Final minutes of the Working Group meeting II in 2021
Analytical Methods and Physico-Chemical Properties
(Meeting date: 01-03 June 2021 – WebEx meeting)

07 September 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:

- Exponent International Ltd
- Covance Consulting Ltd
- Ecolab Deutschland GmbH
- Brenntag GmbH
- Lohmann & Rauscher International GmbH & Co. KG
- Knieler & Team GmbH
- CID LINES NV CID LINES NV
- Hokochemie GmbH
- Ecolab Deutschland GmbH
- Innovative Water Care Europe SAS

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. ECHA highlighted that the commenting of CAR's and PAR's will be conducted by using the interact portal for the next process flow. Hence, the documents for the next working group meeting will be distributed through this tool.

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).

The following items were added to the agenda under AoB:

- Physical hazards testing with regard to the renewal of active substances
- National norms and legislation that might conflict with the conditions provided in Union Authorisations

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 I 2021

The working group members provided two comments for AoB (11.2 Age of 5-batch analyses) on the draft minutes of WG I 2021.

- Clarification whether an e-consultation will be held for clarifying the date of receipt of 5-batch analyses
- The use of quality control (QC) data as confirmation of 5-batch analyses

The chair clarified that an e-consultation on the age of 5-batch analyses was promised during the WG I 2021 meeting. However, after ECHA internal discussion, it was decided to keep the current working practice to count the age of the 5-batch analyses from the date of submission of the draft CAR to ECHA for accordance check. It was highlighted that this approach is the consequence of comments received during the peer-review of previous cases where new analyses were requested as post-approval requirement.

The draft minutes were updated and the possible use of QC data are reflected in the final minutes.

No further comments were expressed at the meeting. The minutes of the working group meeting I in 2021 were agreed by the working group members.

6. Discussion on the outcome of e-consultations

6.1 Waiving and testing of performic acid generated from formic acid and hydrogen peroxide (PFA)

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 Chlorine dioxide generated from sodium chlorite by acidification

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

7 Discussion of active substances

7.1 1,2-Benzisothiazol-3(2H)-one (BIT) – PT 06, 13

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

8 Discussion of Union Authorisations

8.1 Interox Biocidal Product Family 1 – PT 02, 03, 04

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

8.2 Bioquell HPV-AQ – PT 02, 03, 04

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

8.3 Brenntag GmbH Propan-2-ol Product Family – PT 01, 02, 04

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

8.4 L+R Propanol PT1 Family - PT 01

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

8.5 Knieler & Team Propanol Family - PT 01, 02, 04

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

8.6 Active chlorine based products BPF - CID LINES NV – PT 02, 03, 04, 05

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

8.7 HOKOEX – PT 18

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

8.8 Ecolab Lactic Acid single product - PT02

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

8.9 AWPF Calcium Hypochlorite BPF - PT 02, 04, 05

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

9 Any other business

9.1 Physical hazards testing with regard to the renewal of active substances

The question was raised whether the data requirements on physical hazards have to be addressed according to the BPR when the approval of an active substance is renewed. It was highlighted that the guidance on the data requirements and assessment of applications for renewal of approval of active substances under BPR clearly states "The CLP Regulation has fully entered into application in 2015 and physical hazards have to be addressed according to its requirements. Furthermore, new guidance, e.g. entries in the TAB, must be applied for renewal if applicable in accordance with the general rules of application of guidance." Therefore, the applications for the renewal of the approval of active substances have to comply with the information requirements highlighted in the Annexes to the BPR. This also includes the information requirements about physical hazards.

9.2 National norms and legislation that might conflict with the conditions provided in Union Authorisations

The German representative of the APCP working group highlighted to the working group members that in certain cases of Union Authorisations the authorisation conditions might be in conflict with national norms and national legislation. Therefore, the working group members should alert their competent authorities that a verification of national norms and legislation against the authorisation conditions might be appropriate to avoid issues after the authorisation is granted.

Annex 1 - List of attendees registered for the meeting

Working group member		Country
Erich	Neuwirth	AT
Jerome	Colson	AT
Anastasia	Burmistrova	BE
Kristel	Brys	BE
Minh-Dung	Dang Thy	BE
Steven	Fauconnier	BE
Thomas	Cougnon	BE
Amandine	Courdouan Merz	CH
Michael	Aeschbacher	CH
Martin	Vlasak	CZ
Ulrike	Műhle	DE
Natja	Erlingsson	DK
Imre	Vallikivi	EE
David	Cano	ES
Jesus	Escalada	ES
María Luisa	González Márquez	ES
Pedro	Fuertes	ES
Katariina	Vuorensola	FI
Reko	Lehtilä	FI
Sari	Penttinen	FI
Clement	Lebee	FR
François	LUTZ	FR
Loic	Chabanny	FR
Philippe	Weber	FR
Therese	Six	FR
Lucilla	Cataldi	IT
Ieva	Igaune	LV
Julija	Brovkina	LV
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)
Glans Lotta

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

Company	**Agenda item**	**Observer**
Exponent International Ltd	7.1	McGuire Alison
Covance Consulting Ltd	8.1	Tom Candy Meta Schouten
Ecolab Deutschland GmbH	8.2	John Chewins Andrea Wegner
Brenntag GmbH	8.3	Martina Spaan Mathew Jackson
Lohmann & Rauscher International GmbH & Co. KG	8.4	Angela Augustin Jana Zeilinger
Knieler & Team GmbH	8.5	Jana Zeilinger Gunnar Kleist
CID LINES NV CID LINES NV	8.6	Fanny Belhassan Yamina Ihaddadene
Hokochemie GmbH	8.7	Wolfgang Munk
Ecolab Deutschland GmbH	8.8	Klavdija Kovač Liselotte Van Den Eynde
Innovative Water Care Europe SAS	8.9	Ankur Grover Ana Maria Toma

WG-II-2021

Final minutes

8 September 2021

Minutes of Efficacy WG-II-2021

8 and 10 June 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 36th Efficacy Working Group (EFF WG) meeting and informed that this meeting is split into two 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. DE asked for the possibility to introduce an e-consultation to be launched under AOB.

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-I-2021 draft minutes. The revised minutes were agreed at the meeting.

6. Discussion of active substances – 8 June 2021

6.1 1,2-Benzisothiazol-3(2H)-one (BIT) (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 and 10 June 2021

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

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

7.2 UA for product family containing 1-propanol/2-propanol (eCA CH)

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

7.3 UA for product family containing 1-propanol/2-propanol (eCA CH)

There were five open points, which were all closed at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

7.4 UA for product family containing active chlorine released from sodium hypochlorite (eCA BE)

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

7.5 UA for product family containing active chlorine released from calcium hypochlorite (eCA FR)

There were four open points and two provisionally closed points in the discussion table. The open points were closed at the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

7.6 UA for product containing cyromazine (eCA CH)

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

7.7 UA for product family containing hydrogen peroxide (eCA FI)

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

7.8 UA for product family containing hydrogen peroxide (eCA NL)

There were three open points, one was closed at the meeting, for the remaining two an ad hoc follow-up will be launched. Please refer to the confidential minutes in the form of the discussion table for more details.

7.9 UA for product family containing propan-2-ol (eCA DE)

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

8. AOB – 10 June 2021

DE announced that the work on a proposal on how to address disinfectant testing at elevated temperatures when no standardised thermotolerant organisms are available, i.e. mainly for yeast, fungi, and mycobacteria is finalised. This proposal will be presented to the EFF WG members via an e-consultation, and further discussed at the WG level.

8.1. Other information & lessons learned

ECHA informed about provisional dates of the next WG-III-2021 meeting. Short information was given about current guidance updates and foreseen future discussions, publication of Commission Delegated Regulation (EU) 2021/525 amending Annexes II and III to the BPR and its date of applicability, revised templates of PAR and combined template of CAR-CHL and endorsed at the CG a list of definitions of the functions of co-formulants. Moreover, FR presented the conclusion of an Early WG discussion on UA-APP containing Margosa extract from cold-pressed oil of the kernels of Azadirachta Indica extracted with super-critical carbon dioxide (PT 19) based on the replies submitted during ad hoc follow-up. The WG agreed with the conclusion without any further comments.

List of Attendees

Efficacy Working Group II-2021

Core members
JANSEN Irina (DE)
KRÜGER Martin (DE) - alternate
ATTIG Isabelle (FR)
MAXIMILIEN Yann (FR) - alternate
POULIS Joan (NL)
DUH Darja (SI)
GIATROPULOS Athanasios (EL)
Flexible members
BURMISTROVA Anastasia (BE)
DANG THY Minh-Dung (BE)
LEPAGE Anne (BE)
DONZE Gerard (CH)
GRÜNIG David (CH)
ROSSIER Nadine (CH)
WANDELER Eliane (CH)
DOLEZELOVA Katsiaryna (CZ)
PECINKOVA Martina (CZ)
STAHR Christiane (DE)
CLEYTON JØRGENSEN Charlotte (DK)
PLOOMPUU Grethe-Johanna (EE)
NIEMINEN Timo (FI)
RYDMAN Elina (FI)
BILLAULT Catherine (FR)
HADDACHE Nabila (FR)
LYNCH Helen (IE)
OWENS Aoife (IE)
BALDASSARRI Lucilla (IT)
RONCI Maria Beatrice (IT)
MEZULE Linda (LV)
WARMERDAM Sonja (NL)
WIGGERS Hanneke (NL)
HUSZAŁ Sylwester (PL)
JUSZCZUK Marek (PL)
DAN Marius (RO)
FRANK Ulrike (SE)
ÅSLING Bengt (SE)
DANADAIOVA Emese (SK)
ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
RAULIO Mari
SCHAKIR Yasmin
Applicants
Ecolab
Lohmann & Rauscher International GmbH
Knieler & Team GmbH
Innovative Water Care Europe SAS
Hokochemie GmbH
Rapporteur
LEROY Celine (FR)
PORTELA Cristina (ES)
BRYS Kristel (BE)
BROVKINA Julija (LV)
DANG THY Minh-Dung (NL)
Advisor
JONGERIUS Aniek (NL)
IJPELAAR Guus (NL)
KASPRZAK Karolina (PL)
BIELINSKI-BILINSKI Marcin (PL)
GONZALES Maria Luiza (ES)
ANDRIESEN Rob (NL)
Stakeholders
GARMENDIA Irantzu (EBPF)

Environment WG-II-2021

Final minutes

24 September 2021

Minutes of Environment WG-II-2021

3-4 & 9-10 June 2021

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 48 participants present, of which 9 were core members, 27 flexible members, 4 rapporteur and 6 advisers. Two representatives from accredited stakeholder organisation were present at some agenda items. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

The revised CAR/CLH template is available in the ECHA website. It now covers renewal of active substances (RAR template), and the formatting of tables and layout has been improved.

The revised timelines are available on ECHA website and S-CIRCABC, including changes in WG meeting times.

The presentation is available in S-CIRCABC.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. SECR added an additional item under AOB. 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 agreed agenda. None was declared.

5. Agreement of the draft minutes from WG-I-2020

The minutes were agreed without further changes.

6. Discussion on active substances

6.1 DBNPA: Art 75(1)g request

This agenda item was not for agreement but only for discussion. The eCA presented their assessment which was then discussed in general. The item will be scheduled for agreement at a later WG meeting.

6.2 Cyanamide: Art 75(1)g request

Six items related to ED assessment were initially discussed. Three additional items were outside the remit of the ENV WG, where only feedback was collected. The item will be scheduled for a second discussion at a later WG meeting.

6.3 1,2-Benzisothiazol-3(2H)-one (BIT)

The non-confidential discussion table contained 13 open points. The confidential discussion

table contained one open point and one provisionally closed point. All points discussed were agreed upon (closed) with some follow-up actions as indicated below. The eCA will revise the CAR accordingly, the CAR can then proceed to the BPC.

The majority of points concerned the exposure assessment, the groundwater assessment of metabolites, RMMs (which are not in the remit of the WG), the temperature correction for the degradation rate used in EUSES 2.2.0, and the wording of sections 3.1 and 3.2 of Doc I, which should also rather take place at the BPC meeting.

Several points concerned PT 6 emission estimation; one general point is reported in the following:
It was discussed and agreed that for the risk assessment of PT 6 uses in "Detergents and cleaning fluids", the emissions from uses in 6.1.1 Human hygienic products (non-professional users) are not to be added to the emissions from the uses in 6.1.2 Detergents. That is, the assessment of 6.1.1 is independent of 6.1.2.

Actions:

- **SECR** to prepare a **TAB** entry regarding the summing up of emissions from uses in PT 6.1 (see Appendix 1).
- **eCA** to complete the aggregated exposure and add it to the CAR (agreed action for point closed before the meeting following bilateral discussions with the eCA).
- **SECR** to check in general if sufficient information is collected in the meanwhile from WG members to allow an impact assessment for the application of the new Time 2 in the risk assessment.
- **SECR** to add a clarification in the **TAB** regarding the possibility in FOCUS PEARL 4.4.4 to set the number of applications to 12 (agreed action for point closed before the meeting following bilateral discussions with the NL) (see Appendix 1).

7. Discussion of Union Authorisation cases

7.1 UA for product containing L-(+)-lactic acid – PT 02 (LV)

There were no open points for discussion and no further point was raised at the WG meeting, the PAR can proceed to the BPC.

7.2 UA for product family containing 1-propanol / 2-propanol – PT 01 (CH)

There were no open points for discussion and no further point was raised at the WG meeting, the PAR can proceed to the BPC.

7.3 UA for product family containing 1-propanol / 2-propanol – PT 01, 02, 04 (CH)

There were no open points for discussion and no further point was raised at the WG meeting, the PAR can proceed to the BPC.

7.4 UA for product family containing active chlorine released from sodium hypochlorite – PT 02, 03, 04, 05 (BE)

There were no open points for discussion and no further point was raised at the WG meeting, the PAR can proceed to the BPC.

7.5 UA for product family containing active chlorine released from calcium

hypochlorite – PT 02, 04, 05 (FR)

Two points were bilaterally closed before the WG with the respective commenting Members. No further discussion took place at the WG meeting, the PAR can proceed to the BPC.

7.6 UA for product containing cyromazine – PT 18 (CH)

Eleven points were discussed and agreed upon (closed) with some follow-up actions as indicated below. The eCA will revise the PAR accordingly.

The open points concerned the exposure assessment, the metabolite melamine and RMMs (not in the remit of the ENV WG).

The WG agreed in general to distinguish the following main groups:

- Dairy cattle
- Beef cattle & veal calves
- Pigs
- Chicken and broilers (free range)
- Chicken in battery cages[1]
- Non-chicken poultry (turkeys, ducks, and geese)

A major point discussed concerned the relevance of the metabolite melamine. According to the RAC opinion on melamine from Dec 2020 (link), the metabolite should be classified Carc 2 and STOT RE 2. The consequences of this Opinion to the eCA's evaluation of melamine as a 'not relevant metabolite' for groundwater were discussed but could not be clarified by the ENV WG, since the new information available is of toxicological nature. After the ENV WG meeting an ad-hoc consultation of the TOX WG was launched and depending on its conclusion the eCA may need to revise the groundwater risk assessment.

Finally, some RMMs were discussed only for the purpose of collecting information since those need to be agreed upon by the BPC.

Post WG meeting note (UBA): As the majority feedback from MS to the e-consultation on national legislations concerning the keeping of chickens in cages has shown that various cage systems are still relevant for the next years, we propose to combine these two animal categories to main category "chicken", independent if held in free range or battery cages. This is also in accordance to CS3 (core scenario 3), where it was proposed to differentiate between chickens and non-chickens in animal main category poultries. The splitting - as proposed here - was only needed to provide more clarity in case that battery cages are not relevant in any of the EU-MS.

Actions:

- **MS** to provide feedback to CH, how the situation on battery cages (allowed/not allowed) is in their countries. Decision on adding battery cages to the main groups above depends on the feedback from the MS. **SECR** to adjust the conclusions accordingly.

[1] The results of the e-consultation within the ENV Working Group revealed that keeping hens in conventional battery cages is prohibited from 1 January 2012 (according to Directive 1999/74/EC), while enriched battery cages are currently still allowed and used under certain conditions set in the specific national rules in the different EU countries. Therefore, the battery cages described in the OECD ESD PT 18 No. 14 (2006) are currently used as surrogate for the enriched cages still allowed.

- **SECR** to add the decision on the above main categories in the TAB (see Appendix 1).
- Based on the toxicological relevance of the metabolite melamine (to be concluded via ad-hoc consultation of the TOX WG) and the new information available (RAC Opinion (link), also the PBT criteria will need to be re-assessed for the active substance. The **SECR** to follow up on this issue.
- The proposed **RMM are to be agreed by the BPC**

7.7 UA for product family containing hydrogen peroxide – PT 02, 03, 04 (FI)

The non-confidential discussion table contained one open point, as well as the confidential discussion table. Both points concerned the classification of the product for the environment and the discussion took place at the non-confidential meeting.

7.8 UA for product containing hydrogen peroxide – PT 02, 03, 04 (NL)

Two points were discussed and agreed upon. The PAR can proceed to the BPC.

Actions:

- SECR to initiated e-consultation on NLs questions, SECR to add question on the need of a new TAB entry.

7.9 UA for product family containing propan-2-ol – PT 01, 02, 04 (DE)

There were no open points for discussion and no further point was raised at the WG meeting.

8. AOB

8.1 Chesar platform: Core scenario development for PT 3 & PT 18

The core/worst-case scenarios and proposals for simplifications prepared for PT 3 and PT 18 were presented by DE and initially discussed. Following a request of the WG members, the proposal will be further followed up via an e-consultation. SECR further informed on the ongoing preparations of an emission scenario repository, in the frame of the Chesar platform developments.

During the discussion of the document prepared by DE, some questions came up regarding the proposal how to deal with degradation in manure and it was agreed to set up a small EG to follow it up. The EG should cross check the newly proposed and existing routines with regard to the quantitative relation and report back on the differences in the outcome. A Tier 1/Tier 2 approach could then be potentially discussed. Participants: CH, FR, NL, DE, SECR

It was further agreed that the screening step can be omitted.

The point will be followed up by an e-consultation, which SECR will initiate immediately after the WG meeting (timelines: 3-4 weeks). ASOs will be involved in the commenting as long as no confidential information is shared.

Actions: SECR to initiate e-consultation and to set up EG on the point above related to degradation in manure.

8.2 Disinfection by-products

In the presentation of the status of the DBP assessment work, the information provided by MSCAs and data collected from other sources were explained by FR. The open issues and questions on the consolidated data identified by FR were discussed to collect initial views.

DE informed about a parallel DBP research project in their institution and agreed to share the preliminary results which could be relevant for the biocide DBP assessment. This is related for instance to DBP substances and/or groups that could be still missing from the current data compilation, such as halogenated benzoquinones.

The DBP group approach also recommended in the BPR Guidance Vol V was supported for the purpose of reducing the workload and simplifying the assessment. However, the basis of the groups still needs to be defined. In addition, it has to be agreed how to select a representative element of the group. There was agreement that in addition to the monitoring data, other properties such as ecotoxicity and environmental fate properties should be taken into account to identify the worst-case substances.

In order to decide on the way forward in the assessment, an e-consultation will be launched to collect further feedback on the open issues. An overall goal is to create a harmonised List of Endpoints for the DBPs. It was emphasised that due to the complexity and high workload, MSCAs are asked to volunteer for sharing the assessment work. The MSCAs should work closely together since the outcome of the work will have an impact on all dossiers including DBP assessment.

Action:

- **SECR** to launch the e-consultation.
- **MSCAs** to volunteer for the assessment work

8.3 Other information & lessons learned (SECR)

The summary report from the 19th ED EG meeting is available at the ECHA website (link). For more information, please see the ED EG pages.

Revision of BPR Annexes II and III *Commission Delegated Regulation (EU) 2021/525*
The Annexes were published on 26 March 2021, they apply from 15 April 2022. Link to the Regulation.

PAR template
The PAR template has been revised and is available on the ECHA website at: https://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats/

- BPR PAR template_single product
- BPR PAR template_single product_confidential annex
- BPR PAR template_product family
- BPR PAR template_product family_confidential annex
- Instructions for PAR template and confidential annex
- Overview of PC tests

Guidance on groundwater metabolites SANCO/221/2000 Rev. 11: Guidance document on the assessment of the relevance of metabolites in groundwater
The Guidance is under revision at the European Commission level. The amendments proposed to the genotoxicity section were discussed at the SCoPAFF (Standing Committee on Plants, Animals, Food and Feed) meeting in May 2021.

A discussion on the applicability of the guidance for biocides is expected to be resumed when the revised document is available.

Interact collaboration tool
The tool will be used for commenting to be launched in June 2021 for Union authorisations and active substance approval (process flow 41 for UA, process flow 42 for AS). Supporting material is available in S-CIRCABC:

- "Collaboration short user manual" (link)
- Brief presentation provided in WG-IV-2020 (link)

Revised process timelines
The revised timelines cover dates until process flow 45 (WG in September 2022, BPC in November 2022) and are available here:

- AS approval:

  https://echa.europa.eu/documents/10162/4221979/revised_timeline_as_app_en.pdf

- UA: https://echa.europa.eu/documents/10162/4221979/timelines_ua_pf20-33_en.pdf

Note the changes in WG meeting dates!

Next WG meetings
The provisional timing of coming WG meetings:

- 6-17 September 2021 (virtual); exact days are to be established (ENV WG + AHEE-6).
- 15-26 November 2021 (virtual); exact days are to be established.

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

8.4 Cross-check of TAB entries and other open points from previous WG meetings (SECR)

The TAB entries were accepted as proposed and will be added in the TAB database after the WG meeting. In addition an overview on remaining open points from previous WG meeting was shared with WG members.

Appendices:

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

New TAB entry proposal related to item 6.3

ENV 235 Summing up of emissions from uses in PT 6.1 Washing and cleaning fluids, human hygienic products, and detergents (WG-II-2021)

In the risk assessment of PT 6 uses in "Detergents and cleaning fluids", the emissions from uses in 6.1.1 Human hygienic products (non-professional users) are not to be added to the emissions from the uses in 6.1.2 Detergents. That is, the assessment of 6.1.1 is independent of 6.1.2.

Proposal to edit TAB entry ENV 23, in relation to item 6.3 (proposed changes in blue font)

ENV 23 What parameter setting should be applied to FOCUS groundwater scenarios (PEARL) when they are used in biocide exposure assessments Version 2 (AHEE-3, WG-II-2021)

Molar activation energy:
In case of using FOCUS PEARL version 4.4.4 the value for "Molar activation energy" in the TRANSFORMATION tab of the substance parameters should remain at the default value of 65.4 kJ.mol-1 as biodegradation processes in soil are modelled. This value corresponds to the Q10 value of 2.58 assuming a daily temperature correction in FOCUS models in accordance with the EFSA PPR opinion (http://www.efsa.europa.eu/en/efsajournal/pub/622.htm) and the REACH guidance document R.7b.

Plant uptake factor:
A factor of 0 should be used for the plant uptake factor for the purposes of a first tier assessment. Due to discussions (ref. to TMII2010ENV-item Harmonisation of FOCUS groundwater models PEARL.doc and CA-Dec10-doc 6.2 c) this value is considered as a realistic worst case.

Summary on relevant substance specific input parameters for the groundwater simulations with FOCUS PEARL and FOCUS PELMO:

Parameter	Value	Unit	Origin
Molar mass		[g.mol^{-1}]	S
Solubility in water (at test temperature)		[mg.L^{-1}]	S
Molar enthalpy of dissolution	27	[kJ.mol^{-1}]	D
Vapour pressure (at test temperature)		[mPa]	S
Molar enthalpy of vaporisation	95	[kJ.mol^{-1}]	D
Diffusion coefficient in water	4.3 • 10^{-5}	[m^2.d^{-1}]	D
Gas diffusion coefficient	0.43	[m^2.d^{-1}]	D
Reference temperature to degradation, vaporization and dissolution	20	[°C]	D
Exponent for the effect of liquid (degradation moisture relationship)	0.7	[-]	D
Sorption to soil organic carbon (Koc or Kom (Kom = Koc / 1.724)		[dm^3.kg^{-1}]	S
Exponent of the Freundlich-Isotherm (1/n)		[-]	D/S (if available)[1)]
DT50 (20°C)		[d]	S
Arrhenius activation energy	54	[kJ.mol^{-1}]	D
Q10-factor (increase of degradation rate with an increase of temperature of 10°C – relevant for PELMO)	2.2	[-]	D
Plant uptake factor	0		D

1)For the procedure for selecting the appropriate exponent for the Freundlich Isotherm please refer to the previous TAB item.

Furthermore, in FOCUS PEARL version 4.4.4 it is possible to divide the annual dose in 12 equal portions, e.g. applied the first day of each month. This is a change compared to FOCUS PEARL3.3.3, which had limitations regarding the maximum number of annual doses (ten).

SECR note: The values in the screen shot for Arrhenius activation energy and Q10 factor (relevant for PELMO) will be adapted in the TAB entry according to the decision: Arrhenius activation energy: 65.4 kJ.mol-1 / Q10 value: 2.58.

New TAB entry proposal related to item 7.6

ENV 236 Main animal categories in PT 18 (WG-II-2021)

The frequency of application of a biocidal product in manure/stables should be defined per main animal category and not per animal subcategory. The following main categories should be used:

- Dairy cattle
- Beef cattle & veal calves
- Pigs

- Chicken (free range or battery cages)[2]
- Non-chicken poultry (turkeys, ducks, and geese)

The worst-case application frequency within a main animal category should be applied for the hole main category.

In case of unacceptable risks for one animal subcategory, the general category can still be considered safe provided RMMs can be applied on that subcategory resulting in safe use.

[2] Keeping hens in conventional battery cages is prohibited from 1 January 2012 (according to Directive 1999/74/EC), while enriched battery cages are currently still allowed and used under certain conditions set in the specific national rules in the different EU countries. Therefore, the battery cages described in the OECD ESD PT 18 No. 14 (2006) are currently used as surrogate for the enriched cages still allowed.

Appendix 2: List of participants

Core members:

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

Flexible members:

- Christian KANTNER (AT)
- Lukas KÜHRER (AT)
- Anne BRASSEUR (BE)
- Christiaan CEUSTERS (BE)
- Helene JARRETY (BE)
- Celine LEROY (BE)
- Maria A MARCA (CH)
- Tenzing GYALPO (CH)
- Petra KUNZ (CH)
- Maren AHTING (DE)
- Anja KEHRER (DE)
- Julia LOSKYLL (DE)
- Katja MICHAELIS (DE)
- Henrik WENNERMARK (DK)
- Ignacio DE LA FLOR TEJERO (ES)
- Myriam MARTIN VALLEJO (ES)
- Elena Fuensanta RUIZ LOPEZ (ES)
- Oskari HÄNNINEN (FI)
- Sanna KAUKONIEMI (FI)
- Jaana PASANEN (FI)
- Sari PENTTINEN (FI)
- Andrea PASKULIAKOVA (IE)
- Peter VAN VLAARDINGEN (NL)
- Terje HARALDSEN (NO)
- Agnieszka PODLASKA (PL)
- Helena RZODECZKO (PL)
- Jana MOLNAROVA (SK)
-

Rapporteurs:

- Kristel BRYS (BE)
- Stine JENSEN (DK)
- Julija BROVKINA (LV)

Advisors:

- Michael AESCHBACHER (CH)
- Alexandre GURBA (CH)
- Arthur GILSON (FR)
- Séléné VERSTRAET (FR)
- Merel VAN DER PLOEG (NL)
- Rina ANDERSSON (SE)

ASOs:

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

ECHA chairs and experts

Human Health WG-II-2021

Final minutes

16 September 2021

Minutes of Human Health WG-II-2021

1-10 June 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 68 members or advisers registered, of which 11 were (alternate) core members. 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

The revised CAR/CLH template is available in the ECHA website. It now covers renewal of active substances (RAR template), and the formatting of tables and layout has been improved.

The revised timelines are available on ECHA website and S-CIRCABC, including changes in WG meeting times.

The presentation is available in S-CIRCABC.

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 1,2-Benzisothiazol-3(2H)-one (BIT), PT 6, 13 (eCA ES)

The discussion concerned various details of the assessment, where agreement was reached on each point. The eCA will slightly amend the assessment and proceed to the Biocidal Products Committee.

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

This intermediate discussion took place to clarify the eCA's proposed approach towards risk assessment taking into account also endocrine disrupting properties. Another discussion will take place in September 2021.

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

This intermediate discussion took place to clarify the eCA's proposed approach towards risk assessment taking into account also endocrine disrupting properties. Another discussion will take place in September 2021.

6.4 Chlorhexidine: Early WG discussion, PT 1, 2, 3 (eCA PT)

The WG requested the applicant to provide further information and studies already

available to cover the multi-generation endpoint and ED assessment.

The members agreed that the active substance should not be considered as sensitising to skin by applying a weight of evidence approach.

The proposed read-across approach was accepted for the acute oral toxicity and sub-chronic dermal toxicity endpoints.

7. Discussion of Union authorisation applications

7.1 UA for product containing L-(+)-lactic acid, PT 2 (eCA LV)

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 1-propanol / 2-propanol, PT 1 (eCA CH)

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

7.3 UA for product family containing 1-propanol / 2-propanol, PT 1, 2, 4 (eCA CH)

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

7.4 UA for product family containing active chlorine released from sodium hypochlorite, PT 2, 3, 4, 5 (eCA BE)

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

7.5 UA for product family containing active chlorine released from calcium hypochlorite, PT 2, 4, 5 (eCA FR)

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

7.6 UA for product containing cyromazine, PT 18 (eCA CH)

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

7.7 UA for product family containing hydrogen peroxide, PT 2, 3, 4 (eCA FI)

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

7.8 UA for product containing hydrogen peroxide, PT 2, 3, 4 (eCA NL)

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

7.9 UA for product family containing propan-2-ol, PT 1, 2, 4 (eCA DE)

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 draft guidance on information requirements (Vol III Part A) is available at the ECHA website. According to the consultation procedure, other interested parties can also comment using the standard form on the website. ECHA will not provide answers to comments made via this standard form (i.e. outside the formal consultation procedure).

The PAR template has been revised and is available on the ECHA website.

The documents prepared by DE were agreed at WG-I-2021:

- BfR: *Dermal absorption values for anticoagulant rodenticides*
- BAuA: *Dermal absorption values for anticoagulant rodenticides: Alternative approach for the occupational setting*

For the final changes agreed at WG-I-2021, an e-consultation took place to confirm agreement. The documents were finalised and published on 1 June in S-CIRCABC. The study summaries and a version of the BfR document with slightly more information are available to MSCAs.

The eCAs often provide presentations to support the WG discussion. Some members requested earlier that such documents should be made available to members, before or after the WG. SECR proposed to always upload to S-CIRCABC all presentations and documents provided for WG as room documents, unless specifically objected by eCA. The documents will be made available to MSCAs only. The members agreed on the approach and it will be followed from the next meeting onwards.

Interact collaboration tool

The tool will be used for commenting to be launched in June 2021 for Union authorisations and active substance approval (process flow 41 for UA, process flow 42 for AS). Supporting material is available in S-CIRCABC:

- "Collaboration short user manual" (link)
- Brief presentation provided in WG-IV-2020 (link)

Next WG meetings

The provisional timing of coming WG meetings:

- 6-17 September 2021 (virtual); exact days are to be established.
- 15-26 November 2021 (virtual); 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
Jan MIKOLÃS (CZ)
Kristin HERRMANN (DE)
Dagmar HOLTHENRICH (DE)
Isabel GUENTHER (DE) - alternate
Dimitra NIKOLOPOULOU (EL)
Elisabeth LAUMONIER-MAXIMILIEN (FR)
Julia LORI (FR)
Aurelie AUBIN (FR) - alternate
Alan BREEN (IE) – alternate
Carina BOS (NL)
Vladka LESER (SI)
Rapporteurs
Susanne RUDZOK (DE)
Stine JENSEN (DK)
María Luisa GONZÁLEZ MÁRQUEZ (ES)
Julija BROVKINA (LV)
Maria Teresa BORGES (PT)
Flexible members
Ingrid HAUZENBERGER (AT)
Christine HOELZL (AT)
Kristel BRYS (BE)- rapporteur
Yannick HERREMANS (BE)
Anis HOUAMED (BE)
Ann VANHEMELEN (BE)
Dominique Anne BUEHLER (CH) – rapporteur
Christoph GEISER (CH)
Daniela GOLDINGER (CH)
David GRÜNIG (CH)
Nadine ROSSIER (CH) – rapporteur
Manuel RUSCONI (CH)
Frederic SANS-PICHÉ(CH)
Valerie BELLINGARD (FR)

Andrea HOLZWARTH (DE)
Saskia KLUTZNY (DE)
Soyub RIME (DE)
Heiko SCHNEIDER (DE)
Annetta SEMISCH (DE)
Ana DE RIVAS (ES)
José María SÁNCHEZ (ES)
Anna-Maija HÄMÄLÄINEN (FI)
Tuija HYVARINEN (FI) – rapporteur
Elina RYDMAN (FI)
Elina VÄLIMÄKI (FI)
Elodie COLLIN (FR)
Marion REY (FR)
Edlira DEKOVI (IT)
Hilde Mariken ANDERSEN (NO)
Jorid FRYDENLUND (NO)
Astrid GAUSTAD (NO)
Hilde Karin MIDTHAUG (NO)
Roman GÓRECKI (PL)
Karolin ASK BJÖRNBERG (SE)
Petra ČEBAŠEK (SI)
Roman OLHA (SK)
Ružena PILIŠIOVÁ (SK)
Advisors
Orlando MANI (CH)
Francois PYTHON (CH)
Katrin MAUL (DE)
Matthias PEISER (DE)
Marianne DYBDAHL (DK)
Nina Falk GREGERSEN (DK)
Eduardo DE LA USADA MOLINERO (ES)
Pedro FUERTES (ES)
Eleni CHATZIDIMITRIOU (FR)

Ahmed SABAH (SE)
Duarte REBELO (PT)
ECHA Staff
Antero AIRAKSINEN
Micaela DAMSTEN
Carmen ESTEVAN MARTINEZ
Paschalina PAPADAKI
Laura RUGGERI
Claudia SPANU
Katya VASILEVA
Applicants
IFF
Toxminds
Thor
Alzchem
SCC-GMBH

Lanxess
Chemservice
Ecolab
Knieler und Team
Fraunhofer
Brenntag
TSG Consulting
Sigura Water
Cidlines
Hoko
Lonza
Evonik
Bioquell HPV-AQ
Troy
Stakeholders
VAN BERLO Boris (CEFIC)