Minutes of the Working Group meeting IV in 2021
Analytical Methods and Physico-Chemical Properties
(Meeting date: 16-17 November 2021 – WebEx meeting)

29 March 2022

1. Welcome and apologies

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

- Solvay Solutions UK Limited
- Lanxess Deutschland GmbH
- Ecolab Deutschland GmbH
- Colgate-Palmolive (Poland) Sp. Z.o.o
- Reckitt Benckiser Production (Poland) Sp z o.o.
- Veltek Associates Inc. Europe

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 applicants, ASO and the working group members were informed that the recording will not be released to anybody outside ECHA and any further recording was not allowed.

2. Administrative issues

A presentation on the administrative matters was provided for information by ECHA. In addition, the chair invited the working group members to share their experience with the newly introduced interact-tool. This information is useful for ECHA to improve the user-friendliness of 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). It was noted that the evaluations of two post-authorisation requests had already been included in the agenda under AoB. No additional agenda 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 III 2021

The working group members provided comments on the draft minutes of WG III 2021. These comments were included in the updated draft minutes and discussed. The draft minutes were modified accordingly and were agreed by the working group members.

6. Discussion of the outcome of e-consultations

6.1 Substance identification for a future application

This discussion item was addressing issues raised during a pre-discussion between a member state and a future applicant. The working group members exchanged their views and provided advice to the requesting working group member.

6.2 Bromide Activated Chloramine (BAC)

The compilation of the replies received in the course of the e-consultation was presented. However, no discussion took place at the working meeting.

7 Discussion of active substances

7.1 Methylene dithiocyanate

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

7.2 (13Z)-Hexadec-13-en-11-yn-1-yl acetate

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

7.3 1-[[2-(2,4-Dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole (Propiconazole)

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

8 Discussion of Union authorisations

8.1 UA for a product family containing Propan-1-ol

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

8.2 UA for a product family containing Propan-2-ol

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

8.3 UA for a product family containing L-(+)-lactic acid

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

8.4 UA for a product family containing Active chlorine released from sodium hypochlorite

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

8.5 UA for a product family containing active chlorine released from sodium hypochlorite

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

9 Any other Business (AoB)

9.1 Post-authorisation data for Contec IPA product family

For this application Germany took over the role as eCA from the United Kingdom after the BREXIT and evaluated the long-term storage tests at ambient temperature. A shelf life of 24 months could be granted for the biocidal products based on the study results. The working group members agreed with the evaluation conducted by Germany.

9.2 Post-authorisation data for Pal IPA Product Family

For this application Germany took over the role as eCA from the United Kingdom after the BREXIT and evaluated the long-term storage tests at ambient temperature. A shelf life of 24 months could be granted for the biocidal products based on the study results. The working group members agreed with the evaluation conducted by Germany.

Annex 1 - List of attendees registered for the meeting

Working group member		Member state
Jerome	Colson	AT
Michael	Ghobrial	AT
Anastasia	Burmistrova	BE
Steven	Fauconnier	BE
Yannick	Herremans	BE
Dang Thy	Minh-Dung	BE
Michael	Aeschbacher	CH
Amandine	Courdouan Merz	CH
Martin	Vlasak	CZ
Ulrike	Mühle	DE
Katrine	Domino	DK
Imre	Vallikivi	EE
Panagiotis	Gatos	EL
David	Cano	ES
Jesus	Escalada	ES
Sanna	Kaukoniemi	FI
Katariina	Vuorensola	FI
Aurelie	Chezeau	FR
Léa	Riffaut	FR
Philippe	Weber	FR
Therese	Six	FR
François	Lutz	FR
Thomas	Bujard	FR
Francois	leduc	FR
Nathalie	Sleiman	FR
Annabelle	Gour	FR
Anne-Claire	Talhouët	FR
Lucilla	Cataldi	IT
Ieva	Igaune	LV
Sabine	Kruidhof	NL
Trygve	Helgerud	NO
Marianne	Stave Sekkenes	NO
Sylwester	Huszał	PL
Anna	Horczyczak	PL
Agnieszka	Złotorowicz	PL
Mia	Alpe	SE
Andreas	Ryden	SE

Špela	Velikonja Bolta	SI
Zuzana	Drabová Kušíková	SK
Michal	Porubiak	SK

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

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

Applicant	**Agenda item**	**Observer**
Solvay Solutions UK Limited	7.1	Groome Steve Kirkham Sara
Lanxess Deutschland GmbH	7.3	Konrad Ute Joliton Adrien
Ecolab Deutschland GmbH	8.1, 8.2	Febrero Anna Schimanowitz Aneta Hill Rachel
Colgate-Palmolive (Poland) Sp. Z.o.o	8.3	Fraczkowska Anna
Reckitt Benckiser Production (Poland) Sp z o.o.	8.4	Dodd Barry McGuire Alison
Veltek Associates Inc. Europe	8.5	Walker Samantha Buchanan Steve

WG-IV-2021

Final minutes

30 March 2022

Minutes of Efficacy WG-IV-2021

17 and 19 November 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 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 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-2021 draft minutes. The revised minutes were agreed at the meeting.

6. Discussion of active substances – 17 November 2021

6.1 Methylene dithiocyanate (eCA FR)

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

6.2 (13Z)-Hexadec-13-en-11-yn-1-yl acetate (eCA FR)

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

6.3 Propiconazole (eCA FI)

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

7. Discussion of Union Authorisations – 17 November 2021

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

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 Propan-2-ol (eCA NL)

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

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

There were three open points that were closed during the meeting. In addition, there was one provisionally closed point that remained closed at the meeting. Please, refer to the confidential minutes in the form of the discussion table for more details.

7.4 UA for a product family containing Active chlorine released from sodium hypochlorite (eCA FR)

There was one open point that was closed during the meeting. In addition, there were two provisionally closed points that remained closed at the meeting. Please, refer to the confidential minutes in the form of the discussion table for more details.

7.5. UA for a product family containing Propan-1-ol (eCA SE)

There were three provisionally closed points. Two remained closed and one was re-opened at the meeting for discussion and was closed during the meeting. Please, refer to the confidential minutes in the form of the discussion table for more details.

8. Technical and guidance related issues – 17 and 19 November 2021

8.1 PT12 draft guidance – oilfield part (FR)

The EFF WG agreed on the following:

The distinction between preventive and curative treatment regimens was discussed. The oil industry does not differentiate curative and preventive treatment, as the systems are always contaminated, and the biocide treatment is meant to maintain the acceptable level of microbial contamination that does not influence the processes. However, it was pointed out that when the biocide is dosed the level of contamination and the needed dose might differ. Treatment regimens can be divided into two types:

- detrimental microbial growth has already been detected in the form of operational problems, and a higher shock dosing of a biocide is needed;
- the biocide is dosed in a lower dose to maintain the population at an acceptable level.

It was agreed that it might be possible to claim these two dosing schemes by submitting one appropriate laboratory test showing these two activities. The acceptance criteria (previously defined for paper pulp applications for curative treatment are reduction of the number of bacteria (">3 log") and for preventive criteria are to maintain the bacterial load ("no growth"). If data from only one test is submitted, it should demonstrate the ability of test organisms to grow in the matrix ("growth in control") and sufficient reduction of microbes in the treated matrix. This may be achieved by adapting existing methods (ASTM or IBRG) by inoculating a low level of microbes in the beginning, incubating the samples for a certain time and when growth is detected on the level that enables high enough log reductions, dose the biocide in the treated samples. The microbial level in the untreated control should stay on the same level during the treatment period (further growth is not required). It was agreed not to use terms curative and preventive in the oilfields part of the PT12 guidance.

As the conditions at the oil field (pressure, temperature) are very difficult to mimic in the laboratory, the required efficacy test methods were discussed. The conditions at the field should be roughly followed (except pressure) to have rather representative conditions. The efficacy data have to demonstrate efficacy in these conditions for the minimum concentration of the product in the authorised dose range.

It was agreed that methods for testing biocide efficacy against biofilms will be discussed at the PEG meeting due to new IBRG methods published very recently. As acceptance criteria for biofilms 2 log reduction was proposed, but the criteria will be left for PEG to decide. For planktonic bacteria, a reduction of 3 log was agreed on.

It was agreed that from the three organism groups, i.e. general heterotrophic bacteria (GHB), sulphate reducing bacteria (SRB) and thiosulphate reducing bacteria (TRB) two species per group needs to be tested, preferably of different genus. It was also discussed whether TRB may be redundant with SRB and could therefore be removed from testing requirements, but the final decision on the required test organisms was decided to be left for the PEG.

The discussion on the PT11/12 draft guidance will be continued during ECHA consultation procedure (including PEG and CAs consultations).

8.2 TAB proposals

Disinfectants testing at elevated temperatures

DE presented the draft TAB proposal prepared in cooperation with AT and NL. The EFF WG agreed with the proposal. It was underlined that this is a general proposal with the intention to close some gaps, which currently we have in the applicable guidance concerning specific uses and absence of thermotolerant test organisms for yeast, fungi and mycobacteria.

With reference to the draft document and the proposed test organisms, it was suggested to cross-check them with CEN to assure the reproducibility of the generated efficacy data. However, the test organisms listed in the draft and based on the literature research are only examples, so other test organisms are not excluded and can be used.

The thermotolerant non-standard test organisms need to be tested in P2S1 only. However, a complete set (P2S1 and P2S2, if applicable) is always needed for the standard organisms which have to be tested prior to testing with the thermotolerant ones.

The descriptive sentence: '*[Group of target organisms] were thermally inactivated'*, which from the regulatory point of view is not in the scope of the BPR, however, might be important for the users was proposed to be placed in the SPC. As this is not within the EFF WG remit to decide about the SPC content the proposal to include such sentence will be forwarded to the CG and the WG discussion will be continued possibly in March 2022.

PT14 products with lowered AS concentration

The EFF WG agreed on the TAB proposal prepared by DE. The current TAB entry: *PT14: Applications for major changes with lower concentration of an active substance*, Version 1 (WGIV2016) will be amended in the following way:

PT14: Applications for changes with a lower concentration of an active substance or new applications for product authorisations

What kinds of efficacy data are requested as a part of an application for a change of PT14 biocidal products authorisation with a lower concentration of an active substance as well as for a new application for product authorisation, if palatability data from a product with the same formulation (except a higher concentration of the active substance) are available?

Products containing warfarin, chlorophacinone and coumatetralyl (FGARs):

Efficacy has to be demonstrated in laboratory choice and field tests or semi-field and field tests following the current Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C), chapter PT14 Rodenticides.

Products containing bromadiolone, brodifacoum, difenacoum, difethialone and flocoumafen (SGARs):

Efficacy of the 'old' formulation has to be demonstrated in laboratory choice and field tests, or semi-field and field tests following the current Guidance on the BPR: Volume II Efficacy - Assessment and Evaluation (Parts B+C), chapter PT14 Rodenticides. In case a complete efficacy data package for the 'old' formulation has been submitted including at least 20% of palatability in the laboratory tests and the product composition remains unaltered except lower concentration (≥25ppm) of an active substance only new field tests are required.

In case the palatability in the 'old' formulation is lower than 20%, new laboratory choice and field tests or new semi-field and field tests with the product under authorisation are required.

For products with active substance concentration <25ppm, new laboratory choice and field tests or new semi-field and field tests are required.

For any other change in product composition, e.g. bait formulation, that can affect bait attractiveness, other than lower concentration of an active substance, efficacy and palatability have to be demonstrated in new laboratory choice and field tests or new semi-field and field tests.

PT1-5 Use concentration and contact time (CT)

NL presented the draft TAB proposal compiling already discussed UA cases related to CT and use concentration(s).

As a general remark concerning this discussion, there was a concern raised by one of the WG members with reference to the approach taken that such decision is beyond the WG mandate and should be decided on the other (BPC) level. It will be investigated internally by ECHA and the EFF WG will be informed during the next meeting about the way forward.

With reference to rules presented in the document the following agreements were made:

PT1-5 Use concentration and contact time

How to determine the use concentration and contact time for the biocidal products with a variety of different test concentrations and contact times for the various groups of target organisms?

General rules

Rule 1:

The obligatory organisms should get the same use concentration and contact time based on provided test data. The worst-case test data, from P2S1 and P2S2 tests, should be used to determine these parameters*. In Example 1 the obligatory organisms get a use concentration of 5% and a contact time of 5 min.

Example 1: Test results and dosage recommendation PT2, hospitals, obligatory organisms bacteria and yeasts.

Target organism	**Test**	**Result**		**Test**	**Result**		**Conclusion**	
		Time (min)	Conc. (%)		Time (min)	Conc. (%)	Time (min)	Conc. (%)
Bacteria	P2S1	4	2	P2S2	5	3		
Yeasts	P2S1	5	4	P2S2	5	5		
							5	5
Enveloped viruses	P2S1	1	2	P2S2	1	2	5	5
Fungi	P2S1	5	5	P2S2	5	10	5	10

Rule 2:

Optional target organisms can never be assigned a shorter contact time and/or lower use concentration compared to the obligatory organisms**. The background for this proposal is that a disinfectant should work as a minimum against the obligatory organisms. Therefore, additional optional organisms claimed can never get a shorter contact time or a lower use concentration because the basic efficacy cannot be guaranteed at this contact time and use concentration*.

Example 1: Obligatory organisms in hospital surface disinfection have a contact time of 5 min and a use concentration of 5%. Enveloped viruses pass the efficacy tests at 1 min. at a use concentration of 2%. Based on these data the dose recommendation for all organisms claimed is: 5 min. and use concentration of 5%. Thus, the enveloped viruses will not get a separate claim.

Rule 3:

Optional organisms with a higher pass concentration will get a separate dosage recommendation. Optional organisms with a longer pass contact time will get a separate contact time.

Example 1: The fungi need a higher dosage than the obligatory organisms. So, fungi get a separate dosage recommendation (10%).

Rule 4 – as recommendation only

The contact time or use concentration in the efficacy tests of all organisms but especially of the obligatory organisms may be identical. Otherwise, the dosage recommendation will become as in Example 2, which may lead to confusion in practise.

Example 2: test results and dosage recommendation PT2, health care, obligatory (bacteria and yeasts) and optional organisms (fungi).

Target organism	**Test**	**Result**		**Test**	**Result**		**Conclusion**	
		Time (min)	Conc. (%)		Time (min)	Conc. (%)	Time (min)	Conc. (%)
Bacteria	P2S1	5	3	P2S2	5	6	15	6
Yeasts	P2S1	15	1	P2S2	15	2	15	6
Fungi	P2S1	15	3	P2S2	60	3	60	6***

* Exceptions can be made in some cases, e.g. in PT 3 for specific disinfection (see section: *'Disinfection of manure, litter and other substrates for veterinary use'* in the Vol. II, Parts B+C) and PT4 (see entry: *Differentiation of target organisms by contact time and dosage (PT4)* in the TAB).

** Biofilm should not be seen as a target organism in this context but as an additional use.

*** Fungi are effective at 3% and 60 min. However, due to fact that the obligatory organisms are effective at 6% it is not possible to dose at a lower concentration.

9. AOB – 19 November 2021

ECHA informed about ad hoc EFF WG meeting in January 2022, which will be devoted to the draft BPC opinion concerning an unresolved objection during a mutual recognition procedure in accordance with Art. 36 (1) of the BPR of two PT 19 biocidal products. This WG meeting is foreseen for MSs only. In addition, provisional dates of the next WG-I-2022 meeting, deadlines for early WG request and working documents submission were provided, a brief information about current guidance status and update from CEN about recently published EN standards was given. With reference to other issues, a request was made to publish the timelines for upcoming PFs more in advance, as the MSs need to make long-term planning regarding their work.

List of Attendees

1. **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)
2. **Flexible members:**
   - WIDHALM Bernhard (AT)
   - BURMISTROVA Anastasia (BE)
   - LEPAGE Anne (BE)
   - PELMAN Natania (BE)
   - GURBA Alexandre (CH)
   - WANDELER Eliane (CH)
   - DONZE Gerard (CH)
   - MEIER Margrith (CH)
   - DOLEZELOVA Katsiaryna (CZ)
   - PECINKOVA Martina (CZ)
   - 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)
   - Brizard Mathias (FR)
   - HADDACHE Nabila (FR)
   - OWENS Aoife (IE)
   - Lynch Helen (IE)
   - BALDASSARRI Lucilla (IT)
   - RONCI Maria Beatrice (IT)
   - MEZULE Linda (LV)
   - SCHOEP Piet (NL)
   - WARMERDAM Sonja (NL)
   - JUSZCZUK Marek (PL)
   - ÅSLING Bengt (SE)
   - DANADAIOVA Emese (SK)
3. **Rapporteurs:**
   - KAUKONIEMI Sanna (FI)
   - GOUR Annabelle (FR)
   - TALHOUËT Anne-Claire (FR)
4. **Advisors:**
   - BURGER Natascha (AT)
   - DANG THY Minh-Dung
   - Svejstil Roman (CZ)
   - GEDHUN Anke (DE)
   - CHEZEAU Aurelie (FR)
   - Andriessen Rob (NL)
   - BAS Dekker (NL)
5. **ECHA Staff**
   - SZYMANKIEWICZ Katarzyna (Chair)
   - RAULIO Mari
   - VETELAINEN Kaisa
   - SWIJNS Lisa
   - TAVARES RIBEIRO Rodrigo

6. **Stakeholders:**
    - GARMENDIA Irantzu (CEFIC)
    - THEELEN Meredith (AISE)
    - DUCHEMIN Mattieu (CEFIC)
    - Robinson Nik (CEFIC)
7. **Applicants:**
    - Veltek Associates Inc. Europe
    - Ecolab
    - Reckitt Benckiser

Environment WG-IV-2021

Final minutes

15 April 2022

Minutes of Environment WG-IV-2021

Including TAB entries for revision in Appendix I

22-23 & 25 November 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 8 were core members, 28 flexible members, 3 rapporteur and 7 advisers. One 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

SECR reminded the MSCAs to inform when colleagues leave the CA. This is needed for revoking the accesses as relevant.

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-2020

The minutes were agreed without further changes.

6. Discussion on active substances

6.1 Methylene dithiocyanate

Six items were discussed, four related to effects and two related to exposure. All points were closed and the CAR can proceed to the BPC.

Actions:

- **eCA** to provide the final DT50 value two weeks after the WG meeting, SECR to add the value in the minutes
- **NL** to prepare a document describing the new approach for PT 12 for discussion at the next WG meeting (WG-I-2022).
- The existing TAB entry for PT 11 stating abiotic degradation as relevant degradation pathway should be extended also for PT 12. **SECR** to add to TAB.

6.2 (13Z)-Hexadec-13-en-11-yn-1-yl acetate

Seven items were discussed, five related to effects and two related to exposure. All points were closed (one in a follow up discussion) and the CAR can proceed to the BPC.

Actions:

- **SECR** will look into the issue of outdated OECD guideline on pheromones in the BPD guidance to see whether a further discussion is needed.

6.3 Propiconazole

The non-confidential discussion table contained 3 open points (one provisionally closed) related to the ED Assessment. The confidential discussion table contained one open point. All points discussed were closed. The eCA will revise the CAR accordingly, the CAR can proceed to the BPC.

7. Discussion of Union Authorisation cases

7.1 UA for a product family containing L-(+)-lactic acid – PT 02 (FR)

One open point related to a co-formulant was discussed and agreed. The PAR can proceed to the BPC.

7.2 UA for a product family containing Propan-2-ol - PT 02, 04 (NL)

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 Active chlorine released from sodium hypochlorite – PT 02 (FR)

The only open point became obsolete due to the conclusions drawn at the EFF WG related to meta-SPC 2. The PAR can proceed to the BPC.

7.4 UA for product family containing Active chlorine released from sodium hypochlorite – PT 02, 04 (FR)

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 Propan-1-ol – PT 01 (SE)

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

8. AOB

8.1 Other information & lessons learned (SECR)

The **provisional** timing for **WG-I-2022** is 28 March - 8 April 2022. There is no decision yet regarding the possibility of physical meetings and the exact days still need to be established. All meetings organised by ECHA will remain virtual at least until the end of 2021, for 2022 the current plan is to have one physical meeting.

Registrations for WG meetings: SECR noted that the deadline will be stricter than earlier for registrations for the WG, and in principle late registrations would not be accepted anymore. This concerns both members and applicants. This is due to the additional work that late registrations involve, taking place during the peak workload.

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A **new TAB version** was uploaded on 9/11/2021, containing agreements from WG-II-2021 and correction of item ENV 193 (Felim - following remark by NL).

For active substances that were approved without reference specifications or reference sources, a reference specification should be set at renewal (section 1.5 in the renewal guidance[1]). All reference specifications and reference sources of active substances are in S-CIRCABC[2], and for AS renewal, the eCA should check this folder to know if the reference specification was set in the initial approval.

SECR asked for feedback and experiences of using Interact. The feedback provided will be used in improving the tool.

The new Time 2 for PT 8 (and other preservatives) was discussed and it was asked how important it is for MS. The validation of the new Time 2 was agreed at a CA meeting in 2016, SECR requested from eCAs calculation examples to perform validation. So far SECR received over the last 5 years - after several reminders – only 3 examples (from 3 different MS). It seems priority is low, should item be followed up further at all? MS noted that they will provide further examples.

SECR informed further about the development of the Chesar Platform intended to cover risk assessment for biocides (environment for now). It was highlighted that the associated stakeholder community will be involved far beyond the tool building and testing. It will be consulted also on developments of assessment approaches under BPR and REACH which impacts BPR guidance.

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[1] https://echa.europa.eu/documents/10162/2324906/data_req_assessment_applications_renewal_of_approval_as_en.pdf

[2] Path: /CircaBC/echa/BPC-WG/Library/Confidential/02. WG - Analytical methods and PhCh Properties/Reference specifications; https://webgate.ec.europa.eu/s-circabc/w/browse/c8feb839-2926-4281-9a26-e3cb9566c331

Appendices:

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

New TAB entry:

ENV xxx Degradation in PT 12 (paper industry)

Version 1 (WG-IV-2021)

As for PT 11, also for PT 12 in general only abiotic degradation (e.g. hydrolysis) should be taken into account in the paper mill system (during paper making process).

If studies of sufficient quality are available showing further degradation in the paper mill system (e.g. biodegradation), it can be agreed on a case-by-case basis if the respective information is taken into account.

Proposal to edit TAB entry ENV 212, in relation to AHEE item 4.3 (PT 18: Revised Addendum) (proposed changes in blue font)

ENV 212 AHEE recommendation: Addendum to the OECD ESD for PT 18

Version 2 (WG-I-2018, AHEE 6)

The Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems is provided in the CIRCABC TAB repository (file "ENV212_Addendum_OECD-ESD_no14_PT18_manure_v2"):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876-840f-be4878ce8869

The document embedded here below will be added to CIRCABC TAB repository:

ENV212_Addendum_OECD-ESD_no14_PT18_manure_v2:

ENV212_Addendum
_OECD-ESD_no14_PT

Version 1 (WG-I-2018)

The Addendum to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 14: Emission Scenario Document for Insecticides for Stables and Manure Storage Systems is provided in the CIRCABC TAB repository (entry "ENV212_Addendum_OECD-ESD_no14_manure_v1-1_20-8-27"):

https://webgate.ec.europa.eu/s-circabc/w/browse/20a938d6-b2c6-4876- 840f-be4878ce8869

Post WG SECR note: the following comment from DE UBA will be taken into account before uploading the above document in the TAB: "We point out a necessary adjustment of the

Addendum-Version linked here, as DE(UBA) made a comment on the consideration of sorption on suspended matter in the follow-up to the AHEE-6 Meeting, which is currently not reflected in the Version attached here (see our comment in the general minutes of AHEE-6).”

New TAB entry proposal not discussed at WG-IV-2021 but identified in the context of CHESAR Platform project

ENV xxx SURPLUSsludge considering concentration of suspended solids in effluent of 30 mg L-1 in SimpleTreat 4.0

Version 1 (WG IV 2021)

The default value for SURPLUSsludge of 0.019 (kg eq-1 d-1) as given in Biocides Guidance Volume IV Part B+C, 2017 (Table 7) is outdated. It refers to SimpleTreat 3.1 with the corresponding parameter settings for BOD, sludge loading rate (k_{SLR}) and suspended solids concentration in the effluent ($C_{SO,\ SLS}$) and other parameters that are dependent on these three, that are used to calculate SURPLUSsludge. However, the use of SimpleTreat 4.0 has been agreed by the WG ENV and this version is integrated in EUSES 2.2.0. SimpleTreat 4.0 has different values for BOD and k_{SLR} by default (compared to SimpleTreat 3.1) while after WG ENV agreement the former default value for $C_{SO,\ SLS}$ is kept at 30 mg L-1 (ref. TAB ENV 9). The corresponding value for SURPLUSsludge is now 0.0212 (kg eq-1 d-1). Assessors should take care to use the SURPLUSsludge value of 0.0212 (kg eq-1 d-1) when estimating the concentration in dry sewage sludge (Csludge) outside of SimpleTreat 4 or EUSES 2.2.2. Csludge is required to calculate PECsoil via STP sludge application on soil. Both SimpleTreat 4 and EUSES 2.2.0 calculate the value for SURPLUSsludge automatically when the concentration of suspended solids in the effluent is set to 30 mg L-1.

Using the agreed settings and SimpleTreat 4.0, the SLUDGERATE value changes to 813 kg/d (instead of the previous value of 790 kg/d).

New TAB entry proposal related to AHEE item 4.8 (Clarification on which rates (k) and time windows (t) to use in the TWA-factor for PEC and PNEC)

ENV xxx PEC and PNEC calculations – considerations to be included in the CAR/PAR

Version 1 (AHEE-6)

The derivation of the PEC and the PNEC should be clearly explained in the CAR/PAR in what regards the assumptions made when degradation is considered in the derivation of endpoints from ecotoxicological studies.

The time window for deriving an ecotoxicological endpoint based on TWA-concentrations depends on the relevant exposure duration in the study. Once used for PNEC-derivation, the resulting PNEC for the ecosystem is no longer related to a specific test duration, but represents a value that is protective for chronic exposure of the ecosystem as a whole.

The time window for the PEC, for aquatic and terrestrial assessment, is fixed and is based on a reasonable time for the chronic exposure of the ecosystem. For PT 8 the PEC Time 1 is based on 30 days in order to be coherent with a typical life cycle period of soil and water organisms (OECD, 2003).

New TAB entry proposal related to item 7.7 from WG-I-2020

ENV xxx Relevance of performing a quantitative risk assessment for chlorine substances

Version 1 (WG-IV-2021)

For products containing active chlorine released from sodium/calcium hypochlorite, chlorine or other active chlorine releasers, or active chlorine generated in-situ that have relevant releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water, however, should be assessed quantitatively.

Appendix 2: List of participants

Core members and alternates:

- (DE) Daniel Frein
- (DE) Eleonora Petersohn
- (FR) Stéphanie Alexandre
- (FR) Anne Straczek
- (IE) Helena Joyce
- (NL) Barry Muijs
- (NO) Terje Haraldsen
- (SI) Petra Muri

Flexible members:

- AT Lukas Kührer
- BE Anne Brasseur
- BE Celine Leroy
- BE Wiet Raets
- CH Maria a Marca
- DE Maren Ahting
- DE Stefanie Jacob
- DE Katja Michaelis
- DE Torsten Schwanemann
- DK Henrik Wennermark
- EE Helen Sulg
- ES IGNACIO DE LA FLOR TEJERO
- ES Myriam Martin Vallejo
- ES Elena Fuensanta Ruiz Lopez
- FI Oskari Hänninen
- FI Timo Nieminen
- FI Jaana Pasanen
- FR Aurelie Chezeau
- FR Léa Riffaut
- IE Tony O Hara
- IE Andrea Paskuliakova
- NL Peter van Vlaardingen
- NO Karina Petersen
- PL Agnieszka Podlaska
- PL Helena Rzodeczko
- SE Lena Konovalenko
- SE Liselott Säll
- SK Jana Molnarova

Rapporteur:

- FR Annabelle GOUR
- FR Anne-Claire TALHOUËT
- FI Sanna Kaukoniemi

Advisors:

- DK Jesper Johannessen
- FI Katariina Vuorensola
- FR Yannice Convert
- FR Fanny Herard
- FR Jeanne Raynert
- FR Séléné Verstraet
- SE Diana Posledovich

ASOs:

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

ECHA chairs and experts

Human Health WG-IV-2021

Final minutes

31 March 2022

Minutes of Human Health WG-IV-2021

24-26 November 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 12 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

SECR reminded the MSCAs to inform when colleagues leave the CA. This is needed for revoking the accesses as relevant.

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-2021

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Methylene dithiocyanate, PT 12 (eCA FR)

The discussion concerned reference values and absorption values, as well as genotoxicity and the assessment of migration from food packaging. Agreement was reached on each point, and the substance is not considered genotoxic. The eCA will provide the final assessment and proceed to the Biocidal Products Committee.

6.2 (13Z)-Hexadec-13-en-11-yn-1-yl acetate, PT 19 (eCA FR)

The WG agreed that exposure to the general public is negligible, and it was therefore acceptable to waive the majority of the data package for this pheromone. The eCA will provide the final assessment and proceed to the Biocidal Products Committee.

6.3 Propiconazole, PT 8 (eCA FI)

Propiconazole was considered to meet the criteria for endocrine disruption with regard to human health. It was not possible to agree on the methodology to perform the risk assessment, on the point of departure and on the margin of exposure, noting also that no guidance is available for performing the risk assessment for substances that are considered endocrine disruptors.

7. Discussion of Union authorisation applications

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

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 Propan-2-ol, PT 2, 4 (eCA NL)

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

7.3 UA for a product family containing Propan-1-ol, PT 1 (eCA SE)

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

7.4 UA for a product family containing Active chlorine released from sodium hypochlorite, PT 2 (eCA FR)

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

7.5 UA for a product family containing Active chlorine released from sodium hypochlorite, PT 2, 4 (eCA FR)

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

8. Technical and guidance related issues

8.1 Update on guidance development

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

9. Any other business

9.1 Other information & lessons learned

The EL member presented an EFSA project on assessing historical control data, where other stakeholders can also participate. The presentation is available in Interact to MSCAs and in S-CIRCABC to associated stakeholder organisations.

SECR provided a presentation that is available in Interact to MSCAs and in S-CIRCABC to associated stakeholder organisations.

SECR informed about the development of the Chesar Platform intended to cover risk assessment for biocides (environment for now). It was highlighted that the associated stakeholder community will be involved far beyond the tool building and testing. It will be consulted also on developments of assessment approaches under BPR and REACH which impacts BPR guidance.

The PEG meeting on the draft guidance on information requirements (Vol III Part A) took place on 26 October 2021. The next step is the CA consultation that is expected to be launched during 2021. Finalisation of the guidance is expected by the end of March 2022.

One member proposed organising a virtual training on the Advanced REACH Tool (ART). ECHA will investigate the possibility for such a training.

For active substances that were approved without reference specifications or reference sources, a reference specification should be set at renewal (section 1.5 in the renewal

guidance[1]). All reference specifications and reference sources of active substances are in S-CIRCABC[2], and for AS renewal, the eCA should check this folder to know if the reference specification was set in the initial approval.

SECR noted that the deadline will be stricter than earlier for registrations for the WG, and in principle late registrations would not be accepted anymore. This concerns both members and applicants. This is due to the additional work that late registrations involve, taking place during the peak workload.

SECR asked for feedback and experiences of using Interact. The feedback provided will be used in improving the tool.

Next WG meetings

The provisional timing of the next WG meeting:

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

[1] https://echa.europa.eu/documents/10162/2324906/data_req_assessment_applications_renewal_of_approval_as_en.pdf

[2] Path: /CircaBC/echa/BPC-WG/Library/Confidential/02. WG - Analytical methods and PhCh Properties/Reference specifications; https://webgate.ec.europa.eu/s-circabc/w/browse/c8feb839-2926-4281-9a26-e3cb9566c331

Annex 1

Human Health WG attendees

Core members
HOELZL Christine (AT)
MIKOLAS Jan (CZ)
HOLTHENRICH Dagmar (DE)
GUENTHER Isabel - Alternate (DE)
HERRMANN Kristin (DE)
NIKOLOPOULOU Dimitra (EL)
LAUMONIER-MAXIMILIEN Elisabet (FR)
LORI Julia (FR)
AUBIN Aurelie – Alternate (FR)
BREEN Alan (IE)
BOS Carina (NL)
Rapporteurs
RYDMAN Elina (FI)
VÄLIMÄKI Elina (FI)
TALHOUËT Anne-Claire (FR)
Flexible members
HAUZENBERGER Ingrid (AT)
HERREMANS Yannick (BE)
GOLDINGER Daniela (CH)
GRÜNIG David (CH)
RUSCONI Manuel (CH)
KLUTZNY Saskia (DE)
SCHNEIDER Heiko (DE)
HOLZWARTH Andrea (DE)
JENSEN Stine (DK)
DE RIVAS Ana (ES)
SÁNCHEZ José María (ES)
HÄMÄLAINEN Anna-Maija (FI)
HYVARINEN Tuija (FI)
REY Marion (FR)
CAPDEVILLE Perrine (FR)
VAILLANT Vincent (FR)
Applicants
Solvay
Colgate-Palmolive
Cehtra
TSG Consulting
RB
Exponent
Knoell
Syngenta

DEKOVI Edlira (IT)
ANDERSEN Hilde (NO)
MALMGREN Birgitta (SE)
PETTERSSON Emma (SE)
ČEBAŠEK Petra (SI)
OLHA Roman (SK)
PILIŠIOVÁ Ružena (SK)
Advisors
DERLER Angelika (AT)
PIORR Benedikt (DE)
MAUL Katrin (DE)
MATTHES Susann (DE)
VUORENSOLA Katariina (FI)
NDIAYE Lena (FR)
KERGUELEN Mathieu (FR)
CHEZEAU Aurelie (FR)
RIFFAUT Léa (FR)
KOSE Serif (FR)
AMSALLEM Tiffany (FR)
BELLINGARD Valérie (FR)
ECHA Staff
AIRAKSINEN Antero
DAMSTEN Micaela
ESTEVAN MARTINEZ Carmen
PAPADAKI Paschalina
RUGGERI Laura
VAN DER LINDEN Sander
LAITINEN Jaana
ANTAL Diana
VASILEVA Katya
MULLER Gesine
LIPKOVA Adriana
VANGHEEL Matthew
Stakeholders
VAN BERLO Boris (CEFIC)