Final minutes of the Working Group meeting III in 2023

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

(Meeting date: 18 September to 20 September 2023 – hybrid meeting)

06 October 2023

1. Welcome and apologies

The meeting was a hybrid meeting. The Chair welcomed the participants of the working group meeting. 36 members, 8 advisors and 5 stakeholder were registered in the meeting. The list of registered participants and observers can be found in annex I to the minutes.

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

The chair reminded the participants of the purpose of the meeting.

2. Administrative issues

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

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

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).

One new agenda point “global composition” was proposed by Slovenia and added under AoB.

The agenda was agreed with this addition.

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

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

5. Agreement of the draft minutes from WG I 2023

Three comments on the minutes of WG II 2023 were received in the commenting period. Additionally several clerical mistakes were noticed and corrected in the minutes. The working group members reviewed the comments. One reference to the data sharing guidance was inserted into the APCP TAB document. The other comments did not lead to text changes in the minutes. The draft minutes were modified accordingly and were agreed by the working group members.

6. Active Substances

6.1. Bronopol, PT 2, PT 11, PT 11

Please refer to the specific minutes of this agenda item.

6.2. Early WG discussion – alphachloralose

Please refer to the specific minutes of this agenda item.

6.3. Early WG discussion - orange, sweet, extr

Please refer to the specific minutes of this agenda item.

6.4. Early WG discussion - free radicals generated in situ from ambient air or water

Please refer to the specific minutes of this agenda item.

6.5. Early WG discussion - peanut butter

Please refer to the specific minutes of this agenda item.

7. Union Authorisations

7.1. UA for a product family containing Active chlorine released from calcium hypochlorite

Please refer to the specific minutes of this agenda item.

7.2. UA for a product family containing Propan-1-ol/Propan-2-ol

Please refer to the specific minutes of this agenda item.

7.3. UA for a product family containing Propan-2-ol

Please refer to the specific minutes of this agenda item.

7.4. Early WG discussion on UA-APP containing peracetic acid

Please refer to the specific minutes of this agenda item.

8. Technical and guidance related issues

8.1. APCP TAB entry text- Early clarification of AS identity and composition

The working group discussed the proposed addition to the APCP TAB and concluded that the text is not appropriate to include as it is not scientific/technical in nature and is not intended for the general public but rather is addressed at member state competent authorities. There was no conclusion on an alternative publishing location for these kinds of internal agreement papers. The agreement will remain available as part of the minutes of WG II 2023.

The working group also discussed the possibility not to change the basis of setting the specification after an (early) agreement. The requirement regarding the age of 5 batch analysis stems from the BPR guidance[1] where it is specified that "*In general, batches tested should be no older than five years from the date of dossier submission.*". The date of submission is interpreted as the date of submission to ECHA for the purpose of opinion forming by APCP WG I 2021 in item 11.2. While not changing the basis for an agreement on a specification was seen as beneficial, the discussion date of an early working group discussion cannot be seen as "submission date" and therefore does not qualify as reference point for the age of the 5 batch analysis data. Potentially a change in the guidance could be beneficial.

8.2. APCP TAB entry text- Procedure

The proposed text was agreed without further discussion and will be incorporated into the new APCP TAB version 4.

9. AoB

9.1. Summary of e-consultations

There have been 5 e-consultations started after WG II 2023.

- Avoiding unnecessary testing on MMAD (BE)
- Free radicals generated in situ from ambient air or water - case type assignment (AT)
- Christeyns Peracetic Acid Biocidal Product Family - organic peroxide classification (NL)
- orange sweet, ext - identification and status of "carrier" (CH)
    - PART A: BIOCIDAL ACTIVE SUBSTANCE
    - PART B: REFERENCE BIOCIDAL PRODUCT
- identity, physicochemical properties and physical hazards of the active substance peanut butter (CH)

Most of these have been added to the agenda of this meeting and have not been reported separately again.

The e-consultations that were not otherwise discussed, were shortly summarised.

- Avoiding unnecessary testing on MMAD (BE)
- orange sweet, ext - identification and status of "carrier"
    - PART B: REFERENCE BIOCIDAL PRODUCT (CH)

The summaries can be found in the respective documents.

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[1] Guidance on the BPR: Volume I Parts A+B+C Version 2.1 March 2022https://echa.europa.eu/documents/10162/2324906/bpr_guidance_vol_i_parts_abc_en.pdf/31b245e5-52c2-f0c7-04db-8988683cbc4b, p. 19.

9.2. Other information

- The working group was informed of plans to make a collection of finalised working group minutes available in a searchable way. Unfortunately S-CIRCABC was found to be technically difficult to use for this purpose.
- The working group was informed that the EFF WG is handling an assessment of in-use time for wipes which are soaked before use and claimed to be usable for a certain period of days. The assessment of this claim may involve the APCP WG if compositional considerations are invoked.
- SECR was announcing on request that the expected time for publication of the new APCP TAB version 4 is about 2 week.
- It was requested that the APCP WG picks up work on "Handling "carriers" in the authorisation of biocidal products" as discussed and agreed in CA meeting 96 June 2022. Specifically the WGs were mandated to consider "*whether the carrier component is to be considered as a part of the composition of the biocidal product and for the calculation of the AS concentration to be indicated in the SPC*".
- The WG took note and discussed a presentation delivered by Slovenia regarding the understanding of the "global composition" for in-situ substances.

  The working group voiced the opinion that the global composition is always expressed as a range of concentrations of constituents. It should contain the highest concentration actually produced with the in-situ generation system. The intention is to describe the scope that was assessed during the active substance approval.

  For the presented two-stage system it was remarked that the second stage (dilution) could be considered corresponding to the application rate of the biocidal product and therefore part of the biocidal product assessment.

  Regarding the purity of water it had already been concluded in APCP WG II 2023 that the quality of water used needs to be described.

  The working group recommended the eCA to present the subject to the working group as an e-consultation so that a more in-depth assessment can be done and more trageted advice can be given.
- In connection with agenda item 7.1 the WG was discussing whether the shelf-life can be set based on negative accelerated storage stability results plus efficacy data. The general agreement was that this kind of extrapolation is not possible. Especially the identity and quantity of degradation products cannot be reliably extrapolated form accelerated storage stability tests in case on negative results (instable product). But also the extend of degradation after the long term storage cannot be reliably extrapolated. Typically an assessment of efficacy after an accelerated storage stability test is not required

Annex 1 - List of attendees registered for the meeting

Country	Member state participant	
AT	Schindler	Peter
AT	Kriegl	Isabel
AT	Altmann	Dominik
AT	Neuwirth	Erich
AT	Hofmann	Natalie
BE	Bay	René
BE	Huerga-Fernandez	Samuel
BE	Burmistrova	Anastasia
BE	Fauconnier	Steven
BE	Swennen	Kim
BE	Dang Thy	Minh-Dung
CH	Aeschbacher	Michael
CH	Courdouan Merz	Amandine
CZ	Vlasak	Martin
DE	Deden	Tobias
DE	Wintrich	Daniela
DK	Domino	Katrine
DK	Christiansen	Jeppe Juhl
EE	Vallikivi	Imre
ES	Escalada Aguilera	Jesus
ES	Cano	David
FI	Vuorensola	Katariina
FR	Weber	philippe
FR	Lutz	François
FR	Six	Thérèse
IT	Cataldi	Lucilla

NL	Van Rijnsbergen	Peter
NL	Kruidhof	Sabine
NL	Bourke	Alena
NL	Pouwels-Smolenaars	Marianne
NL	Storm	Inge
NO	Sekkenes	Marianne Stave
NO	Gjerde	Ingrid Ur
PL	Juraszek	Magdalena
PL	Horczyczak	Anna
PL	Huszał	Sylwester
SE	Marsh	Göran
SE	Johansson	Anh
SI	Velikonja Bolta	Špela
SI	Zirngast	Klavdija
SK	Drabova Kusikova	Zuzana

Accredited Stakeholder Organisations (ASOs)		
CEFIC	Boris	Van Berlo
A.I.S.E	Marie	Darriet
A.I.S.E	Marie	Regnier

Applicants
Chemservice GmbH
Frida Group
BENS Consulting
Exponent International Limited

Christeyns N.V.
SWISSINNO SOLUTIONS AG
DHD-Consulting GmbH
Oro Agri International Ltd
Contec Cleanroom (UK) Ltd

ECHA staff
Uphoff Andreas
Marcon Eva
Valkovicova Eva
Vetelainen Kaisa

WG-III-2023
Final minutes
5 December 2023

Final minutes of Efficacy WG-III-2023

19, 21 and 28 September 2023

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 them that this meeting is split into three separate days. The list of attendees is given in Annex 1.

2. Administrative issues

SECR gave brief information on the administrative issues.

3. Agreement of the agenda

The Chair introduced the agenda items. The EFF WG agreed on the proposed agenda.

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

The Chair invited all members to declare any potential conflict of interest to the agenda items. None was declared.

5. Minutes

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

6. Discussion of active substances

6.1 Bronopol (eCA ES)

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

7. Discussion of Union Authorisations

7.1 UA for a product family containing Active chlorine released from calcium hypochlorite (eCA NL)

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

7.2 UA for a product family containing Propan-1-ol/Propan-2-ol (eCA NL)

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

7.3 UA for a product family containing Propan-2-ol (eCA NL)

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

7.4 Early WG discussion on UA-APP containing DDAC and Propan-1-ol (eCA CH)

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

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

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

8. Technical and guidance related issues

8.1 Resistance draft guidance (FR)

This session was split into two days. In total 5 presentations related to an overview of the past discussions, mode of action and occurrence of resistance based on information from the CARs and PARs, classification of a risk to resistance, monitoring system of insecticide resistance in mosquito vectors, and about resistance in other regulations (VMP/PPP) were

given by FR. One more presentation about the report concerning the development of (cross-) resistance to antimicrobials, including a qualitative active substance ranking was given by BE.

The first discussion concerned the literature review template which will be implemented in the CAR/PAR template in the future. The outcome of this discussion is presented below.

- Previous resistance data from CAR/PAR (column B) - data from CAR/PAR already assessed will be marked with (*) and a footnote will be added, e.g. (*) data already provided and assessed in CAR/PAR;
- Information on field site (column C) – such information will be taken into account, if reported in the study;
- Information/benefit on resistance terms used (column G) – this column will be removed;
- Conclusion of the study author(s) (column I) – FR will come with a new proposal;
- Proposal of 'Reliability score' for the methodological level – two tables as proposed will be kept to score methodological reliability and relevance;
- eCA conclusion (column J) – will be separated into two fields, one for eCA conclusion and the other field for reliability and relevance/rejection;
- MoA when resistance data available/absent – will be removed, instead the relevant section in the CAR should be filled in appropriately;
- Separate information on the search criteria and results of the literature review as in ED guidance (see tables F.2 and F.3)- FR will come with a new proposal;
- Add ticking box - a ticking box will be added to the other columns (B and C).

The second discussion concerned the FR document (used at the national level) related to the mode of action of active substances and the occurrence of resistance. It is used as a tool (database) to address resistance in different dossiers at the national and EU levels. It facilitates harmonisation between different dossiers with reference to the wording, it is updated, if there is new information after the active substance assessment. The WG appreciated the development of such a document, however, a few issues, e.g. how to update it addressing new information, or how to deal with new information from one applicant only need to be discussed further. FR will prepare a document and it will be presented for discussion.

Moreover, the first time during the EFF WG a breakout groups session took place. Some of the sentences extracted from the frequently used sentences agreed by the CG and related to resistance management were discussed. The aim of this session was to agree on some of these sentences or modify them to establish a non-exhaustive list to be used in future dossiers. Further discussions are foreseen. It was proposed to share this list (when ready) via Collaboration with all the MSs.

8.2 TAB proposal - PT1-5 Use concentration and contact time (ECHA)

TAB proposal was introduced by ECHA. The draft was slightly revised, mainly adjusting the language of this document.

The agreed TAB entry is presented below:

PT1-5: Biocidal products against various groups of target organisms with different use concentrations and contact times within the same use.

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

Rule 1:

The product used against the obligatory target organisms only, e.g. bacteria and yeasts, should have within the same use the same use concentration and contact time for all of them based on the provided test data. The worst-case test data, from phase 2, step 1 (P2S1) and phase 2, step 2 (P2S2) tests, should be used to determine these parameters.*

In example 1 the product used against obligatory organisms gets a use concentration of 5% and a contact time of 5 minutes.

<u>Example 1:</u> Test results and dosage recommendation: PT2 - health care, 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*			*5*	*5*
Fungi	*P2S1*	*5*	*5*	*P2S2*	*5*	*10*	*5*	*10*

Rule 2:

*If also optional target organisms are claimed, the product can never be used having a shorter contact time and/or lower use concentration within the same use compared to these foreseen for the obligatory target organisms**. The background for this proposal is that a disinfectant must work as a minimum against the obligatory organisms. Therefore, the product can never have a shorter contact time or a lower use concentration against optional target organisms claimed as the basic efficacy cannot be guaranteed at this contact time and use concentration*.*

In example 1 the product used against the obligatory organisms in health care surface disinfection have a contact time of 5 minutes and a use concentration of 5%. To be used against enveloped viruses the contact time of 1 minute and the use concentration of 2% is sufficient. Based on these data the dose recommendation for all organisms claimed is: 5 minutes and the use concentration of 5%. Thus, the product used against enveloped viruses will not get a separate dosage recommendation.

Rule 3:

If optional target organisms are claimed within the same use and the product needs to have a higher in-use concentration to pass the relevant criteria, it will get a separate dosage recommendation. The same applies if a longer contact time is necessary for the product to be used against the optional target organisms. The product will get a separate contact time to be used against these optional organisms.

In example 1 the product used against fungi need a higher dosage than the obligatory organisms. Thus, the product used against fungi gets a separate dosage recommendation of 10%.

As recommendation for efficacy testing

The contact time or use concentration in the efficacy tests of the optional target organisms should preferably be identical to the contact time or use concentration of the obligatory organisms. Otherwise, the dosage recommendation will become as in example 2, which may lead to confusion in practise.

<u>Example 2:</u> Test results and dosage recommendation PT2 - health care, obligatory organisms (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 PT 4 (see entry: Differentiation of target organisms by contact time and dosage (PT4) in the TAB), this will be evaluated by the eCA on case by case basis.*
*** Biofilm should not be seen as a target organism in this context but as an additional use.*
**** The product is efficacious against fungi at a concentration of 3% and 60 minutes contact time. However, due to the fact that the product is efficacious against the obligatory organisms at the concentration of 6% it is not possible to lower the concentration in the recommended dose.*

8.3 Guidance needs (ECHA)

The efficacy experts and ASOs were invited to share their views concerning guidance needs. Many proposals were submitted, and support to develop/revise the Vol. II, Parts B+C were given mainly to preservatives (PT 6, 7, 9, 10 and 13), and pest control (PT 18). An interesting proposal concerning guidance on the assessment of animal welfare was submitted by DE. It has to be investigated further if the potential development of such guidance is within the EFF WG remit. The intention of this discussion was to see the guidance needs from the efficacy experts' perspective, in the near future it will be necessary to prioritise which chapter of the Vol. II, Parts B+C will be developed/revised. It was indicated that a preferable method to update the missing information/requirements in the current guidance is to develop a new TAB entry.

9. AOB

9.1 Other information

A brief update on the upcoming EFF WG-IV-2023 meeting was provided including the deadlines for the early WG discussion requests and working documents submission. The WG decided that in the future, the results of all e-consultations should be presented at a subsequent meeting of the EFF WG under AOB, unless further addressed in the frame of a WG discussion. In addition, ECHA shared several updates related to:

- guidance update,
- recently published on the ECHA webpage document concerning e-consultations,
- recently published on the ECHA webpage updated CAR/CLH template including the new hazard classes under CLP,
- overdosing issue, which will be brought by BE to the discussion at the CA level following the EFF WG e-consultation,
- some remarks concerning opinion forming phase for active substances and biocidal products dossiers.

Annex 1

Efficacy WG attendees

Core members	
Country	**Name**
DE	Jansen Irina
EL	Giatropoulos Athanasios
FR	Attig Isabelle
NL	Warmerdam Sonja
SI	Duh Daria

Flexible members	
Country	**Name**
AT	Burger Natascha
AT	Widhalm Bernhard
BE	Anene Abla
BE	Burmistrova Anastasia
BE	Lepage Anne
BE	Pirotte Jennifer
CH	Baumgartner Rebekka
CH	Meier Margrith
CH	Wandeler Eliane
CZ	Doleželová Kateřina
CZ	Svejstil Roman
DE	Fischer Juliane
DE	Schmolz Erik
DK	Jørgensen Charlotte Cleyton
ES	Landa Blanca
ES	Portela Cristina
FI	Nieminen Timo
FI	Rydman Elina
FR	Brizard Mathias
FR	Haddache Nabila
IE	Owens Aoife
IT	Ronci Maria Beatrice
NO	Petersen Karina

NO	Sekkenes Marianne Stave
SE	Åsling Bengt
SK	Danadaiová Emese
SK	Jaššová Juliana

Alternate members	
Country	**Name**
DE	Krüger Martin
EL	Ampatzi Argyro
FR	Maximilien Yann
NL	Dekkers Bas

Advisers	
Country	**Name**
CH	Goldinger Daniela
ES	Fajardo González Lara
ES	Lorenzo Galicia Sara
FR	Bridier Arnaud
FR	Soumet Christophe

ECHA Staff	
Katarzyna	Szymankiewicz (Chair)
Mari	Raulio
Grethe-Johanna	Ploompuu
Anni	Honka
Eva	Hamalainen

Accredited Stakeholder Organisations (ASOs)	
A.I.S.E.	Darriet Marie
A.I.S.E.	Black Elaine
A.I.S.E.	Corner Hannah
CEFIC	Woollen Lorraine
Evonik	Hasenjäger Sophia

Applicants
Contec Cleanroom Ltd
ECA Consortium A/S
DHI