Final minutes of the Working Group meeting IV in 2022

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

(Meeting date: 07-08 December 2022 – virtual meeting)

21 December 2022

1. Welcome and apologies

The meeting was a virtual meeting. The Chair welcomed the participants of the working group meeting. CEFIC registered for the meeting as accredited stakeholder organisations (ASO). The 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.

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

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

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

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).

Several members indicated that they wanted to add additional issues to agenda point 8.1. The chair proposed to extend the time planned for item 8.1 and exchange the order of items 8.2 and 9.1.

The agenda was agreed with these 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 III 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. Nitrogen generated from ambient air (Annex I, cat 2)

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

6.2. Reaction mass of peracetic acid and peroxyoctanoic acid – post approval data PT 2, PT 3, PT 4

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

7. Union Authorisations

7.1. UA for a product family containing mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) PT 6, PT 11, PT 12, PT 13

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

7.2. UA for a product family containing peracetic acid PT 2

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

8. Technical and guidance related issues

8.1. Exchange on problems during evaluation

The working group discussed issues observed in current evaluations to determine whether in-depth discussion is needed.

8.2. Reference specification in renewal assessment

Please refer to the specific minutes of this agenda item.

9. AoB

9.1. Outcome of e-consultations

The outcome of recent e-consultations was presented to the working group for information.

9.2. Outcome of the industry consultation on in situ recommendations

The outcome of the industry consultation on the in-situ recommendations was presented to the working group.

9.3. Update of the APCP TAB

The working group discussed whether a more thorough review of the content of the APCP TAB is justified. Some members will work on a proposal to be presented in the working group.

Annex 1 - List of attendees registered for the meeting

Working group member	Member state

Colson	Jerome	AT
Ghobrial	Michael	AT
Burmistova	Anastasia	BE
Dang Thy	Minh-Dung	BE
Fauconnier	Steven	BE
Herremans	Yannick	BE
Huerga Fernandez	Samuel	BE
Aeschbacher	Michael	CH
Courdouan Merz	Amandine	CH
Vlasak	Martin	CZ
Muhle	Ulrike	DE
Triantafillopoulos	Maria	DK
Vallikivi	Imre	EE
Cano	David	ES
Escalada	Jesus	ES
Vuorensola	Katariina	FI
Aubin	Aurelie	FR
Lutz	François	FR
Six	Therese	FR
Weber	Philippe	FR
Cataldi	Lucilla	IT
Kruidhof	Sabine	NL
van Rijnsbergen	Peter	NL
Stave Sekkenes	Marianne	NO
Ur Gjerde	Ingrid	NO
Horczyczak	Anna	PL
Österwall	Christoffer	SE
Velikonja Bolta	Špela	SI
Drabová Kušíková	Zuzana	SK
Porubiak	Michal	SK

Working group advisor		**Member state**
Altmann	Dominik	AT
Derler	Angelika	AT
Hoelzl	Christine	AT
Kührer	Lukas	AT

Swennen	Kim	BE
Yuksel	Aysel	BE
Anke	Julia Margaretha	DE
Burkart	Corinna	DE
Deden	Tobias	DE
Rey	Juliana	DE
Weinheimer	Viola	DE
Gilson	Arthur	FR
Lori	Julia	FR
Straczek	Anne	FR
Blaga	Cornelia	NL
Bourke	Alena	NL
Storm	Ingeborg	NL
Marsh	Göran	SE

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
CEFIC	Bossert Jules Dressen Sabine
AISE	Darriet Marie Regnier Marie
EurO3zon	Gyssels Roman

Applicant	**Agenda item**
GAB Consulting GmbH	6.1
Ecolab Deutschland GmbH	6.2
TSG Consulting	7.2

ECHA staff
Uphoff Andreas
Marcon Eva
Hamalainen Eva
Szanto Emese
Estevan Martinez Carmen
Airaksinen Antero

EFF WG-IV-2022

Final minutes 14

March 2023

Final minutes of Efficacy WG-III-2022

7 and 8 December 2022

Meeting of the Efficacy Working Group of the Biocidal Products Committee

Efficacy Working Group

1. Welcome and apologies

The Chair welcomed all participants to the Efficacy Working Group (EFF WG) meeting and informed that this meeting is split into 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 had sent comments on the EFF WG-III-2022 draft minutes. The revised draft minutes of WG-III-2022 were agreed at the meeting.

6. Discussion of active substances

6.1 Nitrogen generated from ambient air (Annex I, cat 2) (eCA DE)

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 mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) (eCA NL)

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

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

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

7.3 Early WG on UA-APP containing peracetic acid (eCA NL)

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)

The outcome of the e-consultation on the purpose of the resistance assessment, the draft of the introduction, and the draft of the literature review parts prepared by FR and DE were discussed.

Regarding the e-consultation and the discussion during the meeting, it was agreed that question 2, i.e. 'What resistance against the biocide in question is out there and how does it affect efficacy' is the most appropriate for the assessment of resistance. Cross-resistance will be included in this question as well. Question 1, i.e. 'Can the biocide in question (i.e. the active substance(s) in it) cause the development of resistance (or cross-resistance) and how likely is that' may be relevant in cases when information on resistance or mode of action is available. It was also agreed that the literature review should take place at AS

approval stage. In the case of Main Group III it is not possible to address all possible target organisms at the AS approval stage and the information about resistance needs to be updated at the PA stage. The discussion concerning the nature of data collected from the literature review was forwarded to the discussion on the literature review part.

There were limited comments concerning the introduction part. Some clarifications were given by FR related to biofilm as a factor for resistance development and a multi-generation term. Following these clarifications and the views of the WG members, it was agreed to amend the sentence: *'Active substance able to induce a high frequency of mutation'* it was agreed to amend to: *'Active substance able to induce mutations related to resistance in target organisms'*. From the section concerning factors that may promote the development of resistance, it was agreed to remove the point related to the use of biocide over biofilm and to amend the sentence *'Use of active substances that expose "multi-generations" of the target organism as opposed to single generations to one application is more liable to cause resistance'* to *'Use of active substances that expose the target organism - e.g. due to a short generation cycle of the target organism - is more liable to cause resistance'*.

With reference to the literature review part of the draft guidance first of all it was agreed that the applicant will prepare a separate document containing the literature review and this document will be uploaded as a part of the IUCLID dossier, and then, the eCA will include their own assessment in the CAR. Regarding the target organisms to be addressed in the literature review at the AS approval stage it was agreed that for the Main Group I bacteria, yeasts/fungi and viruses have to be covered unless the AS has any different, specific or additional spectrum of activity. With reference to AS notified in PT8 microorganisms and/or the claimed insects need to be reflected in the literature review, in case no insecticidal activity is claimed at the AS approval stage it has to be addressed at the PA stage if claimed.

Regarding the use of data based on laboratory studies the WG agreed that for microorganisms and macroorganisms ideally the assessment should be based on the field population and high-quality laboratory evolution studies may be treated as an indication only and information from the field should be requested later on.

The section concerning relevance and reliability will be revised, examples will be removed, and it will be highlighted there that the relevant literature should investigate whether resistance arises in conditions that are close to the real-use conditions.

With reference to the test product, it was pointed out that the concentration of the active substance has to be clearly stated and information about other active substances present in the product has to be given. Other information is not mandatory but may be treated as supportive.

Discussion on checkpoint after the literature review was postponed due to the earliest agreements not being implemented yet into the draft guidance. The discussion will be continued during WG-I-2023.

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

Some of the WG members raised their concerns regarding this proposal to unify the requirements for all three SU tests against mosquitoes. The concern raised referred to the average required landing rate achieved during the entire test. As pointed out by some of the members this approach is currently introduced in the room test but not necessarily has to be followed by the AIC and ATC tests. At the same time, IND proposed to amend the current text as followed:

Over the entire test an average of the required landing rate must be achieved. Due to the natural behaviour, variations in mosquito activity during the day are likely. Therefore, landing rates below and above the required landing rate at the different test intervals are acceptable as long as the mean landing rate remains at or above the required landing rate during the whole observation period.

As the WG members shared different opinions the discussion had been postponed to the WG-I-2023 meeting.

8.3 PT21 - Antifouling products for pleasure crafts –improvement between the efficacy and the environmental assessment (SE)

A joint session of EFF WG and ENV WG took place on the improvement between the efficacy and environmental risk assessment. SE presented the background information on previous discussions and presented some proposals on how to improve the assessment, including a new test requirement for the efficacy assessment to include field tests in different regions (reflecting the characteristics of areas where use is intended). Many general issues were raised, considering the MR process, practical enforcement and misuse regarding use only in certain areas, as well as the difficulty to pass the environmental risk assessment, especially for the Baltic region. Several remarks were made that the discussion regarding regulatory implementations should be brought to the CA level. For the ENV assessment, several members noted that ENV assessment should follow the EFF assessment taking into account dry film thickness and service life, but there should be better guidance for the field tests. It was also noted that a minimum efficacious dose should be used for the risk assessment, so it is important to have testing data for relevant use conditions. The WG was generally positive regarding the new test requirements, nevertheless, several regulatory and scientific issues did not facilitate reaching an agreement and finding a clear way forward.

9. AOB

9.1 Other information

Short information was given about the upcoming EFF WG-I-2023 meeting, the deadline for early WG discussion requests and working document submission, the current status of the published and draft guidance and ongoing e-consultations. In addition, ECHA has informed that:

- bilateral cross-check with the COM has started on how to proceed with the overdosing issue, i.e. higher concentration of the active substance in the product than needed and with a higher/lower volume of the product than needed;
- to address better our guidance needs at the beginning of 2023 ECHA intends to launch an e-consultation between the EFF WG members concerning guidance prioritisation;
- the outcome of the court case concerning silver zeolite and silver copper zeolite.

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)
   - GRUNIG David (CH)
   - DONZE Gerard (CH)
   - MEIER Margrith (CH)
   - RUSCONI Manuel (CH)
   - BAUMGARTNER Rebekka (CH)
   - SVEJSTIL Roman (CZ)
   - PECINKOVA Martina (CZ)
   - DOLEŽELOVÁ Katsiaryna (CZ)
   - CLEYTON JØRGENSEN Charlotte (DK)
   - FISCHER Juliane (DE)
   - TRAUER-KIZILELMA Ute (DE)
   - KÄOSAAR Sandra (EE)
   - PEREIRO COUTO Natividad (ES)
   - NIEMINEN Timo (FI)
   - HADDACHE Nabila (FR)
   - BRIZARD Mathias (FR)
   - OWENS Aoife (IE)
   - RONCI Maria Beatrice (IT)
   - BALDASSARRI Lucilla (IT)
   - KASPRZAK Karolina (PL)
   - ÅSLING Bengt (SE)
   - DANADAIOVA Emese (SK)
3. **Rapporteurs:**
   - JANSEN Irina (DE)
   - DEKKERS Bas (NL)
   - JONGERIUS Aniek (NL)
   - WARMERDAM Sonja (NL)
4. **Advisors:**
   - DANG THY Minh-Dung (BE)
   - PORTELA Cristina (ES)
   - BRIDIER Arnaud (FR)
   - SOUMET Christophe (FR)
   - DEKKER Bas (NL)
   - Jongerius Aniek (NL)
   - PORUBIAKOVA Jadza (SK)
   - JASSOVA Juliana (SK)
5. **ECHA Staff**
   - SZYMANKIEWICZ Katarzyna (Chair)
   - RAULIO Mari
   - HONKA anni
   - VETELAINEN Kaisa

6. **Stakeholders:**
   - VAN BERLO Boris (CEFIC)
   - THEELEN Meredith (CEFIC)
   - THOM Ellen (CEFIC)
   - FAHERTY Genevieve (CEFIC)
   - DARRIET Marie (AISE)
   - CORNER Hannah (AISE)
   - GYSSELS Roman (EurO3zon)
7. **Applicants:**
   - TROY CHEMICAL COMPANY BV
   - CID LINES NV

Environment WG-IV-2022

Final general minutes

13-16 December 2022

Final minutes of Environment WG-IV-2022

Including TAB entries for revision in Appendix I

13, 15 and 16 December

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 54 participants present (virtual meeting), of which 9 were core or alternate members. Four representatives from accredited stakeholder organisation were present at some agenda items, as well as two experts from academia for item 8.2. Applicants were registered for their specific substance discussions.

2. Administrative issues

SECR informed on several administrative issues.

3. Agreement of the agenda

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

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

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

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

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

6. Discussion on active substances

6.1 Nitrogen generated from ambient air (Annex I, cat 2), PT 18 (eCA DE)

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

There were no open points.

Action: None

6.2 Early WG discussion on the environmental risk assessment approach for Bronopol PT 2, PT 6, PT 11, PT 12, PT 22 (eCA ES)

The WG agreed with the proposed approach for the environmental risk assessment. Please refer to the confidential minutes provided to Member State Competent Authorities in Interact and to the applicant in R4BP 3.

Action: None

7. Discussion of Union Authorisation cases

7.1 UA for product family containing mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT) PT 6, 11-13 (eCA NL)

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

12 open points and 6 provisionally closed points were discussed, all of which were closed at the meeting. Due to substantial changes to environmental risk assessment following the implementation of the WG agreements it was agreed to have an ad hoc follow-up to review the changes made to the revised PAR before submission to ECHA.

Action: SECR to schedule an ad hoc follow-up with the eCA, DE and FR.

7.2 UA for a product family containing peracetic acid, PT 2 (eCA NL)

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

1 open point was discussed related to a CG-54 agreement that requires clarification of product application frequency instead of stating “as required” or similar. The WG opinion was noted regarding clarification of application frequency.

Action: None

8. Technical and guidance related topics

8.1 Worst case and best case concentrations in a product family

Discussion of this item was postponed to the next WG.

Action: Item moved for discussion in the next WG.

8.2 PT21 - Antifouling products for pleasure crafts – improvement between the efficacy and the environmental assessment

Joint session of EFF WG and ENV WG took place on the improvement between the efficacy and the environmental risk assessment. SE presented the background information on previous discussions and presented some proposals on how to improve the assessment, including a new test requirement for the efficacy assessment to include field tests in different regions (reflecting the characteristics of areas where use is intended). Many general issues were raised, considering MR process, practical enforcement and misuse regarding use only in certain areas, as well as the difficulty to pass the environmental risk assessment, especially for the Baltic region. Several remarks were made that the discussion regarding regulatory implementations should be brought to the CA level. For ENV assessment, several members noted that ENV assessment should follow the EFF assessment taking into account dry film thickness and service life, but there should be better guidance for field tests. It was also noted that lower efficacious doses could be validated and used for the risk assessment, so it is of importance to have testing data for relevant use conditions. The WG was generally positive regarding the new test requirements, nevertheless, several regulatory and scientific issues did not facilitate reaching an agreement and finding a clear way forward.

8.3 Validation on the assessment strategy and endpoints for the substance of concern 2-aminoethanol (CAS 141-43-5) in PT08 products

A discussion took place following an e-consultation regarding the assessment of a substance identified as SoC. Summary of the proposed endpoints was presented by FR. The WG was asked to reply to five questions related to harmonisation of the endpoints for MEA and the risk assessment for groundwater. The WG agreed to only consider MEA as a SoC for PT08 products when it is present at a concentration ≥ 25%. Questions were raised regarding the applicability of the general threshold for groundwater of 0.1 µg/L for co-formulants as SoCs in general, which needs to be clarified at a more general level (CG/CA/COM). It was clarified that at a concentration ≥ 25% the substance would be considered as SoC for environment, so assessment of all compartments would be needed, while at concentrations < 25% only groundwater assessment is needed due to human health concerns.

There was no agreement regarding the value for DT50 in soil presented in the e-consultation, since the WG expressed concerns regarding the sources that the value is based on. It was therefore suggested to use the default value (30 days) until the study reports can be provided to support the DT50 of 7 days as suggested by NL. The WG agreed on the other proposed endpoints and that Henry's law constant K_H should be added.

Action: NL will send a report that would support a DT50 of 7 days. In case, based on additional data (because of literature data or earlier agreements) FR considers the default values are not to be used, FR will bring the topic back for discussion.

Action: FR will revise the TAB proposal, based on the comments received. The TAB entry will be made more general.

8.4 Organic carbon normalisation – follow up WG-V-2019 and WG-II-2020

A discussion took place on the effect assessment for sediment and soil and the need for normalisation to organic carbon. It is a follow-up of earlier WG discussions (ENV WG V 2019; ENV WG II 2020) and included a proposal to reverse an addition to the ENV Guidance document from 2017. DE and NL presented conflicting views on this topic. The WG could not conclude on the topic and there will be a follow-up next year.

Action: SECR to include it on the agenda for a future ENV WG.

8.5 In situ recommendations – outcome of written consultation

The revised chapter of the recommendations for the in-situ active substances was sent for written consultation to the ENV WG and to ASOs for commenting from 3.10 – 4.11.2022. Comments received were analysed by the in situ ENV task group and will be considered.

Three issues were identified for further consultation of the ENV WG:

1. Criterion to define "fully consumed" precursor
2. Setting a concentration threshold for impurities that need to be assessed as SoC in the risk assessment
3. Derivation of K_{oc} for constituents that do not belong to substance classes specified by QSAR methods applicability

The WG agreed on the criteria for “fully consumed” (1), the applicability of a 0.1% concentration threshold for impurities that need to be assessed as substance of concern analysis (SoC) in the risk assessment but under consideration of recent CA decisions (2) and on the inclusion of K_{oc} in Figure 7 as an information requirement (3).

8.6 Chesar Platform development

ECHA provided a presentation on the latest developments on the Chesar platform, including the scenario repository and the inclusion of the emission scenarios in the Chesar Platform library. SECR presented four previously outstanding topics for which agreement was reached at TEG ENVI November 2022: (1) sewer removal; (2) direct release approaches (Application to agricultural soil other than via STP sludge, Direct release to non-agricultural soil, Direct release to static water (pond/lake)); (3) Kp_{sed} and Kp_{susp} differentiation between freshwater and seawater; (4) Temperature correction - Calculation of vapour pressure and water solubility.

8.7 Pollinator guidance

ECHA provided a presentation on the latest developments on the pollinator guidance document and explained the links to the related work ongoing at EFSA. SECR informed experts of the upcoming consultation on the document next year, planned for 2023.

9. AOB

9.1 Other information & lessons learned (SECR)

Next WG meetings
The provisional timing of coming WG meeting: 13-24 March 2023. The meeting takes place as virtual meeting, exact days to be established. It is foreseen to have one physical meeting per year in the future.

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

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

Providing new information during opinion forming
A combined document for AS and UA was endorsed at BPC-45.

Application frequency “as required”
It was agreed at CG-54 that the term “as required” or similar can no longer be used as application frequency in the use instructions, instead the maximum or typical number of applications per day has to be stated.

Article 75(1)(g) COM Mandate - Questions regarding the comparative assessment of anticoagulant rodenticides

SECR informed the working group that the assessment by ECHA is almost finished and that the TOX WG and ENV WG will be consulted on the document next year. The consultation is still to be launched this year and the WG discussion is planned for WG I 2023. The BPC discussion for adoption is planned for BPC-47 (June 2023).

Applicability of fate models for service life

SECR presented the ongoing discussion at the expert group on the rule when to apply the repeated release equations versus situations where to apply the continuous release equation (e.g. house leaching, lake swimming).

PBT/vPvB guidance update

There is currently ongoing PEG consultation for the revised versions of R.11, R.7b and R.7c guidance. The publication of the updated PBT guidance is planned for September 2023. The overview of the progress will be presented in the next WG.

TAB

Updated version of the TAB was published 14 October 2022. Several issues have been raised by WG members to which SECR will follow-up on next year.

Item 8.1 Worst case – best case scenario's

SECR explained that at TOX WG III 2022, the WG agreed on a proposal from DE to determine the best/worst case concentrations in biocidal product families. SECR will introduce the item at the next ENV WG, to discuss adopting a similar approach for the ENV assessment.

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

ED assessment

Reminder to only submit dossiers with a clear ED conclusion and to have an early WG discussion in case of waiving of ED assessment.

Appendix 1: List of participants

Core members and alternates:

- AT Lukas Kührer
- DE Daniel Frein
- DE Eleonora Petersohn
- FR Stéphanie Alexandre
- FR Anne Straczek
- IE Helena Joyce
- NL Barry Muijs
- DE Sascha Setzer
- NL Karlijn Holthaus

Flexible members:

- AT Dominik Altmann
- AT Lea Breul
- BE Celine Leroy
- BE Wiet Raets
- CH Maria a Marca
- CH Tenzing Gyalpo
- CH Petra Kunz
- DE Maren Ahting
- DE Julia Margaretha Anke
- DE Stefanie Jacob
- DE Katja Michaelis
- DK Henrik Wennermark
- EE Helen SULG
- ES Ángeles Jiménez
- ES Myriam Martin Vallejo
- ES Elena Fuensanta Ruiz Lopez
- FI Oskari Hänninen
- FI Sanna Kaukoniemi
- FI Jaana Pasanen
- FI Sari Penttinen
- NL Els Smit
- NL Peter van Vlaardingen
- NO Terje Haraldsen
- NO Karina Petersen
- PL Agnieszka Podlaska
- SE Rina Andersson
- SE Lena Konovalenko
- SE Johan Persson
- SI Bert Van Der Geest
- SK Jana Molnarova

Advisors:

- DK Jesper Johannessen
- FR Yannice Convert
- FR Arthur GILSON
- FR Fanny Herard
- FR Jeanne Raynert
- FR Séléné Verstraet
- NL Zhichao Dang
- NL Peter Okkerman
- NO Sanne Helene Kristensen
- SK Jan Bilohuscin
- SE - Maria Lagerström (Chalmers University of Technology)
- SE - Erik Ytreberg (Chalmers University of Technology)

ASOs:

- Jules Bossert
- Katie Clark-Schmid
- Kadriye Hieronymi
- Roman Gyssels

ECHA chairs and experts

Human Health WG-IV-2022

Final minutes

14 March 2023

Final minutes of Human Health WG-IV-2022

8-9; 13 December 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 57 members or advisers registered, of which 14 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

SECR highlighted the importance of filling in the role of the members when registering.

In Interact, the modification/inclusion time of the document is now visible, which should facilitate following the items added for the meetings. In the future, notifications are expected.

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-III-2022

The minutes were agreed without further changes.

6. Active substances

6.1 Nitrogen generated from ambient air (Annex I, cat 2), PT 18 (eCA DE)

The WG discussed the need of ensuring a safe oxygen level during nitrogen generation. These discussions will be finalised at the BPC.

7. Union authorisation applications

7.1 UA for a product family containing mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT), PT 6, 11-13 (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 peracetic acid, PT 2 (eCA NL)

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

8. Mutual recognition

8.1 Request for ECHA opinion pursuant to Articles 36(2) and 38 of the BPR – biocidal product containing Chlorocresol and lactic acid (PT 3)

This discussion was to inform the members of an e-consultation launched to the Member States and the applicant. Since no WG discussion will be possible for this request, the importance of input during e-consultation was highlighted.

9. Technical and guidance related items

9.1 In situ generated active substances – revision of recommendations

SECR informed of the status of the guidance development in the different task forces. Commenting on the merged full document is expected during Q2 2023. The finalisation is expected by the end of 2023. The presentation is available to members in Interact and to Associated Stakeholder Organisations in S-CIRCABC.

9.2 Implications of GLP in REACH and BPR

SECR gave a presentation on GLP. The presentation is available to members in Interact and to Associated Stakeholder Organisations in S-CIRCABC.

10. Any other business

10.1 Other information

SECR informed of the findings in the bilateral discussions held between the Chair and the (alternate) core members. The presentation is available to the members in Interact.

Documents published

- *Definition of worst-case (wcc) and best-case concentrations (bcc) of a biocidal product family*

  Document provided by DE, discussed and agreed at WG-III-2022 is now published in S-CIRCABC under "Documents agreed at WG meetings"[1].

- *CA-Oct22-Doc.7.3 General approach regarding the relevance of metabolites for groundwater – applicability of existing guidance*[2]

  Revision for the SANCO guidance on groundwater metabolites is foreseen in the near future, but there is no schedule yet. Once revised, the guidance should explicitly mention that it is also applicable for biocidal products.

  The document concludes that 1) the current SANCO guidance (221/2000 rev 11) can be used for biocides, 2) a risk assessment cannot be performed on relevant metabolites, and 3) a Carc. Cat. 2 metabolite should always be considered relevant under the current guidance**.**

- *New information in active substance and Union authorisation opinion forming*

  The document merges the two documents that were until now separate for active substance approval and Union authorisation. Some of the relevant changes were flagged, such as 1) the conditions for accepting new information no more include that the conclusion of the assessment has changed due to the peer review – the

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

[2] https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/4031a508-65dd-4c3c-b136-b60861108530/details

new condition is that the new information has the potential to change the outcome of the evaluation of the eCA; and 2) an ad hoc follow-up is always needed if new information is requested. The document was agreed at BPC-45 and will be published shortly.

- *CG-54_e-c Use of the term "as required" for the application frequency*[3]

  For product authorisation, use frequency has to be given in SPC and PAR. The maximum or typical number of applications per day has to be stated.

  The term 'as required' (or similar terms, e.g. 'daily use') for application frequency is not accepted without further justification; a justification could be based on showing safe use by a reverse reference scenario.

Revision of ECHA Guidance Vol III Parts B+C

The drafting of the guidance has been delayed considering the ongoing CLP revision and several other ECHA guidance developments that are also relevant for the biocides guidance.

According to provisional planning, the drafting will start in January 2023 and invitations to PEG will be sent in September 2023. The PEG consultation is expected in February 2024 and the PEG meeting in June 2024. The consultation of Commission and CAs should be launched in September 2024 to publish the guidance in December 2024. This provisional timing is dependent on the progress of other guidance documents to be delivered before finalising the ECHA Guidance Vol III Parts B+C.

ARTFood WG

A meeting of the ARTFood (Assessment of Residue Transfer to Food) will take place in January 2023. The date will be based on the input from members.

Anticoagulant rodenticides – COM mandate

A COM mandate[4] under BPR Article 75(1)(g) poses questions to ECHA regarding the comparative assessment of anticoagulant rodenticides. Questions (a)- (e) of the mandate were already adopted at BPC-45, and the remaining question (f) is whether some anticoagulant active substances would have a lower overall risk for human health,animal health and the environment than others.

An e-consultation for the Human Health WG and Environment WG will be launched and a WG discussion will follow at WG-I-2023 in March.

Next WG meetings

The next WG in March will be virtual and one meeting during 2023 is expected to be physical. The provisional timing is as follows:

- 13-24 March (virtual)
- 19-30 June
- 18-29 September
- 4-15 December

[3] https://webgate.ec.europa.eu/s-circabc/w/browse/89efe476-1017-46af-8a31-6ad845f79d04

[4] https://echa.europa.eu/documents/10162/3443005/mandate_opinion_request_anticoagulant_rodenticides_en.pdf/492f2e46-fcbb-3626-f695-9d1dd9d00dce?t=1636378792843

Annex 1

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