Minutes of the Working Group meeting IV in 2019

Analytical Methods and Physico-Chemical Properties

(Meeting date: 17 September 2019)

12 November 2019

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. A representative of CEFIC was present at the meeting as an accredited stakeholder organisation (ASO).

Participants of the working group were informed that the meeting is recorded, but solely for drafting the minutes and the recording will be destroyed after the agreement of the 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 by ECHA for information. The major items on which the working group members had been informed were:

- New Process Flows are published with timelines (active substances and Union authorisations)
- Four working group meetings are foreseen in 2020
- The objective of the membership review is to decrease the high number of flexible members
- ED discussions opened for WebEx for training purposes (passive participation only)
- When initiating an e-consultation that refers to an application, the case number and contact details of the applicant(s) should also be provided.

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 item was added to the agenda:

- Efficiency of the APCP working group.
- Waiving justifications for physical hazards properties.

The agenda was agreed.

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

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

5. Agreement of the draft minutes from WG II 2019

The working group members had no comments on the draft minutes. The minutes of the working group meeting III in 2019 were agreed by the working group members.

Efficiency of the APCP working group

The working group members discussed the efficiency of the working meetings. Suggestions for improvement were discussed and will be followed-up by ECHA.

6. Discussions of Union Authorisations

6.1. Biocidal Products Family ClearKlens product based on isopropanol

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

6.2. Iodine based products – CID Lines NV

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

7. Outcome of e-consultation

7.1 Hokoex – Nanoparticle properties of co-formulant silicon dioxide

A document summarising the outcome of the e-consultation was presented to working group members. No discussion took place.

7.2 In situ generated peracetic acid

A document summarising the outcome of the e-consultation was presented to working group members. No discussion took place.

7.3 Renaming of 'active chlorine generated from N-chlorosulfamte'

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

7.4 Union authorisation of active chlorine released from sodium hypochlorite

A document summarising the outcome of the e-consultation was presented to working group members. It was agreed that the discussion will take place at a future working group meeting.

8. Definitions of the function of co-formulants

The chair explained that the document on the definitions of the functions of co-formulants was introduced at the working group meeting III in 2017. During the Coordination Group (CG) 34 meeting, the members supported the development of the definitions of the function of co-formulants since it is a prerequisite for the grouping concept.

The chair stated that following steps have been conducted by ECHA in the meanwhile:

- IUCLID dataset for product authorisations have been extracted for co-formulant functions. All found functions are included in an excel sheet.
- The European Commission database for information on cosmetic substances and ingredients (CosIng) has been consulted for functions on cosmetic ingredients. Definitions which were considered appropriate are included in an excel sheet.
- Regulation (EC) No 1333/2008 on food additive has been consulted on the function of the additives. Definitions which were considered appropriate are included in an excel sheet.

The extract of the IUCLID dataset resulted in a high number of different terms of co-formulants. Therefore, this working group meeting was focusing only on the grouping/merging or deletion of these terms. The proposed definitions can be commented during an e-consultation to which industry is also invited to contribute.

9. AoB

Classification and labelling as organic peroxide

A document on the classification and labelling of organic peroxides was introduced which explains the possible consequences when applying the decision logic for organic peroxides as indicated in the Guidance on the application of the CLP criteria. The document includes questions to the working group members. It was agreed that the document and the questions will be followed-up by an e-consultation and will be further discussed at a future working group meeting.

Hydrogen peroxide classification as oxidising liquid

This agenda item was triggered by a follow-up of the working group meeting II in 2019 on the Union Authorisation for Hydrogen Peroxide Family 1 – PT 01, 02, 03, 04. Germany provided a comprehensive document that explains and justifies that solution of hydrogen peroxide with a content of ≥8 % must be classified as oxidising liquid. It was agreed at the working group meeting that ECHA will further follow-up on this issue and present the final agreement at the Biocidal Products Committee meeting at the latest. The working group members will be informed about the outcome.

Waiving justifications for physical hazard properties

The chair provided a presentation on the coherence of waiving justifications for physical hazard properties. It was highlighted that waiving of physical hazard properties of biocidal products might be possible but the waiving logic must be consistent. It was explained that the following statements should questioned:

- The biocidal product is not classified as xyz without further explanation. The applicant must explain how this statement was concluded.
- None of the compounds is classified as xyz therefore the biocidal product does not require a classification as xyz. In such cases the following should be considered:
    - Sufficient information on the testing or structural considerations or kinetics should be available for all compounds
    - Is this statement based on test results? If yes, are these available on the safety datasheet or from literature?
    - If no information or only partial information is available it cannot be concluded that the compound and the biocidal product is not classified as xyz, then test(s) should be required
- If the property is not addressed, the applicant must be requested to complete the application
- In cases where reference is made to the safety datasheet, the safety datasheet must be available and all necessary information must be indicated on it.
- 'Not classified' could be interpreted in different ways:
    - A test was conducted and the result does not require a classification
        - However, the result should nevertheless be indicated in the SDS
    - A valid waiver justification is available
        - Waiver justification should be indicated in the SDS
    - No test or information available
        - Test on the co-formulant/biocidal product or valid waiver justification should be requested
    - Property has not been considered
        - Test on the co-formulant/biocidal product or valid waiver justification should be requested

- It is not sufficient to tick the box of the prefilled waiver justification in the IUCLID dataset. These justifications might be valid but must be explained why they apply to the specific substance or biocidal product

It was stressed that it is in the responsibility of the applicant to provide this information. In cases where the applicant is not able to provide a valid and scientific sound waiving justification, the substance/biocidal product should be tested.

Annex 1 - List of attendees

Country	Members of WG
Austria	ZUTZ Christoph
Estonia	ILMARINEN Kaja
Finland	VUORENSOLA Katariina
Finland	KARPPANEN Essi
France	WEBER Philippe
Germany	MŰHLE Ulrike
Greece	GATOS Panagiotis
Italy	CATALDI Lucilla
Latvia	IGAUNE Ieva
Norway	HELGERUD Trygve
Norway	STAVE SEKKENES Marianne
Poland	HUSZAŁ Sylwester
Portugal	BORGES Teresa
Slovenia	VELIKONJA BOLTA Špela
Slovenia	CEBASEK Petra
The Netherlands	HUIZING Tjaart-Jan
The Netherlands	STORM Ingeborg

ECHA staff
KREBS Bernhard (Chair)
GLANS Lotta
SCHAKIR Yasmin
HONKA Anni

Company	Observer
Diversey	Van CORVEN Danielle
Cidlines	BELHASSAN Fanny
Cidlines	IHADDADENE Yamina

Accredited Stakeholder Organisations (ASOs)	
Organisation	**Observer**
CEFIC	KASURINEN Ossi

WG-IV-2019

Final minutes

12 November 2019

Minutes of Efficacy WG-IV-2019

18-20 September 2019

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 29th Efficacy WG meeting. There were 6 core members, 1 alternate member and 18 flexible members who participated in the meeting. In addition 4 stakeholder representatives, 2 CEN representatives and the applicants were present for their respective agenda items.

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 gave a brief information on the administrative issues.

3. Agreement of the agenda

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

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

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

5. Minutes

DE had sent comments on the EFF WG-III-2019 draft minutes, and AT made one comment in the meeting. The EFF WG agreed on the revised draft minutes.

6. Discussion of Union Authorisations

The EFF WG agreed that in general within one use there should be one common application rate and contact time for mandatory target organisms. Well-justified exceptions may be accepted only for professional users. For non-mandatory target organisms the application rate and contact time may differ from the common one.

6.1. UA for product containing propan-2-ol (eCA NL)

There was one provisionally closed point for this application, which was re-opened and discussed in the meeting. Please refer to the confidential minutes in the form of the discussion table for more details.

6.2. UA for product family containing iodine/PVP-iodine (eCA NL)

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

6.3. Early WG of general interest (eCA BE)

Please refer to the confidential minutes for more details.

7. Technical and guidance related issues

7.1. Update on guidance development (ECHA)

ECHA, FR and AISE/CEFIC gave the update on current guidance development. Currently, the following efficacy guidance documents are under development/revision:

- TAB: The EFF WG members were asked to submit comments concerning the revised version of TAB. ECHA will check the comments in October and updated version of TAB is intended to be published in November.
- PT11&12: FR organised a 1 day meeting in Paris with ECHA and ASOs to discuss some open points for PT11, e.g. growth in the control, pass criteria, etc. All agreements will be implemented in the new version and send for comments by the EFF WG in October. Next discussion will take place in November at EFF WG-V-2019, this discussion will concern PT11 only. Scope issues with other PTs will be discussed in the CA meeting at the end of September.
- PT19: Drafting of the PT19 efficacy guidance is in progress. IND gave a short information concerning validation of AIC tests, please see item 7.2 below.
  The intention is to discuss in September and November the chapters related to mosquitos, flies on grazing cattle and horses, biting midges and ants, and finalize the first round of discussions for the chapter on stored goods-attacking insects and mites.
- Appendix 4: The discussion is ongoing, some e-consultations will be launched in October to finalise the still open points. Then ECHA will implement all agreements and the revised version will be sent for cross-check to the EFF WG and ASOs.

7.2. Vol II, Parts B+C – PT 19 (AISE/CEFIC, DE, DK, NL)

A presentation related to AIC validation test was given by IND. IND and testing institutes have the opportunity to organize the validation of an alternative test design before finalization of PT19 chapter. It will possibly enable to avoid a requirement for all products to be tested in more realistic field tests. The presentation included testing conditions, i.e. number of volunteers, size of the test cabin (40 L and 64 L), insect species, density, periodicity of tests, application rates (1 g and 0.5 g/600 cm^2 and tested product's formulation. The intention of this validation is to compare the CPT results obtained in the AIC as described in the Vol. II, Parts B+C guidance with the CPT obtained in a semi-field test. The length of the protection will be expressed as CPT and also calculated as percentage of protection (99%, 98%, 95% and 90%). The respective application rates are tested with and without sleeve. The tested sleeves were presented during the meeting. It is expected to finalize this validation in October 2019 and the results will be presented at WG-V-2019 in November. Preliminary results show that the use of the sleeve could be an alternative option instead to expose the entire forearm when tests are performed with aggressive mosquitoes (*Aedes albopictus*), and the doses of 0.5 gram/600cm^2 lead to shorter CPT's. Some issues were raised by the EFF WG members with reference to field test, type of the plastic used in the tested sleeves (will be checked by IND), high biting pressure in the current AIC and real density in the European areas, tested mosquitoes species. In addition to the AIC test validation the EFF WG discussed PT19 draft guidance, chapters related to stored goods attacking insects, flies on grazing cattles and horses and started the discussion on mosquitoes. Due to time constrain it was not possible to finalise section related to mosquitoes and discuss biting midges. These discussions will take place in WG-V-2019 in November.

7.3. Contact time (CT) for wipes (AT)

The initial discussion on this item was planned in WG-III-2019. Nevertheless, it was decided to postpone the EFF WG discussion and revise the document after bilateral meeting between AT and ASOs.

The revised version prepared by AT was presented during the meeting. As indicated during the presentation the surface not necessarily has to be wet during the whole CT. In some cases it is even difficult to observe if it is still wet or not due to the very thin layer formed by the liquid. Moreover, it is not always possible to make a direct link between wet surface and CT, e.g.

The EFF WG slightly modified the proposed conclusion and agreed on it. Passing of the EN 16615 after the claimed CT using the indicated wipes (see WG-III-2019 8.2) for volatile and non-volatile active substances in wipe applications is regarded as acceptable to

indicate that sufficient wetting of the surface occurred without rewetting/keeping the surface wet.

7.4. Harmonised approach to determine a worst case (or representative) test product for a disinfectant BPF PT 1-5 (DE) – closed session.

Please refer to the confidential minutes: *WGIV2019_EFF_minutes_draft_confidential.*

7.5. Vol II, Parts B+C – PT1-5, Appendix 4 (ECHA)

The discussion on '*Appendix 4 - Overview of standards, test conditions and pass criteria (PT 1-5)'* continued from WG-III-2019. Like for PT 2, also for PT 3 and PT 4 general hard surface disinfection sporicidal activity will be added, and contact time (CT) will be amended to 'as claimed', with a footnote that it is recommended to follow the CTs stated in the respective EN standards, and that the minimum contact time needs to be in accordance with the EN standard. CEN reminded that for sporicidal activity EN 17126 should be used only for medical applications, and EN 13704 for all other applications. Regarding room disinfection it was pointed out that there is no such section for PT 3 in the main text of the guidance, but on the other hand there are several biocidal product applications making room disinfection claims for PT 3. Therefore it was agreed that CEN will send a proposal for adding PT 3 room disinfection into Appendix 4, and the proposal will be discussed in the future. A proposal had been made by CEN to harmonise the soiling conditions and CTs for PT 3 pre- and post-milking teat disinfection, but the EFF WG agreed that they will be kept as they are, since this approach has been agreed by EFF WG and has already been used for a number of product applications.

It was agreed to keep test temperature for PT 4 hard surface disinfection as 20°C, and to refer to footnotes including information of temperatures below and above 20°C. CEN will make a proposals on the footnotes. The fact that yeast may be killed by high temperature alone, without any added effect of the biocidal product, was also discussed. It was agreed that Biocides Coordination Group should be consulted on whether it could be stated in the SPC e.g. that product is bactericidal and virucidal, and yeast are killed because of the high temperature.

Footnotes:

- Footnote 4 was agreed to be amended according to the definition of clean surfaces in prEN 14885 rev. This footnote was also amended regarding soiling conditions for PT 2 cosmetic industry and PT 4 meat industry. The soiling conditions for PT 3 teat disinfection and PT 4 milk industry were left unchanged.
- It was agreed to modify footnote 6 so that handwash and handrub will have separate sentences, and the contact time for medical area will be stated as 'usually 30 s'.
- Footnote 9 was agreed to be amended according to the CEN proposal.
- Footnote 13 was agreed to be modified according to the NL suggestion, and adding a CT of 15 min for non-mandatory target organisms.
- Footnote 14 was left unchanged.
- Amendment of footnote 15 will depend of the result of an ad hoc follow-up on virucidal claims.

The Chair informed that the for the remaining open points where there is not an agreement of EFF WG a combined Ad hoc follow-up will be launched. ECHA will subsequently introduce all changes agreed at EFF WGs II, III and IV 2019 into Appendix 4. Also amendments not having been discussed in EFF WG, but where there seems to be an agreement, will be implemented. After all the changes have been introduced (with track changes), a commenting round will be organised.

8. AOB

8.1. PT5 efficacy requirements for drinking water disinfectants used in the Nordic countries (FI)

FI is working on a project concerning drinking water disinfectants: *'Towards suitable and sufficient efficacy requirements for drinking water disinfectants used in the Nordic countries – survey and proposal'*. The project will continue until the end of 2019 and after a full report (in English) will be provided to the EFF WG.

Large water treatment plants in Finland, Sweden and Norway manufacture high quality drinking water from surface waters using chemical disinfectants in combination with other purification steps. Microbial quality of drinking water is managed by the complete process, not only the chemical disinfection step. PT5 EFF requirements should be in line with the current practises. The well-functioning water treatment processes should not be changed because of the BPR EFF guidance requirements.

The water purification procedures currently used in Nordic countries passes the simulated use tests but not EN1276 and even the modified version of this standard test is unsuitable for evaluation of the efficacy of continuously dosed PT5 disinfectants. Monitoring data exists in abundance to be used for assessment of the efficacy of the treatment.

One of the EFF members commented the lack of actual efficacy test data which could show if the current disinfection step is efficacious in concentrations used. Other member shared the concern with FI and stated that the guidance might be too rigid and at least some of the plants have processes where concentrations of disinfectants that will not pass the tests are used. It was mentioned that the users should be able to use as low concentrations of disinfectants as is efficient in their processes.

It was agreed, that EFF WG will wait for the full report of this project and after that decides whether PT5 guidance should be updated.

8.2. Growth quantification or determination of filamentous (AT/FR)

The acceptance of colony forming unit (CFU) counts for quantifying filamentous fungi in non-filterable matrices has been re-discussed. The conclusion agreed during the WG-II-2019 has been modified again. The EFF WG agreed with the compromise solution on how to assess the growth of filamentous fungi in non-filterable matrices unsuitable for visual examination (by a naked eye).

The use of CFU assessment for filamentous fungi proves to be inadequate. Some of the alternative methods may also be insufficient to demonstrate growth of filamentous fungi. Thus in such cases the assessment of growth should be based on a combination of CFU assessment and additional method performed in parallel. The following list of methods poses examples of additional detection methods:

- Microscopical assessment of matrix samples to demonstrate if spores have grown into hyphae. It is recommended to provide pictures of at least 8 samplings per replicate in a respective study report. If hyphae are observed in each replicate, then growth is confirmed. Only complex hyphae structure may be regarded as growth in contrast to the first initial hyphae strand spreading out of the spore which may not be regarded as growth.
- Detection of matrix degradation, like e.g. loss of viscosity, or of biological marker molecules linked to fungal growth like e.g. ergosterol measurement, ATP analysis, or CO_2 development in the matrix (controls should be included such as "non-treated but inoculated matrix" and both "non-treated and not inoculated matrix"). At least three replicates should be performed. Each measurement protocol has to be robust and described in detail. Raw data has to be provided.

Appropriate controls have to be performed.

Growth or metabolic activity has to be demonstrated in both, the CFU assessment and the chosen additional method.

8.3. Worst-case product for PT21 efficacy testing (NL) - closed session

Please refer to the confidential minutes: *WGIV2019_EFF_minutes_draft_confidential.*

8.4. Other information and lessons learned (ECHA)

The EFF WG participants were informed about upcoming meeting in November 2019 and meetings planned in 2020. ECHA prepared and uploaded on S-CIRCABC a template for an early working group discussions, direct link to this document is provided in the presentation. The EFF WG members should use this template when preparing a draft document. The EFF WG members were encouraged to comment on the draft minutes. To facilitate an access to the respective Newsgroup ECHA will circulate an email to the respective EFF WG participants when the draft minutes are ready for comments.

All details are available in the working document: *WGIV2019_EFF_8-4_Other info&lessons learned*.

List of Attendees

Efficacy Working Group

Core members
ATTIG Isabelle (FR)
DUH Darja (SI)
HAMEL Darka (HR)
GIATROPOULOS Athanasios (EL)
POULIS Joan (NL)
ZUTZ Christoph (AT)
Alternate members
JANSEN Irina (DE)
Flexible members
ÅSLING Bengt (SE)
BALDASSARRI Lucilla (IT)
BLODÖRN Krister (SE)
CLEYTON JØRGENSEN Charlotte (DK)
DAN Marius (RO)
DANADAIOVA Emese
FISCHER Juliane (DE)
GURBA Alexandre (CH)
ILMARINEN Kaja (EE)
KRASZEWSKA Joanna (PL)
LEPAGE Anne (BE)
MEZULE Linda (LV)
NIEMINEN Timo (FI)
PECINKOVA Martina (CZ)

Flexible members
PEELMAN Natania (BE)
RONCI Maria Beatrice (IT)
RYDMAN Elina (FI)
SCHOEP Piet (NL)
ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
RAULIO Mari
SCHAKIR Yasmin
HONKA Anni
Applicants
Experts
STEINHAUER Katrin (CEN)
Stakeholders
KASURINEN Ossi (CEFIC)
KECK Melanie (CEFIC)
MORENO Mara (AISE)
VAN SLOUN Petra (CEFIC)

Environment WG-IV-2019

Final minutes

7 November 2019

Minutes of Environment WG-IV-2019

26-27 September 2019

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 19 participants present, of which three were core members, fourteen flexible members and in addition two rapporteurs. No representatives from accredited stakeholder organisations were present. 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 gave a brief presentation on administrative issues.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. 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. The chair declared a conflict of interest with two applicants, the respective sessions were chaired by the deputy chair.

5. Agreement of the draft minutes from WG-III-2019

The minutes will be agreed via a written procedure after the WG meeting.

6. Discussion of Union Authorisation cases

6.1 UA for product containing propano-2-ol (eCA NL) – PT 2

One point regarding a new emission scenario was discussed and closed. The item can proceed to the BPC.

Actions:

- **SECR** to draft a TAB entry.

6.2 UA for product family containing Iodine/PVP-Iodine (eCA NL) - PT 3, 4

Eight points related to exposure assessment and product classification were discussed, all points were closed. The item can proceed to the BPC.

Actions:

- **SECR** to draft **TAB** entry on inclusion of density in all emission scenario where it is not noted already.
- **SECR** to add in **TAB** regarding emission to sewer for certain sub-groups.
- **SECR** to check in relation to the AHEE-3 discussions if the current CIP scenario (based on tonnage per annum used in one plant) should be replaced.

6.3 Early WG: Harmonisation of Union Authorisation cases (peracetic acid) (eCA DE, BE, NL, UK) - PT 02, 03, 04, 05, 06, 11, 12

A harmonised approach was sought among the different eCAs evaluating Peracetic acid (PAA).

Five points related to the exposure assessment and identification of substances of concern were discussed, all points were closed. There were no follow up actions identified.

6.4 Early WG: Product used for aircraft disinsection - PT 18 (eCA BE)

One point related to exposure assessment was discussed and it was closed. There were no actions for a follow-up identified.

6.5 Early WG: GW assessment for PT 1 hand-rub products containing volatile substances (eCA DK)

One point related to exposure assessment was discussed and it was closed: The WG agreed that for products containing volatile alcohols (small scale applications), there is no need to conduct a risk assessment for subsequent environmental compartments following the release path via air. This conclusion concerns all relevant PTs.

Actions:

- **SECR** to draft a respective **TAB** entry.

7. Discussion of Active Substances

7.1 New endpoints for CMK (eCA NL)

New information available for CMK was discussed and concluded. The new information will be send to the BPC for confirmation and follow up.

Actions:

- Under this agenda item general issues with the post approval procedure were discussed, which will be followed up at the next BPC meeting in December (**SECR** to prepare a document, reflecting the feedback from the WG members).

7.2 Chlorfenapyr (eCA PT) - PT 18

Additional RMMs as well as the ED assessment was discussed and concluded. The item can proceed to the BPC.

7.3 Icaridine – ED assessment (eCA DK) - PT 19

One provisionally closed item related to the ED assessment was discussed and concluded. The item can proceed to the BPC.

7.4 Cyanamid – ED assessment (eCA DE) - PT 3, 19

Five open points related to the ED assessment were discussed and concluded. The item can proceed to the BPC.

7.5 Formic acid – ED assessment (eCA BE)

One open point related to the ED assessment was discussed and concluded.

8. Technical and guidance related issues

8.1 Overview on guidance

SECR presented the status on guidance development, issues identified for the AHEE and e-consultations. Updates from WG members during the meeting have been included after the WG meeting (see embedded document in **Appendix 2** below).

Action:

- **SECR** to initiate the item "Guidance on disinfectant by-products formed during the use of products in product types that are not yet addressed" with an e-consultation (=> ask for major issues/problems, any volunteers to take the item up?)
- **FR** will initiate a general consultation of the WG regarding problems coming up with product authorisations in PT 21.

9. AOB

9.1 Other information & lessons learned

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

Next WG meetings

SECR informed of the provisional timing of the next meetings – note that the below dates are now confirmed and they differ from the provisional dates indicated at the meeting:

- 14-15 November 2019 – Environment WG – physical meeting
- December 2019 - AHEE-3 WebEx follow up - (TBD)
- 2-3 April 2020 – Environment WG – exact days to be established, expected to be physical

Endocrine disruption (ED)

SECR informed of the remaining ED Expert Group (EG) meetings scheduled for 2019 as follows:

- 7 October (confirmed)
- 3-5 December (provisional)

In the ED EG of 7 October, one biocidal active substance is discussed: Peracetic acid generated from 1,3-diacetyloxypropan-2-yl acetate and hydrogen peroxide (eCA AT).

The document agreed at CG-34 (12-13 March) "*Assessment of ED properties of co-formulants in biocidal products – draft instructions for applicants*" is now available[1].

The document prepared by BE and FR "*Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA*" was not agreed at CG-37 (17-18 September). Another commenting period was opened and the document will be discussed again at CG-38 in November.

[1] Link to folder in public S-CIRCABC: https://webgate.ec.europa.eu/s-circabc/w/browse/89efe476-1017-46af-8a31-6ad845f79d04

In situ generated active substances

SECR informed that the document "Management of product authorisation for in situ cases" (CA-July19-Doc.4.1-Final[2]) was agreed at the July CA meeting.

It is now necessary to analyse the consequences of the document and where additional guidance is necessary. An e-consultation is expected to be launched for MSCAs and ASOs in order to identify the needs to amend or supplement the guidance, and to identify volunteers for drafting. ECHA will analyse the input received and next discussions are expected to take place at WG-V-2019 or WG-I-2020.

Combined WG minutes

The combined minutes of all Human Health WG meetings (currently until WG-II-2019) are now available to MSCAs[3].

Read-across assessment framework

The WG in general supported applying the RAAF for biocides, pending clarifications on the impact and the timelines for implementation. As an action point, SECR was to clarify the next steps and consider whether an agreement at the BPC and/or CA meeting would be required.

As the way forward, SECR proposed that a full impact assessment would not be performed, but rather there would be an introductory (testing) phase, during which the RAAF would be applied in a flexible manner. Biocide specific instructions for applying RAAF could be developed once more experience has been gained.

SECR will prepare a document that will be brought either to WGs (if technical issues need to be discussed) or for agreement at the BPC.

WGs effectiveness

SECR informed of an ad hoc discussion that took place in the previous Environment WG regarding the follow-up actions to the workshop of February 2019. SECR noted that the same discussion has now taken place at all WGs and asked for further input from the members. SECR will collect the input from different WGs and provide a document.

Literature search for post approval data

A literature search is not needed and should not routinely be requested (it is not requested in the legal text) - should only be requested if new information (provided by applicants) is discussed at WG meeting which is not considered sufficient by the WG.

General items

The revised **ESD v1.1 for PT 6** was uploaded on the ECHA webpage: https://echa.europa.eu/documents/10162/16908203/esd_pt-6_revised_september_2019_en.pdf/040f87fb-433c-bdc6-56e8-8c4cc839931d

ENV WG/AHEE Chair will be **absent** from 1. November 2019 until 31. January 2020 and will be backed up as follows:

- For ENV WG related issues: Deputy Chair Simon Gutierrez
- For AHEE/exposure related issues: Adriana Lipkova
- For EUSES/ESD Excel sheet related issues: Eugenia Nogueiro

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[2] https://circabc.europa.eu/d/a/workspace/SpacesStore/ebde735e-b070-4f02-8910-3e56d9cb2d0e/CA-July19-Doc.4.1%20-%20Final%20-%20in%20situ.docx

[3] https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/9fd5b5da-e915-4215-8936-f05f4ef71644/TOX%20WG_final%20minutes_until%20WGII2019.pdf

9.2 Update on ongoing EUSES projects

The planned release date for **EUSES 2.2.0** is end of September, the software will be uploaded on the following webpage: https://echa.europa.eu/support >"Tools"

To download the software, sign in (ECHA account) and agree to User's licence agreement

As support material a practical guide "How to use EUSES 2.2.0" was prepared which covers the changes and new features in EUSES 2.2.0 compared to EUSES 2.1.2. A webinar to introduce the software is planned for 17 October.

Regarding the **major EUSES update**, the pre-study finalised June 2019. From all evalutad options the third option (merging Chesar and EUSES into a new tool) scored highest from all perspectives (user, tool owner, vision for future):

- All functionalities in one tool, no need to switch / make a connection
- Most possibilities for future → basis for future incorporation of other compartments/models depending on vision and resources
- Fits in ECHA strategy for consolidation and development of sustainable tools
- Most efficient for all parties in the long run
- Easiest to maintain

The new tool will be the central platform for exposure and risk assessment, for chemicals, biocides and beyond. It will include a full REACH CSA workflow and an environmental assessment workflow for Biocides, ensuring flexibility as currently included in EUSES.

9.3 Calculation sheets for emission scenarios prepared by NL

NL volunteered to provide their Excel Sheets for uploading on the ECHA ESD webpage. SECR will screen the Excel Sheets provided by NL for emission scenario which are not yet available on the ECHA webpage. These will then be first validated by the ENV WG and afterwards uploaded to the ECHA ESD webpage.

9.4 Introducing the Activities Coordination Tool (ACT)

SECR gave a presentation and demo of ACT. The presentation is available in S-CIRCABC.

Appendices:

Appendix 1: List of participants

Core members:

- (DE) Eleonora **PETERSOHN – rapporteur**
- (FR) Stéphanie **ALEXANDRE**
- (NL) Barry **MUIJS - rapporteur**

Flexible members:

- Altmann Dominik (AT)
- Brasseur Anne (BE) **– rapporteur**
- Hahlbeck Edda (SE)
- Haraldsen Terje (NO)
- Lefebvre Frederic (BE) - **rapporteur**
- Loskyll Julia (DE)
- Malaguerra Flavio (CH)
- Molnarova Jana (SK)
- Muri Petra (SI)
- Pasanen Jaana (FI)
- Penttinen Sari (FI)
- Podlaska Agnieszka (PL)
- Skou Cordua Birgitte (DK)
- Sulg Helen (EE)

Rapporteurs :

- Borges Teresa (PT)
- Wennermark Henrik (DK)

Appendix 2: Item 8.1 - Overview on guidance

Note:

In the following embedded overview on guidance

- Closed items are provided in green writing
- Unassigned items are provided in red writing
- New items (coming up at the meeting) are highlighted in yellow

WGIV2019_ENV_8-1_
Guidance overview.xls

Human Health WG-IV-2019

Final minutes

18 November 2019

Minutes of Human Health WG-IV-2019

18-19 September 2019

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 30 members registered, of which 9 were (alternate) core members. One stakeholder representative and one expert were registered. Applicants were registered for their specific substance discussions.

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 informed that the objective of the ongoing membership review is to decrease the high number of flexible members, and the MSCAs can consider the role of an adviser for participants that do not join the meetings regularly.

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-2019

The minutes were agreed without changes.

6. Discussion of Union authorisation applications

6.1 UA for product containing propan-2-ol, PT 2 (eCA NL)

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

6.2 UA for product family containing Iodine/PVP-Iodine, PTs 3 and 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. Discussion of active substances

Icaridin – ED assessment, PT 19 (eCA DK)

The WG considered that there are no indications of ED properties, but the available data is not sufficient to conclude.

Chlorfenapyr – ED assessment and additional exposure scenario, PT 18 (eCA PT)

The WG agreed on the new exposure scenario presented by the eCA.

Regarding the ED assessment, the WG supported the need to further investigate the A and S modalities. For the S modality, level 2 assays were supported. For the A modality, the members supported performing the Hershberger assay (covering partially also the S modality). The WG did not support performing the uterotrophic assay.

Cyanamid – ED assessment, PTs 3 and 18 (eCA DE)

The WG concluded that Cyanamid does meet the criteria to be considered as an endocrine disruptor.

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 associated stakeholder organisations and is provided in the same format also to the CA meeting.

8.2 New TAB entry proposal - Local risk assessment

SECR presented a revised version of the TAB entry, which was agreed without further changes.

9. Any other business

9.1 Other information & lessons learned

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

Dermal absorption of rodenticides

DE informed that the document is nearly finalised and will be provided to SECR soon, suggesting to share it with the MS for commenting and indicated that specific support offered earlier by FR would not be needed before commenting. SECR noted that if the proposal includes default values, there may be the need for a legal check by SECR.

Endocrine disruption (ED)

SECR informed of the remaining ED Expert Group (EG) meetings scheduled for 2019 as follows:

- 7 October (confirmed)
- 3-5 December (provisional)

In the ED EG of 7 October, one biocidal active substance is discussed: Peracetic acid generated from 1,3-diacetyloxypropan-2-yl acetate and hydrogen peroxide (eCA AT).

The document agreed at CG-34 (12-13 March) "*Assessment of ED properties of co-formulants in biocidal products – draft instructions for applicants*" is now available[1].

The document prepared by BE and FR "*Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA*" was not agreed at CG-37 (17-18 September). Another commenting period was opened and the document will be discussed again at CG-38 in November.

In situ generated active substances

SECR informed that the document "Management of product authorisation for in situ cases" (CA-July19-Doc.4.1-Final[2]) was agreed at the July CA meeting.

[1] Link to folder in public S-CIRCABC: https://webgate.ec.europa.eu/s-circabc/w/browse/89efe476-1017-46af-8a31-6ad845f79d04

[2] https://circabc.europa.eu/d/a/workspace/SpacesStore/ebde735e-b070-4f02-8910-3e56d9cb2d0e/CA-July19-Doc.4.1%20-%20Final%20-%20in%20situ.docx

It is now necessary to analyse the consequences of the document and where additional guidance is necessary. An e-consultation is expected to be launched for MSCAs and ASOs in order to identify the needs to amend or supplement the guidance, and to identify volunteers for drafting. ECHA will analyse the input received and next discussions are expected to take place at WG-V-2019 or WG-I-2020.

Combined WG minutes

The combined minutes of all Human Health WG meetings (currently until WG-II-2019) are now available to MSCAs[3].

Read-across assessment framework

At WG-III-2019, the WG in general supported applying the RAAF for biocides, pending clarifications on the impact and the timelines for implementation. As an action point, SECR was to clarify the next steps and consider whether an agreement at the BPC and/or CA meeting would be required.

As the way forward, SECR proposed that a full impact assessment would not be performed, but rather there would be an introductory (testing) phase, during which the RAAF would be applied in a flexible manner. Biocide specific instructions for applying RAAF could be developed once more experience has been gained.

SECR will prepare a document that will be brought either to WGs (if technical issues need to be discussed) or for agreement at the BPC.

Next WG meetings

SECR informed of the provisional timing of the next meetings – note that the below dates are now confirmed and they differ from the provisional dates indicated at the meeting:

- 18-19 November – Human Health WG – physical meeting
- 20 November – ARTFood – physical meeting

WG effectiveness

SECR informed of an ad hoc discussion that took place in the Environment WG regarding the follow-up actions to the workshop of February 2019. SECR presented the input received at the ENV WG and asked for further input from the members.

SECR will collect the input from different WGs and provide a document.

9.2 Introducing the Activities Coordination Tool (ACT)

SECR gave a presentation and demo of ACT. The presentation is available in S-CIRCABC.

[3] https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/9fd5b5da-e915-4215-8936-f05f4ef71644/TOX%20WG_final%20minutes_until%20WGII2019.pdf

Annex 1

Human Health WG attendees

Core members
MIKOLAS Jan (CZ)
HOLTHENRICH Dagmar (DE)
HERRMANN Kristin - alternate (DE)
ARAPAKI Niki (EL)
NIKOLOPOULOU Dimitra (EL)
TERUEL Cristina (ES)
LORI Julia (FR)
BARRON Thomasina (IE)
WELTEN Angelique - alternate (NL)
Rapporteurs
KUCHERYAVENKO Olena (DE)
BOYE PETERSEN Annika (DK)
BORGES Maria Teresa (PT)
Flexible members
HOELZL Christine (AT)
HERREMANS Yannick (BE)
HOUAMED Anis (BE)
KÄOSAAR Sandra (EE)
HÄMÄLAINEN Anna-Maija (FI)
VÄLIMÄKI Elina (FI)
DEKOVI Edlira (IT)
GÓRECKI Roman (PL)

LÅSTBOM Lena (SE)
LESER Vladka (SI)
OLHA Roman (SK)
ECHA Staff
AIRAKSINEN Antero (Chair)
DAMSTEN Micaela
RUGGERI Laura
PAPADAKI Paschalina
ANTAL Diana
ESTEVAN MARTINEZ Carmen
VASILEVA Katya
SCHAKIR Yasmin
Applicants
Diversey Europe
CID LINES
Saltigo GmbH
BASF
AlzChem
Stakeholders
KASURINEN Ossi (CEFIC)
Advisors
Kiwamoto Reiko (NL)
Casimiro Elsa (PT)