Minutes of the Working Group meeting III in 2021
Analytical Methods and Physico-Chemical Properties
(Meeting date: 07-10 September 2021 – WebEx meeting)

16 November 2021

1. Welcome and apologies

The meeting was a WebEx-meeting. The Chair welcomed the participants of the working group meeting. CEFIC was present at the meeting as an accredited stakeholder organisation (ASO) with one representative. The following applicants were invited to the meeting as an observer for their agenda items:

- EurO3zon
- Cid Lines

Participants of the working group meeting were informed that the meeting is recorded, but solely for drafting the minutes and the recording will be destroyed after the agreement of the meeting minutes. The recording is not released to anybody outside ECHA and any further recording is not allowed.

2. Administrative issues

A presentation on the administrative matters was provided for information by ECHA.

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 further items were proposed.

The agenda was agreed.

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 agenda. None was declared by the working group members.

5. Agreement of the draft minutes from WG II 2021

The working group members provided three comments on the draft minutes of WG II 2021. These comments were discussed. The draft minutes were modified accordingly and were agreed by the working group members.

6. Discussion of the outcome of e-consultations

6.1 Possible co-formulants in sodium chloride as precursor for the active substance 'active chlorine generated from sodium chloride by electrolysis'

The received considerations of the working group members were presented and discussed. Hence, the working group provided advice to the enquiring member state.

6.2 Substance identification for active chlorine released from sodium hypochlorite in case of a change of the pH value

The received considerations of the working group members were presented and discussed. Hence, the working group provided advice to the enquiring member state.

6.3 Follow-up of WG II - UA for L+R Propanol PT1 Family PT 01

The discussion of the WG II 2021 meeting concluded that further a test can be provided for the BPF. Meanwhile, ahead of the next BPC meeting, the applicant provided the study which was evaluated by the eCA. The working group members agreed with the conclusion of the eCA. Consequently, this point is closed. The eCA should update the PAR and inform the BPC meeting accordingly.

6.4 Follow-up of WG II - UA for Knieler & Team Propanol Family PT 01, 02, 04

The discussion of the WG II 2021 meeting concluded that further a test can be provided for the BPF. Meanwhile, ahead of the next BPC meeting, the applicant provided the study which was evaluated by the eCA. The working group members agreed with the conclusion of the eCA. Consequently, this point is closed. The eCA should update the PAR and inform the BPC meeting accordingly.

7 Technical and guidance related issues

7.1 Physical hazards waiving

The working group members discussed the waiving justifications for a number of hazard classes and agreed on the principles of acceptable justifications. It was agreed that these principles can be modified if more experiences are gained.

7.2 Revision of the working group recommendations for in situ generated active substances – APCP part

The revision of the working group recommendations for in situ generated active substances was discussed at the working group meeting III in 2020. The recommendations were revised according to the conclusions of this discussion and this revision was commented until August 2021. The received comments were discussed and agreed at the meeting.

8 Discussion of active substances

8.1 Ozone generated from oxygen – PT 02, 04, 05, 11

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

8.2 Alkyl(C12-16)dimethylbenzylammonium chloride (C12-16-ADBAC/BKC) – PT 01, 02

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

8.3 Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbondioxide – PT 18, 19

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

8.4 Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvent – PT 18, 19

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

8.5 Didecyldimethylbenzylammonium chloride (DDAC) – PT 01, 02

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

9 Discussion of Union Authorisations

9.1 Contec Hydrogen Peroxide Biocidal Product Family PT02

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

9.2 Lactic acid based products - CID LINES NV PT01, 02, 03, 04

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

Annex 1 - List of attendees registered for the meeting

Working group member		Member state
Erich	Neuwirth	AT
Isabel	Kriegl	AT
Anastasia	Burmistrova	BE
Minh-Dung	Dang Thy	BE
Natania	Peelman	BE
Steven	Fauconnier	BE
Amandine	Courdouan Merz	CH
Michael	Aeschbacher	CH
Martin	Vlasak	CZ
Ulrike	Műhle	DE
Natja	Erlingsson	DK
Katrine	Domino	DK
Imre	Vallikivi	EE
David	Cano	ES
Jesus	Escalada	ES
Pedro	Fuertes	ES
Luisa	Gonzalez	ES
Katariina	Vuorensola	FI
François	Lutz	FR
Philippe	Weber	FR
Therese	Six	FR
Lucilla	Cataldi	IT
Ieva	Igaune	LV
Ingeborg	Storm	NL
Peter	van Rijnsbergen	NL
Sabine	Kruidhof	NL
Marianne	Stave Sekkenes	NO
Trygve	Helgerud	NO
Anna	Horczyczak	PL
Sylwester	Huszał	PL
Andreas	Ryden	SE
Mia	Alpe	SE
Špela	Velikonja Bolta	SI
Michal	Porubiak	SK
Zuzana	Drabová Kušíková	SK

ECHA staff
Krebs Bernhard (Chair)
Uphoff Andreas
Marcon Eva
Schakir Yasmin

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

Company	Agenda item	Observer
EurO3zon	8.1	Ryckeboer Jaak Gyssels Roman
Cid Lines	9.2	Decroix Lies Antczak Sylvain

WG-III-2021

Final minutes

17 November 2021

Minutes of Efficacy WG-III-2021

8, 10 and 14 September 2021

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.

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that the recordings would be destroyed after the agreement of the minutes. 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 members 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-II-2021 draft minutes. The revised minutes were agreed at the meeting.

6. Discussion of active substances – 8 September 2021

6.1 Ozone generated from oxygen (eCA DE)

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

6.2 Alkyl(C12-16)dimethylbenzylammonium chloride (C_{12-16}-ADBAC/BKC) (eCA IT)

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

6.3 Didecyldimethylammonium chloride (DDAC) (eCA IT)

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

6.4 Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbondioxide (eCA ES)

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

6.4 Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents (eCA ES)

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

7. Discussion of Union Authorisations – 8 September 2021

7.1 UA for a product family containing hydrogen peroxide (eCA SI)

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 L-(+)-lactic acid (eCA SI)

There were three open points, two were closed at the meeting, for the remaining open point an ad hoc follow-up was launched. In addition, there were four provisionally closed points, which remained closed at 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 and 14 September 2021

8.1 Antimicrobial resistance **-** draft guidance (FR)

The EFF WG agreed on the following definitions:

Resistance is the naturally occurring, inheritable adjustment in the ability of individuals in a population of a target species to survive a biocide treatment that would normally give effective control (EPPO PP1/213, adapted). For resistance assessment in the frame of the BPR, only acquired resistance is considered. Acquired resistance refers to traits in a given species that have occurred due to biocide use and are thus specific to certain lineages or strains, but not inherent at the species or at higher taxonomic levels.

Cross-resistance is a phenomenon in which individuals in a population, which are resistant to a biocidal active substance or product, are also resistant to one or more other substance(s). This phenomenon can occur through a single or multiple molecular mechanisms. These mechanisms will be considered in the frame of the BPR.

Adaptation is the change in traits of individuals in a population because of a change in their environment. Adaptation goes well beyond the development of resistance and can affect any property of the organism. In the context of this guidance, adaptation refers only to changes in susceptibility towards biocides. These changes include either reversible changes that do not affect the organism's underlying genetic material (phenotypic adaptation) or stable, inheritable changes on the genetic level (genotypic adaptation). Phenotypic adaptation towards reduced biocide susceptibility during exposure with the biocide is not considered as resistance in the context of resistance assessment in the frame of the BPR.

Tolerance is the general ability of organisms to withstand stress (either constitutively or adaptively). Tolerance includes genotypic and phenotypic adaptations. Genotypic adaptation may be considered as resistance in the frame of BPR (see other definitions).

These definitions will be implemented in the draft AMR guidance.

8.2 TAB proposals

The EFF WG agreed on the TAB proposals. The agreed TAB entries are presented below:

PT18: Crack and crevice treatment - test requirements (applicable for all PT18 products, i.e. insecticides, acaricides and other biocidal products against arthropods) with a crack and crevice treatment claim)

What kind of simulated use test should be provided in the context of product authorisation of e.g. an "insecticide against crawling insects with crack and crevice treatment" when using the definition of "the application of a small amount of insecticide directly into cracks and crevices where insects hide or where they may enter"?

To demonstrate the efficacy of a product with a crack and crevice treatment claim, the results of the efficacy tests should meet the pass criteria for a product intended for use as general surface treatment.

For crack and crevice treatment the following test setup is proposed:

- The trial is performed in the laboratory, in a test chamber simulating the real conditions of use, by treating cracks and crevices of a designed "furniture", releasing insects, and counting their knockdown and/or mortality, according to the claim. The furniture which represents the cracks and crevices should be put in the test chamber before its treatment in order to simulate the real condition of use.
- The duration of exposure and results in terms of knockdown and/or mortality should be consistent with the requirements for the species in the efficacy guidance Vol. II, Parts B+C, PT18 Chapter and in accordance with the product's claim. Also, an acclimatization period is required, consistent with the ecology of the target species.
- Depending on the dose expression, e.g. in g par linear meter, and the mode of application, e.g. space between cupboard and floor; cracks in the wall, etc., the space between panels in the furniture should be adapted to the claim and should be relevant regarding the target organisms claimed. The material of the treated surface (porous, non-porous) is not relevant, as the goal is to evaluate the mortality of hidden insects which are directly treated by the product.

Only for a crack and crevice treatment with a residual efficacy claim:

- The insects have the choice not to be in contact with the product and are not forced to be in contact with the treatment to reach water and food sources. In addition, sufficient untreated shelter should be available to the target species (either an untreated section in the test furniture or an additional crack and crevice shelter in the test arena, which can be placed after acclimatization).
- The treated surfaces, e.g. porous and non-porous tiles, inserted into the designed furniture, or treating directly on the furniture surface, should be representative for the surface types claimed. For a general claim (without specific claimed surface types) both porous and non-porous surfaces need to be tested separately, in line with the requirements for that target species in the efficacy guidance Vol. II, Parts B+C, PT18 Chapter. If such guidance is missing for the target species, 2 porous surfaces and 1 non-porous surface need to be tested.

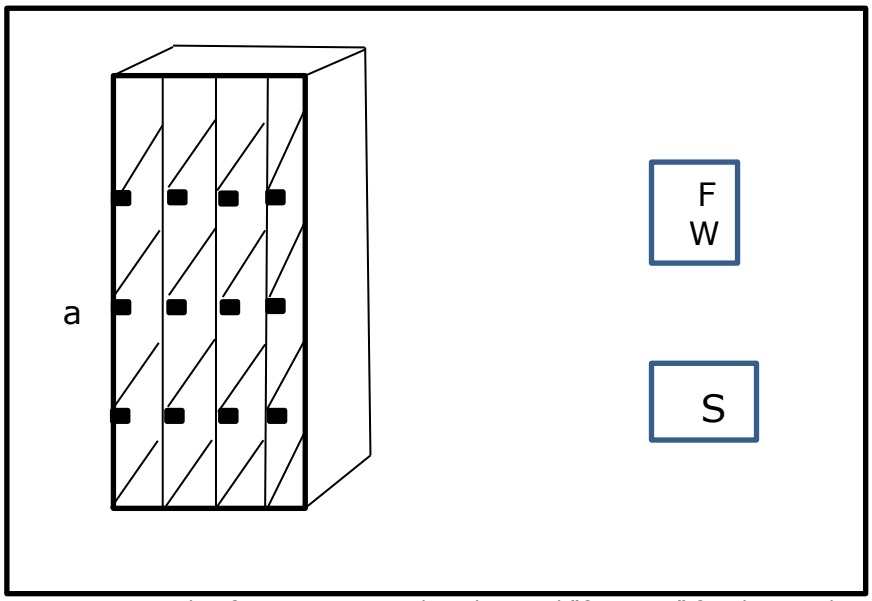

Figure.1: Example of a test arena with a designed "furniture" for the simulated-use test for testing crack and crevice treatment against crawling insects. Treated tiles are inserted into the entry of the simulated use furniture. The location of the additional shelter, food and water are just examples.

Other test designs than the example presented in Figure 1 can be accepted if the protocol is scientifically valid.

PT18: Evaluation of attractants in PT 18 bait products

What kind of efficacy tests should be provided in the context of evaluation of attractants in PT18 bait products?

Efficacy evaluation of attractants (PT19) in PT18 bait products should be done in accordance with the requirements for bait products given in the efficacy guidance Vol. II, Parts B+C, PT18 Chapter.

In the case where no requirements for PT 18 bait products have been defined in this chapter, the efficacy should be proven in:

- a palatability laboratory choice test for bait products whose mode of action requires oral consumption of the product by the target organism. The test should demonstrate the palatability of the fresh product and the product at the end of the claimed maximum storage period. In the test, the test organisms should have a choice between a non-toxic food source (challenge diet, either the non-toxic bait or a non-toxic food source known to be a strong feeding source for the test species) and the bait product;
- a simulated-use test according to the claim;
- a field trial according to the claim.

Simulated-use tests can be waived if a robust field trial is submitted.

An insecticidal product (PT18) containing an attractant (PT19) is normally considered to be "sufficiently effective" if the following results are achieved:

The laboratory palatability choice test (bait and alternative food):

- at least 95% of the test insects have been killed at a given time.

The required results in simulated-use and field tests:

- ≥ 90% mortality at the end of the test period according to the SPC and the label claim.

Deviating requirements for special claims:

Outdoor use:

- a field trial is mandatory to demonstrate ≥ 90% mortality at the end of the test period according to the SPC and the label claim.

Use in stables:

- a field trial is mandatory to demonstrate ≥ 80% mortality at the end of the test period according to the SPC and the label claim.

Nest kill claim:

- a field trial is mandatory to demonstrate 100% mortality at the end of the test period according to the SPC and the label claim.

9. AOB – 8 September 2021

9.1. Art. 75(1)(g) request – opinion on rodent traps (closed session)

Please refer to the confidential minutes.

9.2 PT14: Permanent baiting in sewers – efficacy data (closed session)

Please refer to the confidential minutes.

9.3 Other information & lessons learned

ECHA informed about provisional dates of the next WG-IV-2021 meeting, deadlines for early WG request and working documents submission. A brief information about current guidance status and CG working procedure was given as well.

List of Attendees

1. **Core members:**
   - JANSEN Irina (DE)
   - KRÜGER Martin (DE) – Alternate/Rapporteur
   - ATTIG Isabelle (FR)
   - MAXIMILIEN Yann (FR) – Alternate
   - POULIS Joan (NL)
   - DUH Darja (SI)
   - GIATROPULOS Athanasios (EL)
2. **Flexible members:**
   - WIDHALM Bernhard (AT)
   - BURMISTROVA Anastasia (BE)
   - LEPAGE Anne (BE)
   - RUSCONI Manuel (CH)
   - DOLEZELOVA Katsiaryna (CZ)
   - PECINKOVA Martina (CZ)
   - SCHMOLZ Erik (DE)
   - TRAUER-KIZILELMA Ute (DE)
   - CLEYTON JØRGENSEN Charlotte (DK)
   - PLOOMPUU Grethe-Johanna (EE)
   - PEREIRO COUTO Natividad (ES)
   - NIEMINEN Timo (FI)
   - RYDMAN Elina (FI)
   - BILLAULT Catherine (FR)
   - HADDACHE Nabila (FR)
   - OWENS Aoife (IE)
   - RONCI Maria Beatrice (IT)
   - MEZULE Linda (LV)
   - WIGGERS Hanneke (NL)
   - JUSZCZUK Marek (PL)
   - DAN Marius (RO)
   - FRANK Ulrike (SE)
   - ÅSLING Bengt (SE)
   - DANADAIOVA Emese (SK)
3. **Rapporteurs:**
   - PELMAN Natania (BE)
   - GONZÁLEZ MÁRQUEZ María Luisa (ES)
   - BALDASSARRI Lucilla (IT)
4. **Advisors:**
   - BURGER Natascha (AT)
   - GEDHUN Anke (DE)
   - PORTELA Christina (ES)
   - SOUMENT Christophe (FR)
   - BAS Dekker (NL)
   - BIELINSKI-BILINSKI Marcin (PL)
   - KASPRZAK Karolina (PL)
5. **ECHA Staff**
   - SZYMANKIEWICZ Katarzyna (Chair)
   - RAULIO Mari
   - SCHAKIR Yasmin
   - VETELAINEN Kaisa
   - TAVARES RIBEIRO Rodrigo
6. **Stakeholders:**
   - GARMENDIA Irantzu (CEFIC)
   - THEELEN Meredith (AISE)
   - THOM Ellen (AISE)
   - MORENO Mara (AISE)

- WILTZ Michael (FECC)

7. Applicants:

- CID LINES NV

Environment WG-III-2021

Final minutes

4 December 2021

Minutes of Environment WG-III-2021

7,9, 16-17 September 2021

Meeting of the Environment 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 10 were (alternate) core members. Four Commission observers were registered for items 6.6, 6.7 and 8.2. Two stakeholder representative was registered. Applicants were registered for their specific substance discussions.

The participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes. The list of attendees is given in Annex 1.

2. Administrative issues

Interact collaboration tool is used for the following steps in the peer-review:

- Commenting/Trilaterals/Disagreement in closing points.

  The RCOM, PAR/SPC and CAR are published via Interact Collaboration tool. Commenting/trilaterals/disagreement on closing points should take place in the RCOM provided via Interact Collaboration tool.

- BPC commenting on updated CAR/PAR/draft SPC/BPC opinion

  The Open issue table is published via Interact Collaboration tool. CAR, PAR/SPC and BPC opinion will be provided via S-CIRCABC until further notice.

- Commenting BPC minutes

  The draft BPC minutes will be published for commenting via Interact Collaboration tool.

3. Agreement of the agenda

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

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

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

5. Agreement of draft minutes from WG-II-2021

The minutes were agreed without further changes.

6. Discussion of active substances

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

Three provisionally closed points were discussed and agreed, which concerned ED properties, the assessment of non-standard cooling systems in PT 11 and the assessment of disinfection by products. The eCA will provide the final assessment and proceed to the Biocidal Products Committee.

Agreed action: **SECR** will be organising a Workshop on waiving criteria for (additional) testing when assessing the ED properties of active substances for non-target organisms in autumn 2021. SECR suggests that DE and NL bring forward the general point noted for this case at this workshop.

6.2 Alkyl(C12-16)dimethylbenzylammonium chloride (C12-16-ADBAC/BKC), PT 1, 2 (eCA IT)

One point was discussed and agreed, that concerned the assessment of metabolites identified in a new substance specific soil degradation study. The eCA will provide the final assessment and proceed to the Biocidal Products Committee.

Agreed action: **SECR** to check at BPC level if there is a need to update the LoEP for the previous PTs in which the AS is already approved.

6.3 Didecyldimethylammonium chloride (DDAC), PT 1, 2 (eCA IT)

One point was discussed and agreed, that concerned an additional study and the estimated distribution of the substance to environmental compartments after the STP. The eCA will provide the final assessment and proceed to the Biocidal Products Committee.

6.4 Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbondioxide, PT 18, 19 (eCA ES)

Several items were discussed, that concerned the extract component used in ecotox tests, bioaccumulation, PNECsediment and PNECsoil derivation, RMMs for pollinators as well as three items related to the exposure assessment in PT 18 and PT 19 and NERs.

The WG agreed on all points, one point related to the exposure assessment in PT 18 was followed up in the second WG meeting week. The eCA will provide the final assessment and proceed to the Biocidal Products Committee.

Agreed actions:

- **DE** to prepare an e-consultation related to info-box 9 of Vol IV Part B+C.
- The general need for a general scenario for the ULV application method was identified, this is currently followed up in the frame of the bee guidance development. Depending on the outcome, further steps will be decided together with the ENV WG.
- A general discussion on the PECtwa calculation (interval to be taken into account) is needed for direct release, to be taken up by the **AHEE** – current proposal: use (as for sewage sludge and manure) an interval of 30 days. SECR to prepare a **TAB entry** which will be the basis for the discussion (including equations) - **SECR** to check if a related TAB entry exists (ENV 153).
- The **AHEE** should cross check independent from this case the EPM concept (fixed compartment model versus generic method) in light of the concepts used for PT 8 (see related AHEE recommendation for PT 8).
- **AHEE** to follow up on an agreed scenario for PT 19 is needed (covering terrace and garden use), the scenario proposed at AHEE-3 should be further developed and discussed.

6.5 Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents, PT 18, 19 (eCA ES)

Please refer to the previous agenda item as these discussions took place together.

6.6 DBNPA: Art 75(1)g request, PT 4 (eCA DK)

Several items regarding ED assessment were discussed. The WG agree that currently no thresholds/safe concentration limits can be derived for the ED properties of DBNPA-derived bromide with regard to environmental non-target organisms. The WG also agreed that a quantitative risk assessment for ED properties with regard to non-target

organisms is not possible for DBNPA-derived bromide at this point in time.

6.7 Cyanamide: Art 75(1)g request, PT 3 and 18 (eCA DE)

The WG discussed and agreed on the assessment of environmental background level of cyanamide and biocidal contribution, while it was not possible to conclude on the risk assessment regarding ED properties.

6.8 Early WG: CHDG, Chlorhexidine - ED assessment, PT 1, 2, 3 (eCA PT)

An early WG discussion took place concerning the ED assessment strategy for non-target organisms and the determination of the PNECsediment.

6.9 Early WG: Sodium cacodylate - ED assessment, PT 18 (eCA PT)

An early WG discussion took place concerning the ED assessment strategy for non-target organisms.

6.10 Early WG: K-HDO (RNL): Emission scenario for scaffolding boards, PT 8 (eCA AT)

An early WG discussion took place concerning the exposure scenarios for the use of the substance in scaffolding boards. .

Agreed action: **SECR** to include the agreed defaults in the TAB, provided that the scaffolding board scenario is included in the CAR (to be checked at the peer review phase of the case).

7. Discussion of Union authorisation applications

7.1 UA for product family containing hydrogen peroxide, PT 2 (eCA SI)

There were no open points for discussion.

7.2 UA for product family containing L-(+)-lactic acid, PT 1, 2, 3, 4 (eCA BE)

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

Agreed action: It was agreed in general that for lactic acid a qualitative assessment for soil (direct & indirect release) would be sufficient, in line with the conclusion for groundwater. **SECR** to inform the CG on the decision, to harmonise with other lactic acid cases.

8. AOB

8.1 Other information & lessons learned

The presentation is available in S-CIRCABC to MSCAs and to associated stakeholder organisations.

The **provisional timing of coming WG meetings**: 15-26 November 2021 (virtual); exact days are to be established. All meetings organised by ECHA will remain virtual until the end of 2021, reduced number of physical meetings in the next years.

Update on CAR-CLH template - Version 2.0: The template was updated on 04/06/2021, by mistake the PNEC list was not included in the LoEP section although requested by MSCAs. The PNEC list has now been inserted by a minor revision of the template (published 02/09/2021).

Link to combined CAR-CLH template: https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/formats-for-the-authorities

ED Expert Group: An ad hoc WebEx meeting was organised by the ED EG following a request from AT. The EDEG SECR confirms that is it possible to launch a written procedure in principle at any time, a written procedure can be followed up in a discussion at an ED EG meeting.

Information was further provided on the **EFSA & ECHA drinking water project**: Objective of the guidance to be prepared is to enable the identification of real concerns for public health from exposure to harmful by-products in drinking water. The guidance should focus on the water treatment methods that are frequently used in the EU.

Next steps and timelines: All draft chapters to be ready by 01/08/2022 - public consultation 01/09/2022 – 15/11/2022. ECHA will start drafting the chapter on groundwater and surface water exposure for biocidal products - WG members are invited to participate in the drafting and/or revision of the draft chapter prepared by ECHA.

General lesson learned: Do not add comment bubbles in the minutes – please add proposals for changes directly in the text in track change modus.

8.2 Discussion on warning sentences for bees

The MSCAs discussed the proposal and rephrased the text during the meeting. Large part of the discussion was related to which products should the sentence apply and whether indoor and outdoor uses should be included. The WG finally decided that the sentence should be only applied to PT18, PT19 and PT08 products used outdoor as an interim and pragmatic solution until proper guidance is in place.

In regards to literature data the WG discussed extensively about the type of data that can be received and how to evaluate it. Finally, the WG agreed to leave the text related to literature as simple as possible also considering that guidance is available on how to interpret and use literature studies for the hazard and risk assessment.

The WG discussed whether all products to be used outdoors for PT18, PT19 and PT08 containing neonicotinoids will be warranted the warning sentence. According to some MSCA there is data to demonstrate that all neonicotinoids in the review program are below the threshold and therefore would warrant the warning sentence.

The WG finally agreed on the proposal which can be found in the Appendix I of this document. The final document will be prepared by ECHA and circulated to MS and ASOs.

8.3 Update on emission scenario repository and Chesar platform developments

Status: scenarios fitting the umbrella of core scenario 1 (PT4 slaughterhouses and butcheries), Biocides industrial scenarios (PT 6 textile processing, PT 12 paper production) have been implemented. The core scenario 3 (PT3, PT18 uses with releases to manure) project is completed. A repository is under preparation, PT 1 and PT 2 scenarios are drafted. The reporting (CSR, CAR, PAR) baseline is in progress.

A kick-off meeting of the stakeholder community likely to be organised the last week of October.

The "core scenario" concept is under reconsideration: Go for generalisation only in obvious situations (e.g. PT3/PT18, "house scenario"), for other cases we may have rather "core models" (equations) which are called for particular scenarios while most of the scenarios

are set up individually. The focus is on harmonisation of parameter labels/symbols across PTs.

Other learnings: The software content (scenarios) maintenance is in ECHA's biocides units' (not IT's) hands, we better clean up before we implement. For smooth implementation there is a need for up-to-date biocides emission scenarios harmonised across PTs ("repository"). It is worth to scrutinise them beyond just update.

Appendix 1: Revised proposal for harmonised criteria to apply the warning sentence for bees

A warning sentence should be applied for all biocidal products used outdoor under PT 18, PT 19 and PT 8 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.

Note: The endorsement of this proposal may need to be agreed at CA or CG level

Annex 1

Environment WG attendees

Core members:

- (DE) Daniel FREIN
- (DE) Eleonora PETERSOHN
- (DE) Anja KEHRER - alternate
- (FR) Stéphanie ALEXANDRE
- (FR) Anne STRACZEK
- (FR) Jerome LOZACH - alternate
- (IE) Helena JOYCE
- (NL) Barry MUIJS
- (NL) Karlijn HOLTHAUS – alternate

Flexible members :

- Dominik ALTMAN (AT)
- Elisabeth Drs (AT)
- Christian KANTNER (AT)
- Lukas KÜHRER (AT)
- Anne BRASSEUR (BE)
- Bart HEULENS (BE)
- Frederic LEFEBVRE (BE)
- Wiet RAETS (BE)
- Maria A MARCA (CH)
- Petra KUNZ (CH)
- Maren AHTING (DE)
- Julia ANKE (DE) (former Loskyll)
- Katja MICHAELIS (DE)
- Henrik WENNERMARK (DK)
- Helen Sulg (EE)
- Ignacio DE LA FLOR TEJERO (ES)
- Myriam MARTIN VALLEJO (ES)
- Elena Fuensanta RUIZ LOPEZ (ES)
- Oskari HÄNNINEN (FI)
- Sanna KAUKONIEMI (FI)
- Timo NIEMINEN (FI)
- Jaana PASANEN (FI)
- Sari PENTTINEN (FI)
- Andrea PASKULIAKOVA (IE)
- Roberto MINIERO (IT)
- Els SMIT (NL)
- Peter VAN VLAARDINGEN (NL)
- Merel van der Ploeg (NL)
- Terje HARALDSEN (NO)
- Karina PETERSEN (NO)
- Agnieszka PODLASKA (PL)
- Helena RZODECZKO (PL)
- Edda HAHLBECK (SE)
- Lena KONOVALENKO (SE)
- Jörgen MAGNER (SE)
- Johan PERSSON (SE)
- Liselott SÄLL (SE)
- Jana MOLNAROVA (SK)

Rapporteurs:

- Teresa BORGES (PT)
- Natania PEELMAN (BE)
- Stefanie JACOB (DE)

Advisors:

- Jesper JOHANNESSEN (DK)
- Séléné VERSTRAET (FR)
- Lucilla BALDASSARRI (IT)
- Zhichao DANG (NL)
- Rina ANDERSSON (SE)
- Diana POSLEDOVICH (SE)

Commission Observers :

- Marta CAINZOS GARCIA
- Vincent DELVAUX
- Martinus NAGTZAAM
- Maristella RUBBIANI

ASOs:

- Garmendia IRANTZU (CEFIC representative) – all agenda items except closed ones
- Thom Ellen (CEFIC expert)

Applicants

ECHA SECR

Human Health WG-III-2021

Final minutes

24 November 2021

Minutes of Human Health WG-III-2021

14-16 September 2021

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 62 members or advisers registered, of which 10 were (alternate) core members. Three Commission observers were registered for items 6.6 and 6.7. One stakeholder representative was registered. Applicants were registered for their specific substance discussions.

The participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes. The list of attendees is given in Annex 1.

2. Administrative issues

Interact collaboration tool is used for the following steps in the peer-review:

- Commenting/Trilaterals/Disagreement in closing points.

  The RCOM, PAR/SPC and CAR are published via Interact Collaboration tool. Commenting/trilaterals/disagreement on closing points should take place in the RCOM provided via Interact Collaboration tool.

- BPC commenting on updated CAR/PAR/draft SPC/BPC opinion

  The Open issue table is published via Interact Collaboration tool. CAR, PAR/SPC and BPC opinion will be provided via S-CIRCABC until further notice.

- Commenting BPC minutes

  The draft BPC minutes will be published for commenting via Interact Collaboration tool.

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-2021

The minutes were agreed without further changes.

6. Discussion of active substances

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

The discussion concerned reference values and absorption values, as well as the assessment of primary exposure. Agreement was reached on each point. The eCA will provide the final assessment and proceed to the Biocidal Products Committee.

6.2 Alkyl(C12-16)dimethylbenzylammonium chloride (C12-16-ADBAC/BKC), PT 1, 2 (eCA IT)

The discussion concerned the details of finalising the risk assessment for these product types. There was agreement on all points, and the eCA will provide the final assessment and proceed to the Biocidal Products Committee.

6.3 Didecyldimethylammonium chloride (DDAC), PT 1, 2 (eCA IT)

Please refer to the previous agenda item as these discussions took place together.

6.4 Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with supercritical carbondioxide, PT 18, 19 (eCA ES)

The WG agreed on the reference values and oral and inhalation absorption values, while dermal absorption for the representative product was left open. This will be handled together with the finalisation of the exposure assessment in an ad hoc follow-up.

6.5 Chrysanthemum cinerariaefolium, extract from open and mature flowers of Tanacetum cinerariifolium obtained with hydrocarbon solvents, PT 18, 19 (eCA ES)

Please refer to the previous agenda item as these discussions took place together.

6.6 DBNPA: Art 75(1)g request, PT 4 (eCA DK)

The WG agreed that it is not possible to determine the threshold for ED effects. The approach to compare exposure with intake via food was agreed.

6.7 Cyanamide: Art 75(1)g request, PT 3 and 18 (eCA DE)

The WG discussed and agreed on the exposure scenarios and the assessment performed, while it was not possible to conclude on the risk assessment regarding ED properties.

6.8 Peanut Butter: Art 75(1)g request (SECR)

The request concerned the eligibility of peanut butter for inclusion in Annex I of the BPR. The discussion concerned sensitising properties and immunotoxicity. The WG agreed that peanut butter does not give rise to concern for respiratory and skin sensitisation, while as a food allergen it has immunotoxic properties.

6.9 Early WG: Sodium persulphate - ED assessment, PT 4 (eCA PT)

An early WG discussion took place concerning the ED assessment of sodium persulphate. Based on the currently available evidence, the substance should be considered to be systemically available. The WG supported the need to have access to the existing studies, as well as performing a complete literature search and ToxCast assessment for related persulphates.

6.10 Early WG: Sodium cacodylate - ED assessment, PT 18 (eCA PT)

Regarding the T-modality, mechanistic information is needed concerning the metabolic targets at the rat thyroid, the mode of action and human relevance.

For the E-modality, the eCA will assess the information in ToxCast before concluding on the next steps.

For AS-modalities, further studies were considered necessary.

6.11 Early WG: Etofenprox - ED assessment concerning T-modality, PT 8 (eCA AT)

For the thyroid disrupting mode of action, further in vitro studies are needed, including testing on metabolites and information on metabolites in different species.

7. Discussion of Union authorisation applications

7.1 UA for product family containing hydrogen peroxide, PT 2 (eCA SI)

Please refer to the confidential minutes provided to Member State Competent Authorities

in S-CIRCABC and to the applicant in R4BP 3.

7.2 UA for product family containing L-(+)-lactic acid, PT 1, 2, 3, 4 (eCA BE)

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

8. Technical and guidance related issues

8.1 Update on guidance development

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

9. Any other business

9.1 Other information & lessons learned

The presentation is available in S-CIRCABC to MSCAs and to associated stakeholder organisations.

The PEG commenting on the draft guidance on information requirements (Vol III Part A) has taken place, and the next step is the PEG meeting on 26-27 October. Finalisation of the guidance is expected by the end of March 2022.

SECR informed that ECHA will organise a virtual mixture classification training/workshop on 14-15 December 2021. The training will cover CLP obligations, test data, bridging principles, calculation methods, rules and examples etc. The core of the training consists of practical case studies based on UA questions discussed at HH WG. Only MSCAs may join because of confidential information in the case studies.

The revised timelines for AS and UA have been uploaded to the ECHA website (https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee). The changed dates are highlighted in the files. The main changes are:

- Less time between accordance check and WG
- More time between WG and BPC
- Extending BPC meetings from 1 to 2 weeks
- WG-I-2022 takes place one week later

Next WG meetings

The provisional timing of coming WG meetings:

- 15-26 November 2021 (virtual); exact days are to be established.
- 28 March – 8 April 2022 (virtual or physical); exact days are to be established.

All meetings organised by ECHA will remain virtual until the end of 2021.

Annex 1

Human Health WG attendees

Core/Alternate members
HOELZL Christine (AT)
MIKOLAS Jan (CZ)
HOLTHENRICH Dagmar (DE)
GUENTHER Isabel - Alternate (DE)
ARAPAKI Niki (EL)
LAUMONIER-MAXIMILIEN Elisabeth (FR)
LORI Julia (FR)
WELTEN Angelique – Alternate (NL)
LEŠER Vladka (SI) - Rapporteur
Rapporteurs
HAUZENBERGER Ingrid (AT)
PEELMAN Natania (BE)
RUDZOK Susanne (DE)
GREGERSEN Nina Falk (DK)
GONZÁLEZ MÁRQUEZ Maria Luisa (ES)
DEKOVI Edlira (IT)
BORGES Maria Teresa (PT)
Flexible members
KINZL Maximilian (AT)
HERREMANS Yannick (BE)
HOUAMED Anis (BE)
GOLDINGER Daniela (CH)
GRÜNIG David (CH)
RUSCONI Manuel (CH)
SANS-PICHÉ Frederic (CH)
KLUTZNY Saskia (DE)
RIME Soyub (DE)
SCHNEIDER Heiko (DE)
GOTTLOB Kathrin (DE)
HOLZWARTH Andrea (DE)
JENSEN Stine (DK)
DE RIVAS Ana (ES)

SÁNCHEZ José María (ES)
HÄMÄLAINEN Anna-Maija (FI)
RYDMAN Elina (FI)
VÄLIMÄKI Elina (FI)
HYVARINEN Tuija (FI)
BELLINGARD Valérie (FR)
REY Marion (FR)
BREEN Alan (IE)
ANDERSEN Hilde (NO)
GAUSTAD Astrid (NO)
FRYDENLUND Jorid (NO)
MITHAUG Hilde Karin (NO)
GORÉCKI Roman (PL)
ČEBAŠEK Petra (SI)
OLHA Roman (SK)
PILIŠIOVÁ Ružena (SK)
Advisors
DERLER Angelika (AT)
LOSERT Annemarie (AT)
MANI Orlando (CH)
MAUL Katrin (DE)
NDIAYE Lena (FR)
VAN DEN BERG Suzanne (NL)
CASIMIRO Elsa (PT) only for PT cases
REBELO Duarte (PT) only for PT cases
ECHA Staff
AIRAKSINEN Antero
DAMSTEN Micaela
ESTEVAN MARTINEZ Carmen
PAPADAKI Paschalina
RUGGERI Laura
ANTAL Diana
VASILEVA Katya

Applicants
Nouryon
Lonza
EurO3zon ivzw
IFF
Arrow Regulatory
ToxMinds
Sumitomo
Exponent
Cidlines
Alzchem
SCC-GMBH
Foxyde
LKC-Ltd
Luxpam
Gab Consulting

MULLER Gesine
VAN DER LINDEN Sander
GUTIERREZ ALONSO Simon
Commission
NAGTZAAM Martinus
DELVAUX Vincent
RUBBIANI Maristella
Stakeholders
VAN BERLO Boris (CEFIC)