Minutes of the Working Group meeting III in 2020

Analytical Methods and Physico-Chemical Properties

(Meeting date: 08-09 September 2020 – WebEx meeting)

17 November 2020

1. Welcome and apologies

The meeting was a WebEx-meeting. The Chair welcomed the participants of the working group meeting. CEFIC was present at the meeting as an accredited stakeholder organisation (ASO) with two representatives.

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 for information by ECHA.

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). No further items were added to the agenda.

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 2020

The working group members provided two comments on the draft minutes of WG II 2020:

- Peracetic acid generated in situ – pH regulators as precursors
- Union authorisation containing clothianidin and pyriproxyfen

The modifications were presented and agreed. No further comments were expressed at the meeting. The minutes of the working group meeting II in 2020 were agreed by the working group members.

6. Outcome of e-consultation and discussion

6.1 Sodium persulphate

The outcome of the e-consultation was presented to the working group.

6.2 Taski-Room Care-Sure family

The outcome of e-consultation was presented to the working group members and discussed.

6.3 Chlorine dioxide redefinition

The outcome of e-consultation was presented to the working group members.

6.4 Additional data on alpha-Bromadiolone following APCP WG II 2020

The outcome of the e-consultations was presented to the working group members and discussed.

7. Discussion of Union authorisations

7.1. Union authorisation containing CMIT/MIT PT 02, 04, 06, 11, 12, 13 – eCA: FR

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

8. Discussion of active substances

8.1 MIT PT 6 – eCA: SI

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

8.2 Ethylene oxide PT 02 – eCA: NO

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

9. Technical and guidance related issues

9.1 Definitions of the functions of co-formulants

A final discussion was held on the document 'Definitions of the functions of co-formulants', which has been previously discussed at WG III 2017 and WG IV 2019. The document was agreed by the working group members. The chair highlighted that it is a living document, which may be updated when necessary. The document will be forwarded to the coordination group for endorsement.

9.2 In situ generated active substances

The working group members exchanged their views on how to manage the information requirements for active substances generated *in situ* and their products. The discussion is part of an ongoing revision of the Working group recommendation on *in situ* generated active substances.

Annex 1 - List of attendees registered for the meeting

Country	Members of WG
Austria	Colson Jerome
Austria	Ghobrial Michael
Belgium	Burmistrova Anastasia
Belgium	Dang Thy Minh-Dung
Switzerland	Aeschbacher Michael
Switzerland	Courdouan Merz Amandine
Czech Republic	Vlasak Martin
Germany	Mühle Ulrike
Denmark	Erlingsson Natja
Estonia	Ilmarinen Kaja
Greece	Tzanetou Evangelia
Finland	Vuorensola Katariina
France	Chabanny Loic
France	Six Therese
France	Weber Philippe
France	Gour Annabelle
France	Bujard Thomas
Latvia	Igaune Ieva
Latvia	Brovkina Julija
The Netherlands	Huizing Tjaart-Jan
Norway	Stave Sekkenes Marianne
Norway	Helgerud Trygve
Poland	Huszał Sylwester
Portugal	Borges Maria Teresa
Slovenia	Čebašek Petra
Slovenia	Velikonja Bolta Špela
Sweden	Alpe Mia
Sweden	Johansson Anh
Sweden	Österwall Christoffer
Slovakia	Drabová Kušíková Zuzana
Slovakia	Porubiak Michal

ECHA staff
Krebs Bernhard (Chair)
Glans Lotta
Matthes Jochen

Company	Agenda item	Observer
ERM	8.2 Ethylene oxide	Moloney Claire Elsmore Richard

DuPont	7.1 UA for product containing CMIT/MIT	Lopez Serrano Paloma
Diversey	6.2 Taski-Room Sure-Care family Early working group discussion	Suurmeijer Carine

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

WG-III-2020

Final minutes

24 November 2020

Minutes of Efficacy WG-III-2020

8, 10, and 15 September 2020

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 33rd Efficacy WG meeting and informed that this meeting is split into three separate days.

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that the recordings would be destroyed after the agreement of the minutes. The list of attendees is given in Annex 1.

2. Administrative issues

SECR gave brief information on the administrative issues.

3. Agreement of the agenda

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

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

CZ, DE, FR and NL had sent comments on the EFF WG-II-2020 draft minutes. The revised minutes were agreed at the meeting.

6. Discussion of active substances – 8 September 2020

6.1. Ethylene oxide (eCA NO)

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

6.2. MIT (eCA SI)

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

6.3. Early WG on CHDG (eCA PT)

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

SECR note: In addition, during this session DE informed about ECHA opinion concerning early WG discussion at the EFF WG-V-2019, item: WGV2019_EFF_7-2_Early WG discussion_PT7_10. Please refer to the updated confidential final minutes in the form of the discussion table available on S-CIRCABC.

7. Discussion of Union Authorisations – 8 September 2020

7.1. UA for product family containing CMIT/MIT (eCA FR)

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

7.2. Early WG on efficacy requirements for disinfectants of swimming pools and spas (eCA FR)

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

8. Technical and guidance related issues – 10/15 September 2020

8.1. Vol. II, Parts B+C – PT19

The EFF WG continued working with the PT19 draft guidance. The WG-III-2020 discussion focused on four chapters. The EFF WG made the following agreements:

1. Bed bugs

- The sentence *`Repellent products against bed bugs could provide an accompanying measure in infested homes or hotels to prevent bites and spreading of bed bugs e.g. by treating textiles to cover beds or luggage.´* in the General Introduction was agreed to be amended into: *'Repellent products against bedbugs can be useful as an accompanying measure in areas where the users cannot exclude a bed bug infestation, e.g. people sleeping in hotels or hostels. In such rooms the repellent products could be used to protect themselves as well as their luggage.'*
- In section 2.1 Test species the sentence *`A product against bed bugs should be tested on a demonstrably susceptible laboratory strain of the common bed bug (Cimex lectularius).´* is changed to *`A product against bed bugs should be tested against common bed bug (Cimex lectularius).´* In addition, a sentence will be added concerning the need to state the provenance and rearing of the strain in the test report. Word 'species' will be added into the last sentence of this chapter: *`Due to the specificity of certain active substances (e.g. pheromones), for products based on an active substance with a species specific mode of action, only effects against bed bug species that have been tested under simulated-use and/or field conditions (depending on the type of claim) should be claimed on the product label and in the SPC.´*
- In section 2.2 the phrase: *'These products will not be able to eliminate an existing infestation. They are only useful as a preventive measure. Unless otherwise proven in efficacy trials, the label should include a wording like: 'Repellents/attractants should only be used as a preventive measure'.´* will be amended into: *`They are only useful as a measure to prevent the spreading of bedbug or the entering of bedbugs into e.g. luggage. Unless otherwise proven in efficacy trials, the label and the SPC should include a wording like: 'Repellents/attractants should only be used as a preventive measure'.´*
- In section 2.2.1 the sentence from the fleas chapter will be included: *`Other test designs than the following example can be accepted, if the protocol if scientifically valid.´*
- For a general label claim for surface treatment at least two types of porous and one non-porous surface need to be tested in simulated-use test. Also, if specific type of surface is claimed, e.g. carpet, that surface needs to be tested. This requirement will be harmonized in all chapters including section related to residual efficacy in General Introduction.
- In section 2.2.1.1 the sentence will be added: *`For a general claim for surface treatment test with host mimic is possible but for a claim 'prevents biting' volunteers are needed.´*
- In section 2.2.1.1 the sentence *`The same test design can be used for the evaluation of products claimed to protect goods e.g. applied on surfaces like suitcases to prevent bed bug spreading. Instead of a simulated bed, e.g. a suitcase filled with worn clothing or something similar is placed in the centre of the test arena. The repellent product should be applied on the suitcase surface according to the label claim and SPC (e.g. on the suitcase surface).´* to be amended into: *`To prevent bed bugs spreading the repellent product should be applied on representative surface according to the label claim and the SPC (e.g. suitcase surface).´*
- The simulated use test needs to be conducted with 30 bed bugs.

- In section 2.2.1.1 the sentence *´If bed bugs are found in the treated chamber they should be considered as 'not repelled'´* will be added to simulated-use test design three-chambers-system.
- A sentence will be added stating that the mentioned simulated use test designs are only examples, in-house protocols can also be used.
- In section 2.2.2 and 2.2.3 the sentence: *`For product authorisation a simulated-use test or a field trial is required.´* and a paragraph describing the parameters and controls needed for a field trial will be added.
- The simulated-use test method described in tick chapter will be adapted for bed bugs for products intended for use as topical repellents for human skin and for repellents applied on clothing or incorporated into treated articles. The arm-in-cage test will be excluded from bed bugs chapter.
- Simulated-use test is required for repellent products intended for use as spatial repellents, details will be left open. Test design similar to the arena set-up described in section 2.2.1.1 for surface treatment products is suggested.
- In section 2.2.5 traps description for attractants without PT18 active substance will be left open since it is difficult to define how the traps act at the moment. Side effects on beneficial organisms are not seen relevant since these products are used indoors only.
- In section 3.1 the following criteria were agreed:
    - for topical repellents complete protection time (CPT) is required;
    - for surface treatment products, if biting prevention is claimed, CPT is be required;
    - for surface treatment product with claim on repellency only (without biting prevention claim), 80% repellency is required;
    - for products protecting goods (prevent bed bugs entering a suitcase) 100% repellency will be required;
    - for CPT protection time has to be tested and stated.
- In section 3.1 the sentence: *`≥ 80% attraction within the test period (or according to the claim), at the beginning and until the end of the claimed efficacy period.´* is changed into *`≥ 80% attraction at the beginning of the claimed period´.*
- It must be clearly stated in the label whether the product is repellent or dispellent and the testing has to be conducted according to the claim.
- The number of volunteers in the field trials will be harmonised with other chapters (10 valid volunteers in the end of the trial).

2. Cockroaches

- In section 2.1 the sentence will be added to: *`For insects from laboratory rearing used in the efficacy studies age and feeding condition should be reported.´.* This sentence will be added to other chapters as well.
- No-choice simulated-use test is required for product authorisation. If a choice test is submitted it will be additional, supportive information only.
- In section 2.2.1 the sentence *`Products applied onto surfaces may act either by evaporation or on the surface itself´,* will be deleted.
- In section 2.2.2 the phrase *`For a general claim 'spatial repellents' the repellent effect must be proven. For a specific label claim 'dispelling' the dispelling effect must be proven.´* was added.
- Laboratory or simulated-use test are needed for AS approval. Either a simulated use test or a laboratory test together with a field trial are required for product authorisation.

- In section 2.2.2.1 the following amendments are made:
    - the phrase `*The simulated-use test that evaluates the repellent efficacy of products intended for use as spatial repellents has to be a choice test performed in test chambers with a volume adapted to the claim stated in the SPC (at least 20 m^3). The test has to prove the efficacy of the product at the beginning and until the end of the claimed efficacy period according to the SPC. A minimum of 5 independent replicates together with 5 controls should be performed. Each replicate has to use 10 adult males, 10 adult females and 20 nymphs. Possible insecticidal effects (see General Introduction chapter 1.3.7) have to be examined at the end of the trial.´* was included. Also, it will be clarified in the chapter for spatial repellents that this section is only applicable for spatial treatment products, if the application method leads into surface treatment, applicant should refer to section for surface treatment products;
    - the sentence describing the specifications for control set-up will be added;
    - the sentence `*Both rooms/boxes contain water, a food source and a shelter.´* will be added;
- In section 2.2.3 it was decided to leave the specifications of test design open for the applicants. The test conditions (climate, number of test organisms etc.) will be defined and harmonised with other type of products;
- Side effects of traps on beneficial organisms where estimated to be insignificant due to different behaviour of cockroaches compared to other organisms.

3. Fleas

- A paragraph of other possible target organisms was added to the Introduction of Fleas chapter: `*The Oriental rat flea (Xenopsylla cheopis), also known as the tropical rat flea, is a parasite of rodents and humans, and is a primary vector for bubonic plague and murine typhus. The human flea (Pulex irritans) is a cosmopolitan flea species that has a wide host spectrum. It can also be an intermediate host for the flea tapeworm cestode* Dipylidium caninum*. Tunga penetrans (also known as chigoe flea or jigger) is a parasite of mammals (dogs and humans) in most tropical and sub-tropical climates causing an inflammatory skin disease (tungiasis).´*

  1.1. Biology
  The appearance and parasitic behaviour of Tunga penetrans differs: it is the smallest known flea, measuring 1 mm. After a blood meal males are still mobile like other fleas, but the female flea burrows head-first into the host's skin, leaving the caudal tip of its abdomen visible through an orifice in a skin lesion. This orifice allows the flea to breathe, defecate, mate and expel eggs while feeding from blood vessels. As the flea's abdomen swells with eggs later in the cycle, reaching a size up to 1 cm.´
- In section 2.2.1 the sentence clarifying that if a specific type of fabric is claimed the same type of fabric has to be tested will be added.
- A reference to the General Introduction for conditions simulating the claimed use was added.
- The criteria for repellency in laboratory choice test will be amended to make them clearer.
- The requirements for simulated-use test for topical repellents for human skin and clothing were agreed:
    - minimum probing rate was set to 1/minute, but experts will be consulted to find out whether this is a reasonable approach;
    - cage size minimum volume 27 l;

- minimum probing rate of untreated arm was set to 1/minute, but experts will be consulted to find out whether this is a good approach;
- 'balanced sex ratio' will be deleted.

- Field trials are permitted but not mandatory for topical repellents for human skin and clothing. Either simulated-use test or field test is required. DE will draft a paragraph describing the general requirements for the field trials and number of volunteers will be harmonised with other chapters.
- The number of washing repeats should be stated and tested for products intended to be used as topical repellents on animals and animal clothing for the claim 'unaffected by washing'. This claim will be amended in other chapters as well.
- In section 2.2.2 the sentence *`If the product is intended to be used with other products (biocides/veterinary products), the impact on efficacy should be demonstrated.´* will be deleted.
- The requirement for a negative control for the simulated-use test for products intended for use as topical repellents on animals and animal clothing will be revised in all chapters concerning blood feeding target organisms to be in line with stable fly chapter: *'If the product is acting at very close range it may be possible to make the evaluation by treating parts of the host, like one treated side of the neck compared with the equivalent area on the other, untreated, side of the neck. The advantage of such a setup is the neutralisation of individual host differences in […] attraction'.*
- General requirement for field tests for products intended for use as topical repellents on animals and animal clothing will be added.
- For repellent products intended for use as surface treatment a simulated-use test or a laboratory test and a field trial is required for both consumers and professional users.
- For a general label claim for surface treatment at least two types of porous and one non-porous surface need to be tested. Also, if specific type of surface is claimed, e.g. dog mattress, that surface needs to be tested.
- An attractant source is required to be used in laboratory test design for repellent products intended for use as surface treatment.
- In the simulated-use test a human volunteer instead of heat source can be used but using an animal as host is not accepted.
- The requirements for products intended to be used as spatial repellents as well as for attractants in traps without PT18 active substances will be left open. Only brief paragraphs explaining general details will be added.
- In section 3.1 the following criteria were agreed:
  - CPT is required for topical repellents for both human and animals;
  - for spatial and surface treatment products 80% repellency is required when claim on repellency only (without biting prevention claim);
  - if biting prevention is claimed for a spatial or surface treatment products CPT is required;
  - requirements are the same for field and simulated-use studies. For laboratory tests 80% repellency is required;
  - for attractants 80% reduction in the population is required.

4. Stored goods-attacking insects and mites

- The dossier requirements have been harmonised in line with the draft chapter on fleas.
- A general claim against stored goods-attacking insects and mites or high-level subgroups thereof (e.g. stored goods-attacking beetles) is not possible. Two new

options were presented and discussed: The first option is based on target organisms and the second option is based on goods to be protected. Both options got some support during the discussion. The first option is more logical in relation to other chapters and more feasible in reality since the target organisms are similar, but on the other hand the intended uses are more practical approach in product authorisation. It was decided to leave both options in the document and the final decision was left open for the Partner Expert Group (PEG) meeting. It was agreed that it will be made clear that the list of species is not exhaustive but compiled only as an example;in section 2.2 the minimum number of valid replicates in both simulated-use and field tests will be changed to 5 to be in line with the requirements in other chapters.

- In section 3.1 the sentence *`Levels of efficacy compared to PT 18 contact biocides should be achieved´* will be deleted.

8.2. Harmonised approach to determine a worst-case (or representative) test product for disinfectant BPF (DE)

DE presented the revised version of the document discussed already at WGIV2019 and WGI2020. To facilitate the discussion an informative presentation with the intention to clarify some industry (IND) comments was given. The main concerns of IND were: increasing number of efficacy studies need to be performed/reviewed, further redefinition of BPF concept, and compliance with the CA document (CA-July19-Doc4.2-Final - Guidance note on BPF concept). DE clearly explained that the main goal of the discussed WG document is to help the applicants to apply the new BPF concept by substantiating the choice of worst-case test product using bridging studies. By showing an exemplary BPF, explanation was given with relation to the number of efficacy studies necessary to meet the 'old' concept requirements in comparison to the 'new' approach. There is a clear evidence that the new concept usually will require less efficacy studies. It was also clarified, giving specific examples, that according to the new approach every single use within the BPF should be evaluated using the one worst-case test product. In case the efficacy of the test product cannot be shown for some of the respective, intended uses it means that the uses are not similar and should not be within one BPF. Clarifications will be added to the document.

It was also explained that one core assessment can cover several meta-SPCs containing products having different H&P phrases, concentrates and corresponding RTU products. It also possible to evaluate different target organisms at different concentrations of the active substance. Appropriate examples were given.

The EFF WG agreed that:

- phase 2 step 1 tests should to be performed as bridging studies;
- the appropriate lg reduction threshold to consider potential co-formulant's effect relevant should be 1;
- combinatory effect is not addressed in the testing strategy and additional test(s) should usually not be required. Additional test(s) might be requested by the eCA only in exceptional cases, i.e. if there is a clear indication of combinatory effect. In case of thickeners, which cannot be grouped, additional tests are necessary;
- in section 2.2.3 the sentence: *'At a later stage, it may be possible to test representative substances for whole (sub-)groups of co-formulants , but for the time being bridging arguments from one co-formulant to another may only be accepted in exceptionally well justified cases'* will be deleted;
- in section 2.2.3 the sentence: *'Co-formulants that are present across the entire BPF with a fixed concentration require no bridging/justification. The worst-case test product should contain such co-formulants at their fixed concentration'* will be added to improve the clarity of the document. Clarification that small differences, up to 10% in nominal variation are acceptable (which is covered by Q&A 2 in Annex 2) will be added to this section. In addition, it was pointed out that for consistency

the phrases and nomenclature related to co-formulants will be cross-checked with the APCP WG document concerning definitions of co-formulants;

- in Annex 2, Q&A 5 clarification will be added with reference to test organism dependent worst-case test product: […highest amount. *In this case studies on bacteria should only be conducted with the worst-case test product for bacteria and vice versa for viruses.* No refinement…];
- in Annex 2, Q&A 2 it was agreed that 10% is the permissible deviation of the co-formulant concentration in the product;

DE will send the revised version of this document to ECHA by mid-October 2020. The document will be presented for endorsement at the BPC-37.

8.3. TAB proposals

Regarding hard surfaces disinfection the agreed TAB entry is presented below:

How much product is needed to wet the surface completely and to keep the surface wet for the contact time, or part of it?

- *It is acceptable that there might be a difference between drying time and volume of product containing volatile active substance in the EN 13697 test and in practice. Therefore, in practice, it is accepted that the non-porous hard surface does not necessarily remain wet during the claimed contact time.*
- *A minimum volume of product should be added to the non-porous hard surface to ensure sufficient wetting over the whole treated surface for disinfection without mechanical action. For volumes lower than 18 ml/m^2 a robust justification and/or efficacy data is needed.*

With reference to yeasticidal activity at elevated temperatures the WG members disagreed with the proposed draft TAB entry. There were several comments from the WG members related to valid controls at elevated temperatures, lack of thermotolerant organisms in standardised tests, difficulties in distinguishing what caused the final effect, how such a claim should be formulated in the SPC. As it was difficult to conclude, the proposal will be revised by AT in cooperation with DE and the NL and discussed in the near future (possibly March 2021).

8.4. Certification of testing laboratories for disinfectant efficacy testing (DE)

The EFF WG was in general in favour to accept the obligation to possess a quality management system for laboratories testing disinfectants. It was noted that the approach taken should be in line with other areas, i.e. HH, ENV, APCP. The main concern raised by some WG members concerned small companies performing the efficacy tests (not necessarily according to EN standards) quite often in house and the potential increase in the cost of such tests. This proposal was not concluded, the WG members asked for more time to consider/check potential consequences of such requirement. The current proposal will be revised by DE and discussed again soon (possibly November 2020).

9. AOB

9.1. Other information & lessons learned

ECHA informed about provisional dates for the next WG meeting. Two items were brought to the attention of the WG:

- Compilation of borderline cases into one document. SE pointed out that there is no comprehensive document compiling all borderline cases and decisions made by the COM in the context of AS, NA and UA cases. The EFF WG supported the idea to have such a document. All EFF WG participants were asked to inform their CA representatives and support this proposal at the CA meeting.
- Termites developmental stage used in the SPC editor in relation to PT 8 products. DE noted that in case of termites only the queen and the kings are true adults, all

other castes are kind of larval stages. At the same time to use the term 'larva' as the description of termites workers would be misleading and incomprehensible. Therefore, in case of termites DE proposed not to describe the specific developmental stage in the SPC editor but to use a phrase 'no data' instead. The WG members accepted this proposal and in addition pointed out that this approach should also be applicable to PT 18 products. DE will forward the EFF WG opinion to the CG.

In addition, the EFF WG members expressed their dissatisfaction with the proposal to organise mainly virtual meetings in the future (75% virtual meetings).

All details are in the working document: WGIII2020_EFF_9-1_Other info available in S-CIRCABC.

9.2. Additional item proposed for discussion by DE (closed session).

During the agreement on the agenda items DE asked to discuss one additional issue related to the disinfection of hatching eggs by fogging. The EFF WG agreed that the proposed test according to EN 17272 (with eggs present) can be performed instead of NF T72-281.

List of Attendees

Efficacy Working Group

Core members
ATTIG Isabelle (FR)
DUH Darja (SI)
ESCH Daniel (DE)
GIATROPOULOS Athanasios (EL)
JANSEN Irina – alternate (DE)
MAXIMILIEN Yann - alternate (FR)
POULIS Joan (NL)
ZUTZ Christoph (AT)
Flexible members
BAUMGARTNER Rebekka (CH)
BILLAULT Catherine (FR)
BURMISTROVA Anastasia (BE)
BRIZARD Mathias (FR)
CLEYTON JØRGENSEN Charlotte (DK)
DANADAIOVA Emese (SK)
DANG THY Minh-Dung (BE)
DOLEŽELOVÁ Katsiaryna (CZ)
DONZE Gerard (CH)
FISCHER Juliane (DE)
FRANK Ulrike (SE)
GRÜNIG David (CH)
GURBA Alexandre (CH)
HADDACHE Nabila (FR)
HAUGSTAD Kjetil (NO)
HELGERUD Trygve (NO)
ILMARINEN Kaja (EE)
KRÜGER Martin (DE)
LEPAGE Anne (BE)
LYNCH Helen (IE)
MALMGREN Birgitta (SE)
MEIER Margrith (CH)
MEZULE Linda (LV)
NIEMINEN Timo (FI)

PECINKOVA Martina (CZ)
PEELMAN Natania (BE)
RONCI Maria Beatrice
RUSCONI Manuel (CH)
SANS-PICHÉ Frederic (CH)
WIGGERS Hanneke (NL)
ÅSLING Bengt (SE)
ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
RAULIO Mari
SCHAKIR Yasmin
HONKA Anni
Applicants
Arche Consulting
DuPont
ERM
Evonik
Rapporteurs
AAMODT Solveig (NO)
ALMEIDA Ines (PT)
GOUR Annabelle (FR)
Advisors
ANDRIESSEN Rob (NL)
BORGES Maria Teresa (PT) BPC member
DEKKERS Bas (NL)
IDINK Marie-Cecile (NL)
TRAUER-KIZILELMA Ute (DE)
Stakeholders
GARMENDIA Irantzu (EBPF)
HANON Nathalie (AISE)
THEELEN Meredith (expert)
MORENO Mara (expert)

Environment WG-III-2020

Final minutes

20 November 2020

Minutes of Environment WG-III-2020

17-18 September 2020

Meetings of the Environmental Working Group of the Biocidal Products Committee

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 47 participants present, of which 9 were core members, 30 flexible members, 1 rapporteurs and 7 adviser. Two representatives from accredited stakeholder organisation were present at some agenda items. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

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. SECR added under AOB the conclusions of AHEE-5 on the agenda. The agenda was agreed.

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

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

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

The minutes were agreed without further discussion.

6. Discussion on active substances

6.1 Ethylene oxide - PT 2 (NO)

Two points were discussed, one related to the assessment of the P criterion, one related to the emission estimation, specifically emissions to air. One item regarding monitoring data on emissions to the atmosphere was provisionally closed before the meeting. One point regarding the P assessment remained open and will be followed up via an ad hoc follow up.

Actions:

- **SECR** to initiate AHF regarding the P-assessment
- **SECR** to initiate discussion at BPC level on standard requirements for later product authorisation

6.2 MIT - PT 6 (SI)

Four items were discussed, one point related to the ED assessment, one point related to the PNEC derivation in soil, one point related to the degradation rate and temperature correction in SimpleTreat and one point related to the summing up of tonnages of two applicants in the review program. Two points regarding the ED assessment remained open

and will be followed up via an ad hoc follow up.

Actions:

- **SECR** to initiate AHF regarding the PNEC soil derivation
- **SECR** to prepare agreed TAB entry
- **SECR** to initiate agreed AHEE consultation regarding SimpleTreat (deadline for conclusion: four weeks)
- **SECR** to follow up internally on how to present the risk assessment based on tonnages from few applicants without breaching confidentiality.

6.3 1R-trans-phenothrin - PBT assessment (IE)

One point regarding the fulfilment of the P and B criterion was discussed. It was agreed that 1R-trans-phenothrin fulfils the P-criterion but does not fulfil the B-criterion. The WG agreed further that the assessed metabolites/degradants of 1R-trans-phenothrin do not fulfil the P nor the B criterion.

7. Discussion of Union Authorisation cases

7.1 UA for product family containing CMIT/MIT - PT 2, 5, 6, 11, 12, 13 (FR)

Ten open points and five provisionally closed points were discussed at the meeting, all points were related to the exposure assessment. One point regarding the ED assessment remained open and will be followed up via an ad hoc follow up.

Actions:

- **SECR** to initiate AHF on the assessment of the releases from paper mills
- **NL** to propose a quantification of the refinement for emission to separate sewer systems to the AHEE
- **SECR** to forward item on fraction of painted houses to the AHEE
- **SECR** to revise TAB entry ENV A-7
- **FR** to prepare a proposal for discussion on how to deal how to deal with service life in case the use does not fall under PT 6 or PT 8 to the AHEE.

8. AOB

8.1 Overview on guidance (ECHA SECR)

SECR presented the status on guidance development and issues identified for the AHEE. Updates from WG members before the meeting have been included in the overview.

8.2 Update on TAB Environment database

SECR presented the new TAB tool and explained the way how TAB entries will be prepared internally in the future. They will e.g. contain timelines for applicability of the entries in the future. The format of the TAB as such to be shared with MS and stakeholders will remain unchanged.

8.3 Other information & lessons learned (SECR)

<u>Lessons learned:</u>

- Due to issues with a recent case, in the future a substance will not pass the accordance check without a reference specification (5-batch analysis)
- For e-consultations where ASOs were involved, MS should check for feedback in the specific newsgroups for ASOs (link to CIRCA side for ASO: https://webgate.ec.europa.eu/s-circabc/w/browse/7f037f95-8861-45c2-85cd-485b90dd0edc)
- Proposals to modify existing TAB entries should be sent to the Environment FMB – MS should not use RCOM tables to propose changes since the point might be closed in the RCOM and has then no visibility.

Other information:

Provisional timing of coming WG meetings:
- **WG-IV-2020:** 18-19 November 2020 (ENV session), virtual meeting
- **WG-I-2021:** 15-26 March 2021, exact ENV session dates TBC, virtual meeting
- There is always a possibility of additional ("extraordinary") ad hoc WebEx meetings, if needed.

All meetings organised by ECHA will remain virtual at least until the end of March 2021, moving to virtual meetings on a more permanent basis is currently under discussion.

Items sent to CG or BPC: Harmonised LoeP for peracetic acid and hydrogen peroxide for UAs - follow up WG-IV-2019:
- Document provided to CG for information and BPC for agreement => uploaded to CRICA as separate file (FYI)
- See *WGIII2020_ENV_8-3a_Harmonisation of UA cases_PAA_INFO.docx* - incl. LAU statement

RMM-related items identified in the frame of the PT 18 TEG meeting discussion as being relevant for CG:
- Forwarded to next CG for information
- NL and FR to provide specific documents for discussion at a future CG meeting

Re-structuring of WG CIRCA sides: All **AHEE** meeting folders have been moved to the Ad hoc WG on Environmental Exposure IG on CIRCA. For **Environment WG** meetings, separate spaces for conclusions as well as for draft and final minutes of previous WG meeting were added.

Information submitted after active substance approval: ECHA/COM are still in discussion about when the LoEP should be updated, WGs will be informed on the outcome. Around 8 cases are currently pending.

Clarification on substances of concern: ECHA will discuss with COM, ECHA prepared beginning of 2020 list of questions raised by WG and CG. The way forward is TBD.

Status on Guidance for pollinators:

ED EG meeting dates 2020: 1 October and 17-19 November (provisional dates). Both meetings will be held as virtual meetings.
Biocides in ED EG: IPBC (eCA DK) on 1 October, Terbutryn (eCA SK) is under written consultation in ED EG until 4 October 2020.

In-situ recommendations – revision: The first draft for the Biocidal Products part is expected in October to be commented by the task groups. The active substance part is on hold since a possible new approach is under discussion. The first WG discussions will take place possibly in November WG-IV-2020, planned publication is in Q2/2021.

Harmonised list of endpoints for pyrethroid metabolites: The LoEP was endorsed by the BPC, it was previously discussed via a written procedure in July-Aug 2020. Use of the LoEP according to the agreed BPC document:

- Can be used by the MSCAs and the applicants immediately after BPC endorsement.
- During a transitional period until end of 2020, not mandatory to apply the harmonized endpoint.
- As of January 2021 the agreed endpoint values shall be used in new and on-going AS approval and product authorisation (for AS approval and UA as of PF 40)

Revisions of the LoEP: when new data available at renewal stage of the pyrethroid AS, or if relevant information becomes available from a BPC Opinion section 2.5 request. In this case the eCA should inform SECR about new relevant data!

Further clarifications are expected on data sharing/ LoA, the related item will be discussed at BPC-36 October (PAA and HP).

Access to BPC-paper and the data matrix: it is available in S-CIRCABC under all relevant AS cases (LoEP folder), the BPC paper was provided to relevant AS applicants by email.

8.4 AHEE-5 conclusions (SECR)

SECR provided a brief summary on the discussions at AHEE-5, which took place in the same week:

AP 5.1: AHEE recommendation - Environmental emission scenario for breweries (prepared by the Netherlands)

- The proposal of NL was agreed (=> assess a default brewery size in terms of production volume in combination with a default STP; not necessary to define small and large breweries)
- The final AHEE recommendation will be published on 18 September.

AP 5.2: Remaining open points of PT 18 TEG

- The majority of remaining open points were closed
- AHF: FCE and scenario(s) to be used to assess bed bug treatment.

AP 5.3: PT 11: Calculation of substance dependent emission factors for volatilisation (NL)

- The WG agreed with the proposed method based on mass transfer rates
- The WG supported the further collection of information for substance specific mass transfer rates (Action).

AP 5.4: Proposal for updates of the ESD for PT 5 (revised and new emission scenarios)

- The proposed revision of the ESD for PT 5 was agreed and will be added to the TAB
- An AHF for new proposal for disinfection of water for animals and disinfection of stored drinking water was agreed.
-

AP 5.5: Development of core scenarios

The item was provided only for information, an e-consultation to be initiated by SECR

AP 5.6: Application of bank slope scenario in PT 14

- The WG agreed that the scenario should be assess at active substance approval stage, SECR to check if this agreement needs further confirmation procedural wise
- The scenario should be evaluated for "open area" as well as for "in and around buildings".

Appendices:

Appendix 1: List of participants

Core members:

- (DE) Daniel **FREIN**
- (DE) Sascha **SETZER –** alternate
- (EL) Ioannis **KANDRIS**
- (FR) Stéphanie **ALEXANDRE** – rapporteur CMIT/MIT AQUEOUS
- (IE) Helena **JOYCE**
- (IE) Mike **Broderick**
- (NL) Barry **MUIJS**
- (NL) Karlijn **HOLTHAUS -** alternate
- (SI) Petra **MURI** – rapporteur MIT

Flexible members:

- Altmann Dominik (AT)
- Kantner Christian (AT)
- Kührer Lukas (AT)
- Ceusters Christiaan (BE)
- Cougnon Thomas (BE)
- Heulens Bart (BE)
- Jarrety Helene (BE)
- A Marca Maria (CH)
- Gyalpo Tenzing (CH)
- Kunz Petra (CH)
- Ahting Maren (DE)
- Schwander Maura (DE)
- Wennermark Henrik (DK)
- Sulg Helen (EE)
- Ruiz Lopez Elena Fuensanta (ES)
- Martin Vallejo Myriam (ES)
- Hänninen Oskari (FI)
- Pasanen Jaana (FI)
- Penttinen Sari (FI)
- Lozach Jerome (FR)
- Straczek Anne (FR)
- Conroy Kenneth (IE) – rapporteur 1R trans phenothrin
- De Magistris Isabella (IT)
- Smit Els (NL)
- van Vlaardingen Peter (NL)
- Aamodt Solveig (NO) – rapporteur Ethylene oxide
- Podlaska Agnieszka (PL)
- Konovalenko Lena (SE)
- Van Der Geest Bert (SI) - MIT
- Molnarova Jana (SK)

Rapporteurs:

- Gour Annabelle (FR) - CMIT/MIT AQUEOUS 1.5-15

Advisors:

- Borges Maria Teresa (PT) – BPC Member
- Johannessen Jesper (DK)
- Gilson Arthur (FR)
- Herard Fanny (FR)
- Verstraet Séléné (FR)
- van der Ploeg Merel (NL)
- Säll Liselott (SE)

ASOs:

- Garmendia Irantzu (CEFIC representative) – all agenda items except closed ones
- Mason Paul (CEFIC expert)

ECHA chairs and experts

Human Health WG-III-2020

Final minutes

24 November 2020

Minutes of Human Health WG-III-2020

15-16 September 2020

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 48 members registered, of which 12 were (alternate) core members. Two stakeholder representatives 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 from WG-I-2021 onwards, the agenda and meeting documents will be shared via Interact. Training will be provided before this takes place.

Only one Rapporteur declaration is needed per AS/UA case per eCA per WG. If the same person acts as Rapporteur in all four WGs, the members were advised to mark all WGs in one declaration.

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-II-2020

The minutes were agreed without changes.

6. Discussion of active substances

6.1 Ethylene oxide, PT 2 (eCA NO)

The WG agreed that it is not possible to conclude on the ED properties, but in this specific case no further testing for ED properties is needed. The WG agreed on the DMEL and inhalation absorption values proposed by the eCA. The WG agreed not to derive AELs, ADI, ARfD, or values for dermal and oral absorption.

6.2 MIT, PT 6 (eCA SI)

The WG did not support the proposed quantitative risk characterisation for sensitisation. This will be removed from the CAR that was otherwise agreed on, including the qualitative assessment.

6.3 Relevant fraction to consider for inhalation exposure: burnt lime, hydrated lime, burnt dolomitic lime and hydrated dolomitic lime (RefMS DE)

The WG agreed that the AEC value derived from limes should be understood as referring to the inhalable dust fraction.

7. Discussion of Union authorisation applications

7.1 UA for product family containing CMIT/MIT, PTs 2, 4, 6, 11, 12, 13 (eCA FR)

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

7.2 UA of product families containing lactic acid (early WG discussion), PT 3 (eCA LV)

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

8. Technical and guidance related issues

8.1 Update on guidance development

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

NL volunteered to work on the guidance on disinfection by-products.

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 of the document and the approach taken. An e-consultation is ongoing until 5 October and input is requested from the members. Due to confidential information, this e-consultation cannot be extended to stakeholder organisations. If possible, it was considered useful if the final document or a cleaned version of it can be published once agreed.

Endocrine disruption (ED)

In the ED Expert Group taking place on 1 October 2020, one biocidal active substance will be discussed: IPBC (eCA DK).

There is one more ED Expert Group meeting taking place in 2020, provisionally scheduled 17-19 November.

Guidance revision - Vol III Part A

Input was requested from members and ASOs during summer 2020 and received from DE, DK, EL, ES, FR and NL.

Drafting will begin in September 2020. The Partner Expert Group (PEG) will be formed early 2021, and the draft for PEG consultation is expected to be ready in May 2021. A PEG meeting is provisionally scheduled in October 2021. This will be followed by COM and CA consultation, expected to be launched by the end of 2021. Publication of the guidance is foreseen in March 2022.

Next WG meetings

SECR informed of the provisional timing of the next meetings:

- 24-25 November 2020 (dates to be confirmed)
- 15-26 March 2021 (exact days to be established)

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

Annex 1

Human Health WG attendees

Core/Alternate members
MIKOLAS Jan (CZ)
HOLTHENRICH Dagmar (DE)
HERRMANN Kristin – Alternate (DE)
MEYER Jessica - Alternate (DE)
ARAPAKI Niki (EL)
NIKOLOPOULOU Dimitra (EL)
AUBIN Aurelie – Alternate (FR)
MAXIMILIEN Elisabeth (FR)
BREEN Alan (IE)
WELTERN Angelique – Alternate (NL)
LEŠER Vladka (SI)
Rapporteurs
GOUR Annabelle (FR)
IGAUNE Ieva (LT)
Flexible members
HAUZENBERGER Ingrid (AT)
HOELZL Christine (AT)
HOUAMED Anis (BE)
GRÜNIG David (CH)
ROSSIER Nadine (CH)
RUSCONI Manuel (CH)
SCHNEIDER Heiko (DE)
SEMISCH Annetta (DE)
BOYE PETERSEN Annika (DK)
HÄMÄLAINEN Anna-Maija (FI)
HYVÄRINEN Tuija (FI)
RYDMAN Elina (FI)
VÄLIMÄKI Elina (FI)
REY Marion (FR)
VAILLANT Vincent (FR)
DEKOVI Edlira (IT)
ANDERSEN Hilde (NO)

FRYDENLUND Jorid (NO)
GAUSTAD Astrid (NO)
HAUGSTAD Kjetil (NO)
LEEVES Sara (NO)
MIDTHAUG Hilde Karin (NO)
ASK BJÖRNBERG Karolin (SE)
ČEBAŠEK Petra (SI)
ROMAN Olha (SK)
Advisors
MANI Orlando (CH)
PEISER Matthias (DE)
RIME Soyub (DE)
AMSALLEM Tiffany (FR)
BELLINGARD Valérie (FR)
KOSE Serif (FR)
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AIRAKSINEN Antero
DAMSTEN Micaela
ANTAL Diana
ESTEVAN MARTINEZ Carmen
FRANKEN Stefan
PAPADAKI Paschalina
RUGGERI Laura
VASILEVA Katya
Applicants
Arrow Regulatory
DuPont
ERM
SCC GmbH
Thor GmbH
Stakeholders
VAN BERLO Boris (CEFIC)
Experts: DOOME Roger, MOSTERT Volker