

Minutes of the Working Group meeting VII in 2018 for Analytical Methods and Physico-Chemical Properties

(Meeting date: 03 December 2018)

19 March 2019

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting which was held as a virtual meeting. CEFIC was registered as accredited stakeholder organisation (ASO) for this meeting with one persons.

The chair highlighted that only registered members can participate in this meeting although it is a virtual meeting, hence non-registered persons were requested to leave. Participants of the working group were informed that the meeting is recorded, but solely for the purpose of drafting the minutes and that 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.

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:

- Update on the status of post-authorisation data for the active substances:
 - Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide,
 - Silicium dioxide (Silicium dioxide/Kieselgur),
 - Synthetic amorphous silicon dioxide (nano).

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 by the working group members.

5. Discussion of Union Authorisation applications

5.1. UA for BPF Iodine VET

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

5.1.2 Mass medium aerodynamic diameter (MMAD)

The need to determine the MMAD was raised several times during the peer-review of the Union Authorisation applications that were discussed during this working group meeting. The guidance on the BPR, Information requirements, Volume I provides imprecise information about the situation when the MMAD must be determined. It is stated: "The particle size distribution of powder biocidal products and granules must be addressed ... For all powder biocidal products and biocidal products that are applied in a manner that generates exposure to aerosols, particles or droplets then the MMAD (mass medium aerodynamic diameter) must be determined." Hence, it was unclear under which situations the MMAD must be determined. Austria, as eCA of the Union Authorisation of BPF Iodine VET, prepared a document as a thought starter on this issues. Although the MMAD is a data requirement, there is still the possibility of waiving if scientific sound justifications are provided by the applicants. In general, it was agreed that other experts, in particular human health exposure and efficacy, must be consulted to decide if the MMAD will be needed for the evaluation of the biocidal

product. Hence, in cases where the MMAD is not needed for the exposure assessment or to demonstrate efficacy, it may be possible to waive the MMAD. In cases where the working group members cannot reach an agreement on the need of the MMAD, the issue may be forwarded to the Biocidal Products Committee for deciding.

As indicated in the document prepared by Austria, all of the following criteria must be fulfilled when the determination of the MMAD is waived:

- 1. The product is not sold together with a spraying device, applicable for solid and liquid products;
- 2. The MMAD is not required as an input parameter for the human exposure assessment;
- 3. The MMAD is not relevant to demonstrate efficacy.

In addition it was agreed, in cases where the MMAD is required it must be determined before and after storage as the pressure in the packaging may change and impact the droplet size.

5.2. UA for Iodine products family Boumatic

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

5.3. UA for CVAS Disinfectant product based on propan-2-ol

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

5.4. UA for Pal IPA product family

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

5.5. UA for product family containing propan-2-ol (UK)

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

6. AoB

Update on the status of post-authorisation data for the active substances (Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide, Silicium dioxide (Silicium dioxide/Kieselgur), Synthetic amorphous silicon dioxide (nano))

The evaluating competent authority of the active substance reported that no new information has been received from the applicant. The eCA is continuing requesting this information about the analytical method and the result thereof to demonstrate that the content of crystalline SiO2 is below 0.1% (w/w) in the active substance.

Annex 1 - List of attendees

Country	Members of WG
Austria	KRIEGL Isabel
Belgium	VAN BERLO Boris
Denmark	SKOU CORDUA Birgitte
Estonia	ILMARINEN Kaja
Finland	KARHI Kimmo
Finland	KARPPANEN Essi
France	WEBER Philippe
Germany	MŰHLE Ulrike
Italy	CATALDI Lucilla
Norway	HELGERUD Trygve
Poland	HUSZAŁ Sylwester
Slovenia	VELIKONJA BOLTA Špela
Sweden	ALPE Mia
Switzerland	AESCHBACHER Michael
The Netherlands	HUIZING Tjaart-Jan
United Kingdom	WARBURTON Anthony

ECHA staff
KREBS Bernhard (Chair)
VIEIRA LISBOA Duarte
MATTHES Jochen
SCHAKIR Yasmin
CIOATA Nadia

Company	Observer
F-oxyde	THONHAUSER Christian
Arche-consulting	DHOOP Barbara
Calvatis	ESCHBACH Bruno
SCC-GmbH	KOZIOL Felix
Contec Inc	MURPHY Siobhan
TSG consulting	ALBAYA John

Accredited Stakehol	der Organisations (ASOs)
Organisation	Observer
Cefic	KASURINEN Ossi



WG-VII-2018 Final minutes 22.1.2019

Minutes of Efficacy WG-VII-2018

3-4 December 2018

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 25th Efficacy WG meeting. There were five core and one alternate member, 10 flexible members, two advisors, and three rapporteurs who participated in the meeting. In addition two stakeholder experts joined for agenda item 7.1., 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. Discussion of active substances¹

5.1 Early WG discussion of free radicals (eCA AT) (closed session)

Three questions were discussed. An agreement was reached for one point of the discussion related to the testing strategy.

The second point proposed for discussion was considered as a scope related issue. The eCA was invited to consult the Commission.

One point was left open to be agreed in an ad hoc follow-up by a written procedure. The eCA will prepare the summary of the key studies and it will be presented to the EFF WG.

For more detailed description of the disccussions, please refer to the EFF WG conclusions in S-CIRCABC.

6. Discussion of Union authorisation applications

6.1 Union Authorisation for product family containing Iodine/PVP-Iodine (eCA AT)

There were four provisionally closed points in the discussion table, one of which was reopened during the meeting. The EFF WG agreed on all points.

6.2 Union Authorisation for product family containing Iodine/PVP-Iodine (eCA NL)

The were no open points in the discussion table. The EFF WG agreed with the evaluation made by the eCA.

6.3 Union Authorisation for product family containing propan-2-ol (eCA UK)

There were four open points and 15 provisionally closed points in the discussion table. Two points were left open to be agreed in an ad hoc follow-up.

6.4 Union Authorisation for product family containing propan-2-ol (eCA UK)

 $^{^{\}rm 1}$ The details of the substance discussions are considered restricted. Only the non-restricted conclusions are reported here.

There were four open points and 18 provisionally closed points, two of which were reopened in the meeting. One point was left open to be agreed in an ad hoc follow-up.

6.5 Union Authorisation for product family containing propan-2-ol (eCA DE)

There were three open points and one provisionally closed points in the discussion table. The EFF WG agreed on all points.

7. Technical and guidance related issues

7.1 Vol II, Parts B+C – draft guidance PT19 (DE)

A part of the chapter on Mosquitoes related to Arm in cage (AIC) test of the PT19 draft efficacy guidance was discussed by the EFF WG. In total 156 comments had been received, some of which were already incorporated into the draft. The EFF WG agreed with part of the comments, but some were left open to be agreed in a written procedure. DE is preparing a publication on the testing performed to compare different types of AIC tests (AIC full forearm, AIC sleeved arm, Arm to cage). The EFF WG members were not able to reach an agreement without looking at the obtained results, therefore it was agreed that once the manuscript is submitted for publication, DE will also provide it to EFF WG members (provisionally in January 2019). Subsequently the chapter of arm-in-cage test will be discussed again. Cefic informed the WG that they might be able to organise a ring trial comparing the traditional AIC test and the modified test, after the recommended protocol has been agreed by the EFF WG. This should preferably be done before the finalisation of the draft PT19 guidance.

Due to time constraints the chapter on Ticks was not discussed. The next EFF WG discussion on PT19 draft guidance is planned for EFF WG meeting in March 2019, and possibly a workshop could be organised in connection to WG meeting in May 2019.

8. AOB

7.1 Proposal for a guidance for efficacy testing of PT21 products for aquaculture use (NO)

A proposal from NO of a guidance for efficacy testing of PT21 products for aquaculture use was presented. The NO CA is a reference MS for an application for authorisation of a biocidal product family. For the time being, there is no guidance for efficacy testing of PT21 products for aquaculture. Therefore, the NO CA initiated a project to develop such a guidance document in cooperation with SINTEF. This proposal was circulated for comments to the EFF WG members and based on the received comments the following questions were discussed by the EFF WG:

1. <u>Whether there is a need to define a cut-off value for efficacy? If so, how should this value be defined?</u>

The EFF WG could not agree on this question. Different views were expressed, i.e., some members could accept the NO proposal to set evaluation criteria based on difference between treated and control nets, some members supported to set 25% threshold as a cut-off value. Overall it was concluded that there is not enough expertise in the EFF WG to evaluate such products. It was noted that there is a large variation in biofouling in different regions.

 Does the EFF WG agree that it should be a requirement that the sample analysis of the test panels is performed according to the description of analysis type B (% biofouling cover is determined for defined categories, i.e., slime, macroalgea, invertebrates), or can a sample analysis performed according to the description of analysis type A (quantification of biofouling load of sample using the nominal rank scale) be acceptable?

Different views were again expressed by the EFF WG members, there was no general agreement. In order to be able to decide on the efficacy criteria, the claims made by the applicants should be clarified. The EFF WG also questioned whether

protection time could be used as possible efficacy criterion. Finally, it was decided that further discussion is necessary on this point.

3. <u>Does the EFF WG agree that it is acceptable to keep the possibility to include an</u> <u>optional control consisting of a reference product with known efficacy in the test?</u>

The EFF WG agreed that the reference product could be included as additional supporting information. However, it should be ensured that an uncoated control is always included in the tests.

4. Does the EFF WG agree that it is adequate to require efficacy testing at one worst case location, or would the proposal of requiring tests at 3 different locations in order to cover the variability of fouling between areas be preferred? Does the EFF WG agree that dose-response data for efficacy testing of PT21 products should be required?

In general the EFF WG supported that testing should be done in the region for which the claim is made by the applicant. It was also noted that it is not possible to define one worst case location. Further discussion is necessary.

Due to time constraint, the second part of question related to the dose-response was not discussed during the meeting.

5. <u>Does the EFF WG agree that it is necessary to include an overview of the key species</u> <u>groups in the biofouling communities in Europe?</u>

The EFF WG agreed that it is not possible to define the key species groups for this particular use for the time being.

6. <u>Should this proposed guidance document for efficacy testing of PT21 products</u> <u>intended for use on aquaculture nets be included as an annex to the Volume II</u> <u>Efficacy, Assessment + Evaluation (Parts B+C)?</u>

This point will be reflected when an agreement on the possible guidance will be reached in the EFF WG.

It was pointed out that there seems to be an urgent need for a workshop with experts from all concerned MSs.

7.2 Other information & lessons learned (ECHA)

The Chair informed that the next EFF meeting will be a virtual meeting on 22 January 2019, with one UA application discussion and a COM request according to Art 38(2) of the BPR planned on the agenda.

Regarding Vol II Efficacy guidance Parts B+C, Appendix 4 on standards, test conditions and pass criteria PT1-5, DE has reviewed inconsistencies and contradictions. In addition two set of extensive comments have been received from CEN, along with proposal from NL regarding PT3. It is planned to circulate Appendix 4 for comments of the EFF WG in January, and WG discussion is foreseen for March 2019.

The Chair also reminded that the new distribution list for UA applications is in use, that according to the new working procedures for active substances and Union authorisations the eCA is responsible for communication with the applicant, including sending WG documents and minutes to the applicant, and that R4BP3 should be used for sending confidential material. It was also mentioned that there is a plan to revise the UA working procedure in relation to trilateral discussion, providing the RCOM and disagreements in closing points phases.

List of Attendees

Efficacy Working Group

Core members	Advisors		
ATTIG Isabelle (FR)	BLÖCHER Nina (NO)		
DUH Darja (SI)	WIAK Joanna (PL)		
HAMEL Darka (HR)	ECHA Staff		
GIATROPOULOS Athanasios (GR)	PRIHA Outi (Chair)		
ESCH Daniel (DE)	STASKO Jolanta		
Alternate members	SCHAKIR Yasmin		
WORM Petra (NL)	Rapporteurs		
Flexible members	HAUGSTAD Kjetil (NO)		
BURMISTROVA Anastasia (BE)	SMITH Ryan (UK)		
FISCHER Juliane (DE)	ZUTZ Christoph (AT)		
BALDASSARRI Lucilla (IT)	Applicants		
ILMARINEN KAJA (EE)	Contec Cleanroom (UK) Ltd		
BILLAULT Catherine (FR)	Boumatic Boumatic Iodine product family		
NIEMINEN Timo (FI)	CVAS Development GmbH		
PECINKOVA Martina (CZ)	Applied Biocides GmbH		
PEELMAN Natania (BE)	AMiSTec GmbH & Co. KG		
RYDMAN Elina (FI)	Stakeholders		
CLEYTON JØRGENSEN Charlotte (DK)	MORENO Mara (AISE)		
	VAN SLOUN Petra (CEFIC)		



Environment WG-VII-2018 Final minutes 18 March 2019

Minutes of Environment WG-VII-2018

3 - 4 December 2018

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 21 participants present, of which six ere core members (one represented by alternate) and fourteen flexible members. No representatives from accredited stakeholder organisation 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.

5. Agreement of the draft minutes from WG-V-2018

The minutes of one active substance and the general minutes were agreed without further changes, for two cases a written procedure was initiated (closed in the meanwhile).

6. Discussion of Union authorisations

6.1 UA for product family containing Iodine/PVP-Iodine (eCA AT) – PT 3

Four points were discussed, one item was provisionally closed before the meeting. All points were closed, the PAR can proceed to the BPC.

Actions:

• **eCA** to check bilaterally cross-check the calculations for arable land with DE since they came to different results.

6.2 UA for product family containing Iodine (eCA NL) - PT 3

One point related to exposure assessment was discussed. All points were closed, the PAR can proceed to the BPC.

6.3 – 6.5 UA for three product families containing propan-2-ol (eCA DE, UK) - PT 2,4

Four point related to exposure assessment were discussed. All points were closed, the CAR can proceed to the BPC.

Actions:

- **SECR** to prepare a **TAB** entry concerning the groundwater assessment for volatile substances.
- **SECR** to prepare a **TAB** entry on the correct way on how to calculate kvolat.
- **SECR** to check one **TAB** entry concerning the application frequency in PT 2.

6.6 New endpoints for Permethrin after active substance approval (eCA NL)

Three point related to effect assessment were discussed. One item remained open, for which an ad hoc follow up was agreed.

Actions:

• SECR to initiate the Ad hoc follow up agreed at the meeting.

6.7 Questions of MS/CG related to product authorisations

1. Read across between leaching studies (NL)

Under which conditions can leaching studies with another formulation be accepted?

Should both formulations be identical except for pigments or is some further variation in composition acceptable?

Conclusion: No conclusion could be drawn on the questions asked by NL.

Action: SECR to contact EBPF to ask for a first proposal for discussion at a future WG/AHEE meeting.

2. Default leaching rate for new TIME 2 (NL)

It is acceptable to apply in the absence of leaching data as default value for 365 days a percentage leached of 75%?Point closed.

Conclusion: The WG agreed to use a default value of 75% for the amount of substance leached after 365 days, if no leaching data is available.

Action: SECR to prepare a TAB entry.

3. Commenting product authorisation reports (NL)

NL like to hear how other member states assess PARs and what their opinion is regarding the activities during the first and second assessment.

Conclusion: The items is provided only for information and discussion. No conclusion is drawn since it is a general topic and not a scientific or technical item related to environmental risk assessment. If needed, a follow up at BPC/CG can be initiated.

4. PT 2: How should the disinfection of sewage sludge and waste water be assessed? (DE)

- Do other MS have national regulations for the case of disinfection of municipal waste water?
- Do other MS know if such a disinfection is common practice in your country? Are there common mechanisms and/or devices in the standard STP for such a disinfection?
- Feedback to the above mentioned approaches from CAR and PAR to assess disinfection of municipal waste water: do other MS share DEs doubts?
- Do other MS evaluate further b.p. which are intended to disinfect municipal wastewater? What kind of approach is used in these PARs?

• Theoretically, the disinfection of sewage sludge may be an intended use as well. Do other MS have experiences in the environmental exposure assessment of disinfection of sewage sludge?

Conclusion: No conclusion could be drawn on the questions asked by DE, only limited feedback was collected.

Action: SECR to initiate and e-consultation to follow up the item.

5. Anticoagulants in surface water – new information to be considered in the 2nd renewal of PT 14 products? (CG)

Should the information in the paper of Kotthoff *et al.* 2018 be considered for the 2^{nd} renewal of PT 14 products?

Conclusion: The WG agreed that the study should be taken into account only at the next AS renewal stage in order to agree on a harmonised way forward on how to take the outcome of the study into account.

7. AOB

7.1 Other information & lessons learned

The following "**Other information**" was provided:

Next WG meetings: The provisional timing of the next **ENV WG** was noted to be 31. January to 1 February. *Post WG meeting note: the next ENV WG meeting will take place 28-29 March 2019, including an expert group meeting on PT 8 on 27 March 2019.* The next **AHEE** meeting is scheduled for June or July 2018.

New open public CircaBC site: Path: /CircaBC/echa/Documents agreed at BPC WG meetings/Library

Link: https://webgate.ec.europa.eu/s-circabc/w/browse/845c07a2-b0d1-49c5-9620-90a037c6d1e4

The site contains:

Final WG documents:

- To prevent pending documents awaiting publication e.g. via TAB
- Date of uploading of final documents = publication date
- For completeness, earlier agreements have been included
- Date of uploading of final documents ≠ publication date

Draft WG documents:

• For information only

Endocrine disruptors: Link to publicly available information on ED EG substances: <u>https://echa.europa.eu/ed-assessment</u>

ECHA requested tentative information from MSCAs regarding ED EG discussions during 2019, information was received from FI, DE, SK, SE, AT, ES.

Provisional ED EG meeting dates 2019:

- 5-7 March
- 1-3 October
- 3-5 December

The meetings may be shorter depending on the number of substances ED EG members are mostly from REACH, MS were invited to consider whether they could provide an ED EG member.

The next ED EG meeting takes place on 5-7 March:

• Deadline for confirming the substances: 8 January

- Please consider confirming in December if possible
- Confirm by email to <u>ed eg@echa.europa.eu</u>

Feedback from CG meeting:

- RMMs for PT8 products for in-situ outdoor applications: CG members agreed that the RMM to mitigate risk to the environment by covering the ground with a plastic cover is acceptable for professionals and non-professional users (as long as the cover is disposed off in a safely manner)
- UK presented the results of the study comparing the assessment of the salt-water scenario using the new PT21 tool and the current OECD method - the comparison showed that new tool provides more conservative results

Some lessons learned:

- Early WG for new emission scenarios/non-standard exposure assessment should be mandatory proposal for update working procedures
- WG members were invited to send items for the agenda at least 5 weeks before the WG meeting (better 6!) the agenda is published 4 weeks before the meeting and the information is need for the planning of meeting time/number of meeting days
- There is no WebEx access for ENV WG meeting possible when taking place as physical meeting unless guidance related items are discussed
- If an MS is checking the ERA during commenting and comes to different results, the eCA is invited to provide detailed their calculations in the RCOM table
- Agreed items after AS approval should not be brought forward again to WG meeting, unless there is new information available justifying the re-discussion.

7.2 Update on EUSES

An updated on the ongoing EUSES projects was provided, for further details please refer to the minutes of AHEE-2.

Appendices:

Appendix 1: List of participants

Core members:

- (DE) Eleonora **PETERSOHN**
- (DE) Daniel FREIN as alternate
- (FR) Stéphanie **ALEXANDRE**
- (IE) Helena JOYCE
- (NL) Barry MUIJS
- (UK) Clare LANE

Flexible members:

Buchner Iris (AT) Brandt Charlotte (BE) Jarrety Helene (BE) a Marca Maria (CH) Kunz Petra (CH) Ahting Maren (DE) Wennermark Henrik (DK) Pasanen Jaana (FI) Pasanen Jaana (FI) Pasttinen Sari (FI) Haraldsen Terje (NO) Hadam Anna (PL) Konovalenko Lena (SE) Muri Petra (Slovenia) Viana Bruno (PO)



Human Health WG-VII-2018 Final minutes 4 April 2019

Minutes of Human Health WG-VII-2018

4-5 December 2018

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 20 members registered, of which 6 were core members. One stakeholder representative was present. Applicants were registered for their specific substance and Union authorisation 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:

- According to the UA Working Procedure, the eCAs are responsible for sending the discussion tables and minutes to applicants.
- The rapporteurs need to register via the links provided in the invitation. They are reimbursed by ECHA if no core members are attending from the eCA. The CWT travel agency has to be used.
- There is an increasing number of nominations of new WG members and there may be some delay due to the high number of WG meetings (newly nominated member might not be yet in the WG mailing list). It was reminded that members cannot nominate themselves.

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-V-2018

The minutes were agreed without further changes.

6. Discussion of Union authorisation applications

6.1 UA for product family containing Iodine/PVP-Iodine (eCA AT)

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 (eCA NL)

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

6.3 UA for product family containing propan-2-ol (eCA UK)

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

6.4 UA for product family containing propan-2-ol (eCA UK)

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

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

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

7.1 Addressing the genotoxicity of CHED (eCA NO)

The WG agreed on the approach for assessing the possible genotoxicity of the active substance. For details, please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

7.2 Glucoprotamin: early WG discussion (eCA DE)

The WG provided input to the eCA regarding non-testing approaches for several endpoints. Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

8. Technical and guidance related issues

8.1 Update on guidance development

SECR presented the current status of several guidance-related documents which are at different stages of development, including general documents as well as those developed in the context of the ad hoc Working Groups on Human Exposure (HEAdhoc) and Assessment of Residue Transfer to Food (ARTFood). The identified needs for further guidance development were also presented. The document is available in S-CIRCABC to members and associated stakeholder organisations.

8.2 HEAdhoc: Harmonisation of PT 2 surface disinfection exposure scenarios

The member in charge of developing the document presented its scope and clarified that it is intended for exposure scenarios of small-scale disinfection. The members supported the approach described in the document for scenarios A) to C). The WG agreed on the wording of the document with minor amendments. The final version of the document will be provided in S-CIRCABC and the HEAdhoc website¹.

The WG did not support the proposal for harmonisation of Scenario D) "Mixing & Loading/ Refilling", which will be forwarded to the ad hoc Working Group on Human Exposure (HEAdhoc) for further revision.

8.3 Dermal absorption of rodenticides

SECR presented the document, reviewing the previous attempts to reach harmonisation in deriving dermal absorption values for anticoagulant rodenticides, and presenting the request from the Coordination Group to prepare a thought-starter document and initiate a discussion at the HH WG.

The DE member volunteered to prepare a document for the WG, and the FR member volunteered to provide support to DE.

9. Any other business

9.1 Other information & lessons learned

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

¹ <u>https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure</u>

UA trilaterals

The eCAs and commenting MSCAs are requested to make an effort to fulfil the purpose of the trilateral discussions, i.e. to ensure that the main points can be agreed. The eCA should mark as closed as many points as possible in the RCOM, as the commenting MSCAs can reopen them in case of disagreement.

TAB

The Technical Agreements for Biocides (TAB) is now split to separate documents for each WG. The TABs are available in public S-CIRCABC (Documents agreed at WG meetings) and the link is available on ECHA website².

The TAB contains some entries that may not be fully adequate anymore and SECR will launch an additional commenting period to identify points that are not up to date.

CLH

SECR reminded the members about the CLH process related to active substances (AS), the templates and submission tool. SECR recommended that CLH dossiers for active substances are submitted as early as possible in the process, in order to identify substances falling under the substitution and exclusion criteria.

Endocrine disruption (ED)

Publicly available information on ED EG substances is available on the ECHA website: <u>https://echa.europa.eu/ed-assessment</u>.

SECR informed that three ED Expert Group (EG) meetings are scheduled for 2019 based on the information received from MSCAs. The provisional dates are:

- 5-7 March
- 1-3 October
- 3-5 December

The deadline for confirming the substances for the ED EG in March 2019 is 8 January 2019. SECR asked the members to confirm the substances already in December 2018 if possible, by sending an e-mail to <u>ed eg@echa.europa.eu</u>.

SECR informed that there are ongoing discussions at the CG/CA and that ED is a topic for the AS workshop early 2019. An ED training for AS will take place in February 2019.

Amending BPR annexes

SECR informed that the European Commission hopes to adopt the amendments during 2019. A revision of the ECHA Guidance on information requirements will be needed and the members were asked to inform SECR of any needs to revise the guidance.

Next WG meeting

SECR informed of the provisional timing of the next Human Health WG meeting (post-WG note: the January WG meeting has been cancelled).

² <u>https://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups</u>

Annex 1 Human Health WG attendees

Core members	
MIKOLAS Jan (CZ)	
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