIMILIEN	Core Member
FR	Julia	VARET	Core Member

FR	Julia	LORI	Core Member
FR	Perrine	CAPDEVILLE	Flexible Member
FR	Elodie	COLLIN	Flexible Member
FR	Valérie	BELLINGARD	Flexible Member
FR	Eva	JOLIVET	Flexible Member
FR	Marion	REY	Flexible Member
FR	Vincent	VAILLANT	Member's Advisor
IE	Alan	BREEN	Alternate Member
IT	Edlira	DEKOVI	Flexible Member
NL	Carina	BOS	Core Member, Rapporteur
NO	Hilde Mariken	ANDERSEN	Flexible Member
NO	Astrid	GAUSTAD	Flexible Member
NO	Sara	KJAERVIK	Member's Advisor
NO	Sabrina	AUVRAY	Member's Advisor
PL	Roman	GÓRECKI	Flexible Member, Rapporteur
PL	Helena	RZODECZKO	Member's Advisor, Rapporteur
SE	Ahmed	SABAH	Member's Advisor
SE	Rebecca	HENRIKSSON	Member's Advisor
SE	Anna	GRÄSKE	Member's Advisor
SI	Nataša	PETROVIČ	Alternate Member
SI	Vladka	LEŠER	Core Member, Rapporteur
SI	Petra	ČEBAŠEK	Flexible Member
SI	Katja	VERDNIK	Flexible Member
SK	Ružena	PILIŠIOVÁ	Flexible Member
SK	Roman	OLHA	Flexible Member
SK	David	DRAB	Member's Advisor

Accredited Stakeholder Organisations (ASOs)	
CEFIF	Jules Bossert
CEFIC	Boris Van Berlo
CEFIC	Katie Clark-Schmid
AISE	Marie Darriet
AISE	Joanna Kupny

Applicants
Ecospray Limited
Exponent
Lanxess
SCC Gmbh
Huvepharma
Kersia Group
SPECTRA

ECHA staff
Antero Airaksinen
Micaela Damsten
Eva Hämäläinen
Pia Korjus
Gesine Muller
Jonas Nygren
Lina Papadaki
Kostas Prevedouros
Katya Vasileva