Minutes of the Working Group meeting II in 2020

Analytical Methods and Physico-Chemical Properties

(Meeting date: 08 June 2020 – WebEx meeting)

08 September 2020

1. Welcome and apologies

The meeting was a WebEx-meeting. 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 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 I 2020

The working group members provided two comments on the draft minutes of WG I 2020.

The commenting working group members clarified that they actually agree with the draft minutes but they wanted to make additional comments on these agenda points. The minutes of the working group meeting I in 2020 were agreed by the working group members.

6. Outcome of e-consultation and discussion

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

7. Discussion of Union authorisations

7.1. Union authorisation containing clothianidin and pyriproxyfen PT 18 – eCA: NL

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

8. Discussion of active substances

8.1 alpha Bromadiolone PT 14 – eCA: FR

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

8.2 Hydrogen peroxide released from sodium percarbonate PT 02 and 03

The open issues were discussed by the working group members.

9. Any other business (AoB)

The chair gave a presentation on the progress of the active substance action plan (ASAP) which was agreed at the biocides efficiency workshop in 2019.

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
Belgium	Herremans Yannick
Switzerland	Aeschbacher Michael
Switzerland	Courdouan Merz Amandine
Germany	Mühle Ulrike
Estonia	Ilmarinen Kaja
Greece	Tzanetou Evangelia
Finland	Vuorensola Katariina
France	Chabanny Loic
France	Six Therese
France	Weber Philippe
France	Gour Annabelle
France	Bujard Thomas
France	Rat Benjamin
Italy	Cataldi Lucilla
Latvia	Igaune Ieva
The Netherlands	Huizing Tjaart-Jan
Norway	Stave Sekkenes Marianne
Poland	Huszał Sylwester
Slovenia	Čebašek Petra
Slovenia	Velikonja Bolta Špela
Sweden	Alpe Mia
Sweden	Johansson Anh

ECHA staff
Krebs Bernhard (Chair)
Glans Lotta
Matthes Jochen

Company	Agenda item	Observer
Sumitomo Chemical	7.1 UA for product containing clothianidin and pyriproxyfen	Gartland Kevan Symonds Brett
Lipatech	8.1 alpha-Bromadialone	Del Pozo Garrido Esther Cor Gabrielle
Soelltec / DLAC	8.2 Hydrogen peroxide released from sodium percarbonate	Willuweit Thomas Schmitz Cordula

	Early working group discussion	
Arrow Regulatory	6.1 troclosene sodium, sodium dichloroiso cyanurate dihydrate and symclosene	Kirkham Sara Kuechler Thomas

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

WG-II-2020

Final minutes

8 September 2020

Minutes of Efficacy WG-II-2020

2, 4, and 10 June 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 32nd 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 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 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 and NL had sent comments on the EFF WG-I-2020 draft minutes. The revised minutes were agreed at the meeting.

6. Discussion of active substances – 10 June 2020

6.1 Alpha-bromadiolone (eCA FR)

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

6.2 Early WG on Free radicals generated in situ from ambient water catalysed by transition metal oxides (eCA AT)

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

7. Discussion of Union Authorisations – 10 June 2020

7.1 UA for product containing clothianidin and pyriproxyfen (eCA NL)

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

8. Technical and guidance related issues – 2, 4 and 10 June 2020

8.1. Vol. II, Parts B+C – PT19

The EFF WG continued working on PT19 draft guidance. The WG-II-2020 discussion focused on two chapters:

1. General introduction

It was the first discussion on this section. The EFF WG made the following agreements:

- the sentence *'Efficacy data from scientific literature are considered only as supportive data and should not replace efficacy data obtained from efficacy tests,*

which should be performed according to recognised standards or intra-company Standard Operating Procedures. Results from these studies are compared with the specified criteria' will be removed from section *1.2 - Global structure of the assessment*;

- in section *1.3.1 - Biocidal products containing "existing active substances" as co-formulants* the sentence *'If the relevant information cannot be submitted, a study should be submitted showing that the formulation containing the co-formulant but without the active substance does not have any repellent/attractant effect at the claimed application rate'* will be amended *into 'If the relevant information cannot be submitted, a study should be submitted showing that the efficacy of the formulation with the active substance but without the co-formulant(s) does not differ from the product containing this active substance and co-formulants*';
- in section *1.3.3.3 - Simulated-use versus field trials* the sentence *'In order to eliminate the risk of disease transmission to study participants individuals in field settings, field trials with repellents against ticks, mosquitoes and other organisms that function as a vector are not recommended as key studies' will be amended into 'In order to eliminate the risk of disease transmission to study participants individuals in field settings, field trials with repellents against ticks, mosquitoes are not required, however they can serve as additional information'*;
- in section *1.3.6 - Attractants in traps* the second paragraph *'The Standing Committee on Biocidal Products […] whether authorisation is required for such products'* will be removed. Instead the sentence informing that the monitoring traps are not within the scope of this guidance will be added in section *1 – Introduction*. Additionally the sentence *'The traps used for the test should be identical to the product to be marketed'* was proposed to be amended into *'The traps used for the test should ideally be identical to the product to be marketed, the variations are acceptable if suitably justified'*. As there was no clear agreement the participants may send a written proposal to DE, this will be included into the text and discussed in November;
- in section *1.3.7 - Proof of non-lethal effect for repellent products* the sentence *'Mortality in the treatment group should be similar to the control group; if mortality will exceed 10%, justification from the applicant is needed'* will be amended into *'Mortality in the treatment group should be similar to the control group; if mortality in the treatment group will exceed 10%, justification from the applicant is needed';*
- in section *1.4 Methodology of assessment* a brief information about resistance will be added. FR will send a proposal to DE, this will be included into the text and discussed in November;
- in section *1.4.1 Assessment of specific claims* the sentence *'For example: If a product claims a complete protection time of 5 hours complete against ticks, the data submitted must show a 100% repellency within 5 hours after application in order for these claims to be acceptable'* will be amended into *'For example: If a product claims a protection time of 5 hours, the data submitted must show a 100% repellency'*;
- in section *1.4.1.2 Claims relating to storage of a product* the sentence 'When a product is claimed to be effective after more than two years, it is necessary to demonstrate that the product will still be effective after the stated storage period' will be amended into 'When a product is claimed to be effective after more than two years and the product composition is not stable after storage (according to APCP evaluation) having more than 10% decrease of active substance, it is necessary to demonstrate that the product will still be effective after the stated storage period.' With reference to bait products approach taken for PT14 products will apply. Regarding accelerated storage stability studies the requirements will be in line with APCP guidance;

- in section *1.4.1.3 Claims relating to outdoor use* the sentence *'If for a product "indoor" and "outdoor" use should be claimed, efficacy studies under outdoor conditions cannot be used for authorisation of the claim "indoor use"'* will be amended into *'If for a product "indoor" and "outdoor" use should be claimed, efficacy studies under indoor conditions cannot be used for authorisation of the claim "outdoor use" provided that application rate, frequency etc. remain the same'.* The sentence *'The same applies for efficacy studies under indoor conditions that cannot be used for authorisation of the claim "outdoor use"'* will be removed. In addition in the first sentence of this section it is stated […(e.g. for surface or space treatment …)…]. The e.g. abbreviation will be deleted to make this sentence clearly referring to surface or space treatment or attractants in traps.
- in section *1.4.1.4 Claims for residual efficacy* the sentence will be added '*The duration of repellent effect (protection time of repellent) demonstrated in efficacy tests should preferably be stated on the label' as critical information for the users.* Weathering conditions were left open for future discussion (EN 152 will be considered);

2. Biting midges

Final discussion at WG level took place for this chapter. The EFF WG made the following agreements:

- section *2.1 Test species*, it was agreed that for the general claim against biting midges the specimens have to be identified at the start of the trial;
- section *2.2 Requirements per type of claim and test methods*, no distinction between professionals and general public is needed, bridging data from one host species to another have been accepted - specific examples will be added;
- section *2.2.2 Simulated-use test*, the same approach will be taken as in other chapters in this guidance, means SU test or field test will be required. In addition the sentence '*No specific temperature or humidity are recommended, but it must be warm and not too windy*' will be amended into *'No specific temperature or humidity are recommended, but the environmental conditions should allow the biting midges activity high enough'*. A sentence related to the hair colour of the tested animals will be added.
- section *2.2.3 Field trials*, with reference to geographical location the same approach will be taken as for *Stable flies* chapter, in addition the tethered hosts will be removed from field trials;
- section *3.1 Norms and criteria*, information about attractants will be aligned with *Flies on grazing cattle and horses* and *Stable flies* chapters.

The revised version of this chapter will be sent by DK to ECHA by end of August.

8.2. Vol. II, Parts B+C – PT12

FR informed that in the 88th CA meeting, most borderline uses specified in a discussion document drafted by Cefic (CA-May20-Doc.8.1.a) were agreed upon. Agreement was not reached regarding preservation of air washer systems and sump water in air conditioning systems, and claims against *Legionella*. For these claims discussion will be continued and decisions will be taken at the next CA meeting in September 2020.

The PT 11 part has been agreed upon in EFF WG discussions V-2018, II-2019, V-2019 and I-2020, and in this meeting the PT 12 part concerning paper mills was discussed. FR noted that in order to be able to finalise the drafting of the remaining part of PT 12 oilfields, a relevant expert would be needed. Cefic informed that they are looking for an expert and will let ECHA/FR know within few weeks.

From the PT 11 discussions a point of how to define growth in the untreated controls remained open. It was agreed that in addition to a 0.5 log increase, also statistical significance should be required to show growth in the untreated controls for preservative

action in PT 11 + PT 12. For statistical significance it was proposed that 95% confidence level (probability value $p \leq 0.05$) should be followed, or, if properly justified, a 90% confidence level ($p \leq 0.1$). It was concluded that discussion of this requirement will be flagged for Partner Expert Group (PEG) meeting.

For the PT 12 paper mills part it was noted that oxic/anoxic conditions need to be used in the tests depending on the test organisms used (and thus claims made). The test organisms stated in Table 3 for a general claim against bacteria (*Pseudomonas aeruginosa, Enterobacter cloacae, Aeromonas hydrophila, Klebsiella aerogenes*) grow in aerobic conditions. If specific activity against anaerobic bacteria like sulphate reducing bacteria (SRB; specified test organism *Desulfovibrio* sp.) is claimed, the tests need to be done in anoxic conditions. It was agreed to clarify this in the draft guidance for both PTs.

It was also agreed to amend the temperature to be used in the tests from 20-25°C into 20-30°C for all relevant uses in the guidance.

8.3. Vol II, Parts B+C – Appendix 4 (ECHA)

Appendix 4, Overview of standards, test conditions and pass criteria (PT 1-5), was published for the first time at the EFF WG webpage in May 2016, and updated in March 2017. Subsequently it was updated for PT 5, and included in the main guidance Vol. II, Parts B+C in 2018. Corrections (89 comments) were proposed in 2018 and 2019 and discussed at WGs II, III and IV 2019, and in an ad hoc follow-up launched in March 2020. ECHA had revised the Appendix based on WG discussions, and for the revised version 87 comments were received from EFF WG members, and ASO and CEN representatives. In WG-II-2020 the remaining issues not yet agreed upon were discussed, and the EFF WG made the following agreements:

- "Optional" requirements will be changed into "If claimed" throughout the Appendix, and footnote 1 amended accordingly.
- PT 2 hard surface disinfection uses will be kept as "use in healthcare area" and "use other than in healthcare", and agreed definition of healthcare area will be added (footnote P).
- Log reductions stated in EN 13697 remain applicable also for surface disinfection in the medical area, as long as the surface test for medical area is not endorsed and published. Further explanations concerning PT 2 surface disinfection without mechanical action in the medical area were agreed upon (footnotes 19 and c).
- EN 16777 will be indicated as a virucidal phase 2, step 2 test for non-healthcare area in PT 2 and PT 4, and footnote 15 will be amended accordingly.
- The definition of "frequently touched surfaces" in footnote 13 will be amended as agreed in the meeting.
- Fungal spores will be changed into optional target organisms for PT 2 instrument disinfection.
- PT 2 "room disinfection" will be amended into "room disinfection / automated airborne disinfection of surfaces". A tiered approach of phase 2 step 1 and phase 2 step 2 tests is kept. EN 17272 will be indicated as the phase 2, step 2 test instead of NF T 72-281.
- "Room disinfection / automated airborne disinfection of surfaces" use will be added to PT 3 and PT 4. Phase 2, step 1 tests (as basic requirements) will be taken from PT 3 / PT 4 hard surface disinfection, test temperature will be 10°C for PT 3 and 20°C for PT 4, and soiling clean/dirty for both PTs. FR will make a draft proposal for corresponding text to be included in the Vol. II Parts B+C main text.
- For PT 2 textile disinfection the log reductions for ASTM tests will be kept as they are. The comments from AISE/EBPF will be flagged for potential future updates, as they did not contain concrete proposals for amendments, but rather questions and comments.
- The non-porous phase 2, step 2 EN standards will not be replaced by DVG test guidelines for porous surfaces for disinfection of hatching eggs, hoofs, beehives and beekeeping equipment.

- Since required log reductions in DIN SPEC 10534 depend on different test factors, they will not be indicated in Appendix 4.
- Requirements for water for animals (PT 5) will be kept as they are.
- The proposed addition into footnote 19 concerning the issue of high temperature alone killing the test organisms will not be added. The issue will be discussed at the next EFF WG based on a TAB proposal that will be prepared by AT.
- Footnote 19 on temperature will be amended for PT 3 and PT 4.

The Chair informed that Appendix 4 and the main text in Vol. II, Parts B+C will be revised according to WG agreements, and will once again be provided for cross-checking for EFF WG before WG-IV-2020.

8.4. Hard surfaces disinfection – contact time and application rate (NL)

During previous discussions on Union authorisation applications of surface disinfectants based on volatile active substances questions were raised related to application rate, contact time and efficacy. Highly volatile active substances may evaporate during the contact time, especially if the contact time required is long, making the surface dry too quickly or change the composition of the product.

The EFF WG agreed that for the time being it is acceptable that in practice the surface might not remain wet during the whole contact time, and the minimum volume of product based on volatile active substance(s) is 18 ml/m^2 on non-porous surfaces in order to ensure sufficient wetting for disinfection without mechanical action. However, there should be evidence of wetness of the area for the applied dose – if the product can be spread over the whole area in such small amount (the material of surface should be also defined). If lower volume is used, it needs to be justified. CEN should be addressed with a proposal to develop a standard with a lower volume-to-surface ratio as close as possible to realistic application rates.

TAB proposal will be prepared by NL to be discussed in September WG.

8.5. TAB proposals

EFF WG agreed on TAB entries as follows:

Hard surface disinfection and differentiation of virucidal claims

Should different virucidal claims be allowed for hard surface disinfection in PT2?

- For disinfectants used in healthcare and non-healthcare areas (e.g. hotels, public sanitary, homeless shelters, public transport or clean rooms for production of pharmaceuticals) by professional users in addition to the currently accepted full virucidal claim, also limited spectrum virucidal activity and activity against enveloped viruses can be claimed;
- For disinfectants used in non-healthcare areas by the general public only full virucidal activity and activity against enveloped viruses can be claimed.

EN 1276 and EN 14476 test requirements for PT 5 active chlorine based disinfectants

Are efficacy tests in accordance with EN 1276 and EN 14476 obligatory for PT 5 active chlorine based disinfectants?

According to the Guidance on the Biocidal Products Regulation Vol. II Efficacy - Assessment and Evaluation (Parts B+C) version 3.0 (April 2018), passing modified EN 1276 and EN 14476 tests is a basic requirement for PT 5 disinfectants.

Based on the current information there is enough evidence that the active chlorine-based products (most widely used water disinfectants), cannot pass these tests at typical use concentrations that have long been established. In addition, it was acknowledged that the active chlorine concentration in drinking water cannot be increased to a level that passes these criteria. Consequently, the modified EN 1276

and EN 14476 tests mentioned in the guidance are considered as not obligatory for PT 5 active chlorine based disinfectants. Efficacy of such products should be demonstrated with a simulated-use test and/or a field test.

Tiered approach to testing preservatives

What efficacy tests are required for authorisation of biocidal products belonging to Main Group 2: Preservatives?

When testing preservatives, the tiered approach should be followed in accordance with the Guidance on the BPR, Volume II Efficacy - Assessment and Evaluation (Parts B+C). Nevertheless, it does not necessarily mean that all three tiers are necessary in each case. When appropriate and valid Tier 2 tests supporting the claimed use are submitted to demonstrate efficacy of a preservative biocidal product, Tier 1 tests are not needed and can be waived. In case that Tier 3 tests (field tests) are submitted instead of Tier 2 tests, additional laboratory evidence (Tier 1 or Tier 2 tests) needs to be submitted, unless the applicant can comprehensively justify why it is not possible to mimic relevant conditions of use in a laboratory setting.

What are the requirements for Tier 2 efficacy tests for preservatives?

Vol. II, Parts B+C efficacy guidance specifies the requirements for Tier 2 tests stating that efficacy should be demonstrated under "real life conditions". A special focus is put on simulating ageing[1] of the treated matrix. Typically, the following ageing procedures are relevant for preventive Tier 2 tests, depending on the specific uses applied for[2]. Other ageing modes, which have not been named here, may be necessary depending on the individual use.

- PT 6 – Long storage of the claimed treated matrix at ambient temperature or accelerated ageing at elevated temperature[3].
- PT 7 – Evaporation in air, leaching by water, UV irradiation, temperature-related ageing, or a relevant combination thereof[4]. Alternatively, outdoor ageing, if relevant.
- PT 9 – As for PT 7. For treated textiles, washing cycles should be considered.
- PT 10 – As for PT 7.
- PT 11 – Usually not relevant.
- PT 12 – Usually not relevant.
- PT 13 – Temperature-related ageing and addition of appropriate soiling[5].

In certain cases, ageing procedures can be omitted if ageing is demonstrably not relevant for the specific use, e.g. a PT 6 product would not require tests with an aged matrix if the matrix is preserved only for periods that are covered by biological testing anyway (typically 1-6 weeks).

Apart from ageing procedures, care should be taken to simulate realistic conditions in Tier 2 tests. Hence, solid matrices should usually not be tested on agar plates in Tier 2 tests. Agar holds high amounts of available water, while humidity in most real life applications is a limiting factor on bioavailability and thus efficacy of biocides. Furthermore, even very pure agar often contains unspecified amounts of nutrients that

[1] In this document the generic term "ageing" includes all relevant factors that can cause loss of the biocidal effect in a treated matrix, such as e.g. weathering, UV exposure, extended storage, leaching, or washing and cleaning regimens.
[2] This is a non-exhaustive list.
[3] Ageing protocols can be adapted from the chapter on storage stability in Volume I (Parts A/B/C) of the BPR guidance.
[4] Ageing protocols already established for wood preservation (e.g. EN 73, EN 84, EN 152 Annex F) can also be applied to other solid matrices.
[5] E.g. as done in IBRG FFG16-001.4: add 1% of 1% yeast extract solution

are nevertheless sufficient to support microbial growth. If it is necessary to simulate soiling that would cause biological growth in reality, it should be added separately in a controlled way.

Likewise, biocides for liquid matrices must be tested in a matrix that is relevant for the respective use. To simulate soiling that would be encountered in the real-life use, very low amounts of defined nutrient media may be added. Tests of preservatives in microbiological nutrient media are not relevant to demonstrate efficacy.

9. AOB

9.1. Other information & lessons learned

ECHA informed about provisional dates for the next WG meeting. The eCAs may request an early WG discussion in September (WG-III-2020) by sending a request to ECHA by 9 July 2020. Short information concerning revision of the WG recommendation on in situ generated substances was given. In addition ECHA kindly reminded that each point in the RCOM table submitted to ECHA after trilateral discussions in accordance with the working procedure for active substance approval and UA should be marked clearly by the eCA as 'open' or 'closed'.

All details are in the working document: WGII2020_EFF_9-1_Other info available in S-CIRCABC.

9.2. Report on follow-up actions of the active substance action plan (ASAP) (ECHA)

ECHA reported on actions identified during the active substance workshop in 2019 and taken by ECHA to facilitate the active substances approval process. There are some general aspects addressed in the active substance action plan (ASAP), e.g. prioritisation of backlog dossiers (submitted to COM before 2013), support the eCAs in procedural and/or regulatory issues, coordination of the evaluations of similar substances, and developing capacity of eCAs (training on ED assessment and visits of MSCA experts to ECHA). In addition, it has been identified that ECHA needs to analyse further the impact of ED assessment, which is one of the main reasons for the delay in review program.

One of the targeted aims discussed at this workshop was to increase the effectiveness of the WG meetings. Several proposals were considered and some of them are already partly implemented, e.g. solving issues proactively (promoting early WG discussions, using break-out groups during WG meetings and topic-specific expert groups), earlier sharing of WGs' agenda and meeting documents and coordinating similar cases evaluated by different eCAs.

Internally, regular meetings between the Chairs of WGs and BPC Chair have been organised to increase procedural harmonisation.

A question was raised concerning obligations and commitments of WG members. This issue needs to be clarified, especially among new members. Moreover, the role of the WGs in active substance approval process was mentioned. It was noted that the tasks of the WGs are becoming more complex and challenging, especially with reference to the available time.

List of Attendees

Efficacy Working Group

Core members
ATTIG Isabelle (FR)
GIATROPOULOS Athanasios (EL)
HAMEL Darka (HR)
POULIS Joan (NL)
ZUTZ Christoph (AT)
DUH Darja (SI)
Flexible members
ÅSLING Bengt (SE)
BURMISTROVA Anastasia (BE)
BLODÖRN Krister (SE)
BURMISTROVA Anastasia (BE)
CLEYTON JØRGENSEN Charlotte (DK)
DOLEŽELOVÁ Katsiaryna (CZ)
FISCHER JULIANE
FRANK Ulrike (SE)
GRÜNIG David (CH)
ILMARINEN Kaja (EE)
JANSEN Irina (DE)
KRÜGER Martin (DE)
LEPAGE Anne (BE)
LYNCH Helen (IE)
MAGNER Jörgen (SE)
MALMGREN Birgitta (SE)
MAXIMILIEN Yann (FR)
MEIER Margrith (CH)
MEZULE Linda (LV)
McGEE Conor (IE)
NIEMINEN Timo (FI)
PECINKOVA Martina (CZ)
PEELMAN Natania (BE)
RONCI Maria Beatrice
ROSSIER Nadine (CH)
RYDMAN Elina (FI)

SÄLL Liselott (SE)
SCHOEP Piet (NL)
STAHR Christiane (DE)
WARMERDAM Sonja (NL)
ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
RAULIO Mari
SCHAKIR Yasmin
Applicants
Liphatech
Stakeholders
GARMENDIA Irantzu
THEELEN Meredith (expert)
MORENO Mara (expert)
GRUSON Bernard (expert)
Advisors
REY Juliana

Environment WG-II-2020 (incl. PT 18 TEG)
Final minutes
28 August 2020

Minutes of Environment WG-II-2020

11-12 June 2020

Incl. PT 18 TEG of 8th July 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 50 participants present, of which 8 were core members, thirty flexible members, five rapporteurs and seven 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. 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 Alpha-bromadialone - PT 14 (FR)

Three points were discussed, one in relation to ED assessment, two points related to the exposure assessment. One of these points was linked to the bank slope scenario, for which it was agreed that it always needs to be assessed if applications of products close to water bodies are intended. The assessment can however be provided at product authorisation stage and does not need to be provided at active substance approval stage, where the assessment of soil is sufficient.

Regarding the ED assessment, an AHF was initiated since the point remained open.

Actions:

- **SECR** to initiate AHF
- **SECR** to include a TAB entry on the use of the bank slope scenario
- **SECR** to forward a discussion to AHEE-5 if the bank slope scenario should be assessed for open areas as well as for around buildings.

6.2/6.3 ADBAC/BKC and DDAC - ED assessment - PT 3, 4 (IT)

One point was discussed related to the ED assessment respectively, to which the WG agreed that no conclusion can be drawn with the information available.

Actions:
No actions were defined.

7. Discussion of Union Authorisation cases

7.1 UA for product containing clothianidin and pyriproxyfen - PT 18 (NL)

Two open and two provisionally closed items were discussed, mainly STP-related. Two items are followed up in an AHF.

Actions:
- **SECR** to initiate AHF.

7.2 Early WG: UA for product family containing CMIT/MIT selected items - PT 2, 4, 6, 11, 12, 13 (FR)

Six points mainly related to the exposure assessment were discussed, all points were closed. The full case discussion will take place at the next WG meeting.

Actions:

- **SECR** to forward to AHEE: Further clarification is needed on the related TAB entry referring to the increase of dilution factor post STP - can the dilution factor also be increased in the case of on-site treatment?

7.3 $PNEC_{soil}$ derivation for cyromazine containing biocidal products - PT 18 (DE)

One point was discussed and concluded regarding the use of a specific study for product authorisation.

Actions:
No actions were identified.

7.4 Harmonised assessment of groundwater concentrations for lactic acid in product authorisations (FR)

It was concluded that a quantitative assessment of Lactic acid (CAS number 200-018-0) and L-(+)-Lactic acid (CAS number 79-33-4) in groundwater is not necessary; only arguments to support a qualitative assessment without further calculations should be provided. A harmonised text justifying the qualitative assessment was discussed and agreed.

Proposed justification (confirmed by the WG):
Lactic acid is a naturally occurring simple organic acid found in plants, animals and humans. It is an endogenous metabolite in many organisms, a common naturally occurring food constituent and also a growth regulator intended to increase nut and fruit set. Furthermore, the environment is exposed to Lactic acid via the excretion of faeces and urine by humans (and their subsequent release from the STPs), as well as the direct disposal of excreta by other mammals. In soils, L-(+) lactic acid naturally occurs as a fermentation by-product of anaerobic degradation of organic matter. This substance may covalent bind with organic material in sewage sludge, manure, and soils. In microorganisms, lactate formation is one of the usual pathways for NAD+ regeneration and when formed, lactate can be further metabolized through the pathway of pyruvate

metabolism. As lactate is metabolized by microorganisms, its degradation in the environment is rapid. It should also be noted that biodegradation during storage of sludge as well as transformation and dilution in deeper soil layers is not taken into account in soil concentration calculations – and thus in subsequent groundwater concentrations (tier 1). Modelling of groundwater exposure in case of lactic acid largely overestimates concentrations and is considered unrealistic.
For all these reasons, it can be stated that Lactic acid does not cause unacceptable risk for groundwater and no further calculations are needed.

Actions:
No actions were identified.

7.5 Harmonisation of environmental fate endpoints for a SoC (DE)

Five points regarding the harmonised assessment and list of endpoints of a specific substance of concern in the frame of Union Authorisations was discussed. All points were closed.

Actions:
No actions were identified.

8. Technical and guidance related issues

8.1 Overview on guidance (SECR)

Item was not discussed at the meeting and will be followed up in a written procedure (initiated 17 July 2020).

8.2 Open questions regarding PT 18 (e.g. treatment areas) (NL, FR)

Two items brought forward by FR and NL related to PT 18 household and professional use were initially discussed at the WG meeting. Due to time constraints it was initially concluded to follow the topic up in in writing. However it was finally decided to do the follow up more efficiently via a dedicated PT 18 TEG meeting, which took place on 8th July 2020. The outcome of the PT 18 TEG meeting is provided **in Appendix 2** below.

The proposed conclusions and suggestions for closed points will be distributed to the AHEE for confirmation. Remaining open point will then be discussed at AHEE-5.

After the TEG meeting ASOs and the NL provided additional comments, which are not yet included in Appendix 2. They will be added only in the document to be distributed to the AHEE.

Actions (following PT 18 TEG):
- **SECR** to forward identified items to the CG
- **SECR** to initiate AHEE-consultation to confirm closed points
- **SECR** to schedule remaining open points for discussion at AHEE-5
- See Appendix 2 for further MS/ASO related actions before AHEE-5.

8.3 Organic carbon normalisation (DE)

A summary of the planned revisions and the suggested way of working was presented at the WG meeting for information.

8.4 Open TAB entries after TAB v2.1 commenting (SECR)

Item was not discussed at the meeting and will be followed up in a written procedure.

9. AOB

9.1 Other information & lessons learned (SECR)

Lessons learned:

ECHA contact points: In case of questions related to WG membership/changes in membership, organisation of WG meetings (e.g. travel, WebEx connection) or any other administrative questions concerning the WG meeting => contact ECHA WG FMB (bpc-wgs@echa.europa.eu)

- For any scientific or technical content related issues (e.g. request for e-consultations, case or guidance related questions) => contact ENV FMB (bpc-environmentalexposure@echa.europa.eu) and not any specific person
- Please always copy in the chair for any scientific or technical content related issues (heike.schimmelpfennig@echa.europ.eu)

e-consultations - current procedure:

- eCA prepares the document for the consultation and provides it to ECHA
- ECHA launches the consultation with at least two weeks commenting period
- The eCA summarised the outcome of the e-consultation – if clear WG is only informed, if unclear further discussion at WG meeting takes place (eCA prepares the meeting document)
- e-consultation procedure currently under discussion at ECHA!

Additional items for the WG meeting agenda:

- Please provide additional items for the WG meeting agenda either six weeks before the meeting or at the latest in the week after the draft agenda was distributed
- Later items cannot be taken into account due to planning reasons (=> e.g. number of meeting days)

Other information:

Provisional timing of coming WG meetings (updated post WG meeting):

– September 2020 – all meetings take place as virtual meetings
  - **WG-III-2020:** ENV session planned for **17-18 September** 2020
  - **AHEE-5:** planned for **14- 15 September**
– Possibility of additional ("extraordinary") ad hoc WebEx meetings, if needed

Endocrine disruption: Provisional ED EG meeting dates 2020

- 29 September - 1 October: virtual
- 17-19 November: tentatively physical

Endocrine disruption – products

- Agreed earlier at CG-34: *Assessment of ED properties of co-formulants in biocidal products – draft instructions for applicants* https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/dc42856d-9209-44bc-8595-b8f5a185664c/CG-34-2019-02%20AP%2016.5%20e-consultation%20ED%20potential%20of%20co-formulants_final.pdf

- Agreed at CG-41 in May 2020: *Practical approach for the assessment of ED properties of a biocidal product by rMS/eCA*

https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/3e9d01eb-3a46-461f-9c80-fbe1cdf02dbb/CG-41-2020-03%20AP%2016.5%20ED%20co-formulant_assessment%20by%20MS_vf_PUBLIC.pdf

- S-CIRCABC public folder with CG documents: https://webgate.ec.europa.eu/s-circabc/w/browse/89efe476-1017-46af-8a31-6ad845f79d04

ENV WG items forwarded to the BPC: Discussions and conclusions of ENV WG items forwarded to BPC-34 are provided in the embedded document:

WGII2020_ENV_9-1a_
BPC-34_AP%2009.01_

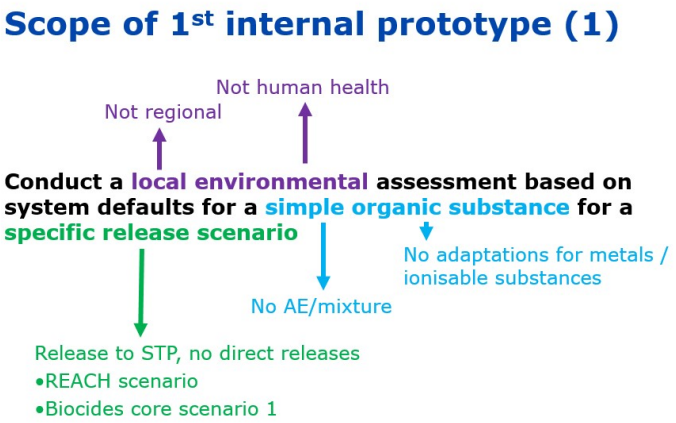
In-situ recommendations – revision: Work in progress
- Planning to have a first draft ready in the summer – for commenting
- Discussion: in November WG
- Planned publication: April 2021

9.2 Update on EUSES (SECR)

SECR informed on the progress of the current EUSES/CHESAR project:

…where it started:
- **New tool combining CHESAR and EUSES** under development
- Inception study in 2018/2019
- Development started in January 2020

…what is going on:
- Development of architecture baseline
  - Different modules and how they are related
  - Next step is refining and adding content to the modules
  - Implemented so far:
  - Front-end dealing with substance, scenarios and impacted target
  - Next steps:
  - IUCLID back-end
  - Syncing mechanism
  - Calculation engine
  - Library (June)



Ongoing further analysis:

- Complex substances (Mixtures, Multi-constituents: Assessment Entities)
- Glossary / harmonization of naming (CHESAR/EUSES)
- Use/scenarios
  - Hierarchy/categorization
  - Combination of Release Routes/Impacted Target definition
- Users/role definition
- UX flow for risk assessment

Other open points:

- Name of the new tool: Chesar 4 vs new name, what name if new name?
- Stakeholder interaction
- Working relationship with sectors (e.g. Concawe/PetroRisk, Eurometaux, …)

9.3 Report on follow up actions of the active substance action plan (ASAP) (SECR)

SECR informed on the following:

Facing the facts

- After 17 years Review Programme and 4 years left, 1/3 of AS/PT combinations evaluated
- After a promising period, submission of CARs dropped drastically in 2018
- Not only one problem to be solved by a "silver bullet" – plethora of issues and factors affecting the situation

➢ Workshop held in February 2019: identify, address most important issues, seek solutions

➢ **ASAP: Active Substance Action Plan**

Progress of ASAP implementations (1)

- Prioritisation of dossiers
  - ➢ ECHA and MSCAs prioritised progress of backlog cases that have been a long time in peer-review phase
- ECHA support to eCAs
  - ➢ Procedural and/or regulatory support for 3 active substances
  - ➢ Technical/scientific advice provided for 14 active substances
  - ➢ Coordination of evaluations of similar substances in different eCAs - sharing work in developing related assessments (in situ, Article 93)

Progress of ASAP implementations (2)

- Advise and support on relationship with applicants
  - ➢ MSCAs followed BPC agreement on submission of additional information and withdrawal of applicants
- Capacity building in eCAs
  - ➢ Training to WG members on ED assessment
  - ➢ Visits of MSCA experts (alternatives under discussion)

Impact and next steps

- Impact:
  - Reduction of number of dossiers blocked in evaluation
  - Reduction of number of issues identified in peer-review
  - Capacity in MSCAs: developing expertise in MSCAs on both regulatory and scientific/technical aspects
  - Impact of pending ED assessments on the progress of the Review Programme to be further analysed
- Next steps:
  - Keep on the progress of the actions in the ASAP
  - Detailed planning / monitoring of the implementation

ASAP implications on WGs: Improving WGs effectiveness

Completed actions (1)

- Proactive solving of topics
  - Promotion of early WGs which take place now on regularly basis => spares time at peer review stage
  - Use of break-out groups during WG meetings
  - Use of topic-specific expert groups (EG) so far in ENV to facilitate discussion of difficult topics (e.g. PT 8/PT 18 EG supporting the ENV WG)
- Regular meetings between the WG and BPC chairs to increase procedural harmonisation
- Additional time to prepare WG meetings
  - Earlier sharing of WG meeting documents if possible

Completed actions (2)

- Best practices for more efficient WG meeting preparation/improving documentation for meetings
  - Early sharing of draft WG meeting agenda
  - Avoid embedded documents
  - Provision of concise WG meeting documents
  - Set up UA/AS related discussions on different meeting days - so far for ENV and TOX - when possible
- SECR coordination of similar cases
  - Ongoing for two UA and four AS cases; for national authorisations to be organised by CG

Completed actions (2)

- Training for newcomers
  - WG meetings will be open for passive remote participation when physical meetings start again
  - Specific trainings took place on genotoxicity, degradation studies and EDs
  - Future trainings are planned
- Simplifying document jungle
  - Guidance map was prepared
  - Public CIRCABC site opened to collect all WG related documents

Ongoing actions/preparations

- Avoid discussions on already closed points
  - WGs agreed on separate documents dealing with reopening points in 2016
  - Common document currently under preparation
- TAB database under preparation
  - Collects previous WG meeting agreements including date of applicability of new TAB entries
- Clarification of obligations and commitments of WG members
- Discussion forum for WG members

Appendices:

Appendix 1: List of participants

Core members:

- (DE) Daniel **FREIN** (rapporteur for cyromazine)
- (DE) Eleonora **PETERSOHN**
- (DE) Sascha **SETZER –** alternate
- (EL) Ioannis **KANDRIS**
- (EL) Akrivi-Chara **PAXINOU –** alternate
- (FR) Stéphanie **ALEXANDRE**
- (IE) Helena **JOYCE**
- (NL) Barry **MUIJS**
- (NL) Karlijn **HOLTHAUS -** alternate (rapporteur - UA for product family containing clothianidin and pyriproxyfen)
- (SI) Petra **MURI**

Flexible members:

- Altmann Dominik (AT)
- Brasseur Anne (BE)
- Cougnon Thomas (BE)
- Leroy Celine (BE)
- A Marca Maria (CH)
- Gyalpo Tenzing (CH)
- Kunz Petra (CH)
- Ahting Maren (DE)
- Kehrer Anja (DE)
- Wennermark Henrik (DK)
- Sulg Helen (EE)
- De La Flor Tejero Ignacio (ES)
- Martin Vallejo Myriam (ES)
- Ruiz Lopez Elena Fuensanta (ES)
- Kaukoniemi Sanna (FI)
- Pasanen Jaana (FI)
- Penttinen Sari (FI)
- Straczek Anne (FR)
- Lozach Jerome (FR)
- De Magistris Isabella (IT)
- Smit Els (NL)
- van Vlaardingen Peter (NL)
- Aamodt Solveig (NO)
- Haraldsen Terje (NO)
- Randall Marit Espevik (NO)
- Podlaska Agnieszka (PL)
- Hahlbeck Edda (SE)
- Persson Johan (SE)
- Safholm Moa (SE)
- Molnarova Jana (SK)

Rapporteurs:

- Gour Annabelle (FR) - CMIT/MIT AQUEOUS 1.5-15
- Rat Benjamin (FR) - Alpha-bromadiolone
- Mantovani Alberto (IT) - ADBAC/BKC and DDAC

Advisors:

- Jesper Johannessen (DK)
- Hänninen Oskari (FI)
- Herard Fanny (FR)
- Verstraet Séléné (FR)
- Convert Yannice (FR)
- van der Ploeg Merel (NL)
- Säll Liselott (SE)

ASOs:

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

Appendix 2: Conclusions of the PT 18 TEG on WG-II-2020, item 8.2 (open PT 18 issues)

Background

The following discussion is related to two e-consultations initiated by NL and FR and a preliminary discussion held at WG-II-2020:

NL (background of discussion items):

At present the Netherlands is assessing a number of PT18 products. Reading the latest PT18 guidance (referred to in TAB 2.1 of 2019 – ENV A21), we noted some inconsistencies with the ESD PT18 and final conclusions of the 2nd PEG of December 2017 and WG-I-2018 ENV 7.3 Follow up WG-IV-2017 item 8.2 C. Moreover, some additional issues (also from Poland – please refer also to Appendix 4) are unclear and included in the table below. Below we included the table with all our questions, proposals and comments. Four member states responded to the e-consultation: BE, CH, DE and SE. **Please refer to separate document containing the Appendices provided in the original DT**.

FR (Background of discussion items, see also further detailed provided in Annex 1 below):

To cover the use of PT18 products on non-regularly wet washable surfaces as soft furnishings and carpeted areas to treat fleas and bedbugs infestations, the barrier scenario has been adapted as proposed by UK (and adopted in WG-IV-2017). It has been formalized in the TAB (as soon as v2.0, 2018), under section ENV147.

A number of recent product authorisation dossiers presenting these uses have given rise to referrals, in particular on the situations the scenario can be applied and also on the RMMs that can be used, since the different Member States did not have the same interpretation of the TAB entry. Therefore, we propose to launch a discussion in order to clarify:

On the actual scenario:

1- The requirements for the application of this scenario,

2- The textiles/surfaces covered by the scenario,

3- The application of RMMs and/or instructions for use in case of acceptable or unacceptable risks.

If extrapolation can be made:

4- For other textile pests such as dust mites, lice, ...

It was generally noted at WG-II-2020 that SECR will follow up with regard to item 8.2 internally (including PCs and CG SECR) in order to further clarify the remit of the noted items for discussion (specifically regarding RMMs). Some items, purely related to RMMs will therefore be exempted from the TEG discussions. The items for discussion are noted in **black** writing (not grey) and are provided in two tables (Part 1 for NL and Part 2 for FR).

<table>
<tr><th colspan="4">Part 1: NL open items for PT18 risk assessment (follow up of 8th July 2020)</th></tr>
<tr><th>a) No</th><th>b) Issue and background</th><th>c) PT 18 TEG conclusions</th><th>Status</th></tr>
<tr><td>1.</td><td>Indoor use against crawling and flying insects
At WG-I-2018 it was agreed that for crawling insects spot applications relate to treatment with powder, gel and bait stations, and for spray treatment a larger treated surface is relevant (at least 5.9 m2). In addition, for flying insects it was agreed that spray application only relates to space spray e.g. treatment of a room (58 m^3/38.5 m^2).

At WG-II-2018, this approach was adapted and became confusing. Because (1) for crawling insects spot application and barrier treatment are intermingled (and both could be either 2 m^2 or 5.9 m^2 – when looking at Remarks 1 and 2). And (2) the new table/approach suggests that it is possible to use spot application (2 m^2) also for spray to control crawling insects (for flying the type of product (powder, spray,..) is not stated).

Questions:
a. Should the table included in TAB 2.1 (2019) be updated, making more clear distinction between spot and barrier (when looking at Remarks column)?
Proposal: Update the table, stating clearly in the Remarks column that target spot relates to 2 m^2 (Remark 1) and barrier relates to wet cleaning zone of 5.9 m^2
b. Is the spot application (2 m^2) relevant to assess the control of crawling insects, also for spray products?
Proposal: Spot application for sprays can only be used when the product is sold with a nozzle/lance attached to the spray can, and when efficacy data are provided (with a specific limited treated area). If this is not the case, at least barrier</td><td>Items a and b were discussed and agreed at WG-II-2020, no further discussion is needed at TEG level
Only item c should be further discussed.

Ad a: The WG confirmed that the following information should be included in the related TAB entry A21.

<table><tr><th>Treatment</th><th>Treated zone</th><th>Wet Cleaned zone</th></tr><tr><td>Standard - house</td><td>130</td><td>38.5</td></tr><tr><td>Standard - building</td><td>609</td><td>180</td></tr><tr><td>Spot - house</td><td>2</td><td>2 (no correction)</td></tr><tr><td>Spot - building</td><td>9.3</td><td>9.3 (no correction)</td></tr><tr><td>Barrier- house</td><td>20</td><td>5.9</td></tr><tr><td>Barrier - building</td><td>93</td><td>27</td></tr></table>
If there is no volunteer to update the full table in TAB entry A21, at this point in time only the above table will be included by SECR for further clarification.

Ad b: It was agreed that the full surface treatment or at least barrier treatment should be assessed in case no efficacy data is provided that allows to reduce the assessment on a specific limited area.
With regard to nozzles: In case the product for spray application is specifically designed for spot applications, a respective device to concentrate the spraying area should</td><td>Proposed to be closed.</td></tr>
</table>

	treatment or even full surface treatment should be used in the risk assessment for sprays. (Update table (TAB ENV A21) to clearly state that spot treatment is for powder and gels, and that for sprays larger surfaces are relevant) c. Should the spot application be used for spray products to control flying insects as well? **Proposal**: Spot application for sprays can only be used when the product is sold with a nozzle/lance attached to the spray can, supported with efficacy data in which a limited fraction of the available surface area is treated resulting a sufficient efficacy). This refinement could be used for professionals only (as it cannot be expected of non-professionals to be able to locate infested areas and establish specific treatment). If data are not available, space spray treatment/treatment of a room should be used in the risk assessment. (and update table (TAB ENV A21) to clearly state that spot treatment is for powder and gels, and that for sprays larger surfaces are relevant)	added. This would be a case by case discussion, to be done within the EFF and APCP sections (*added by PT 18-TEG*, 8 July 2020). Ad c: No clear conclusion could be drawn at the WG meeting, there were diverging views from WG members expressed. **TEG conclusion ad c:** The TEG agreed that the standard scenario for flies should be used, unless efficacy data and APCP data on the spray-can can show that the target spray surface can be reduced to a spot application like size (e.g. by a spray lance, attached to a bottle). This would be a case by case discussion, to be done within the EFF and APCP sections.	

Background (e-consultation):

Feedback commenting MS (The appendices, provided in a separate document, include the full responses from various member states).

a. All agreed on the proposed update/clarification.

   In addition, BE proposes to include a table with the treated and wet cleaning areas:

Treatment	Treated zone	Wet Cleaned zone
Standard - house	130	38.5
Standard - building	609	180
Spot - house	2	2 (no correction)
Spot - building	9.3	9.3 (no correction)
Barrier- house	20	5.9
Barrier - building	93	27

	Point proposed to be closed –> update of table included in TAB 2.1 (2019) required. b. All agree to the need for efficacy data showing the effectiveness of the specific use. Regarding the nozzle: BE, SE and CH. However, DE states that targeted surface application can be carried out with different formulations (powders, granules, sprays and gels). In addition, CH would prefer to replace the term nozzle/lance with "spray head designed to allow for precise application, e.g. including a capillary tube". Furthermore, SE added that "If the treatment pattern used in the efficacy studies leads to unacceptable risks to the environment using default values from the ESD, the product could still be approved accordance with Article 19(5) provided that the conditions in that article are met. Taking into account the approach agreed in document CA-Nov16-Doc.4.2 – Final, an agreed SPC only concerns those cases for which the conditions in Article 19(1) are met. This means that following an authorisation in accordance with Article 19(5) each MS may apply national risk mitigation measures without consensus from the other cMS or the refMS". **Point proposed to be closed ->** efficacy data required to demonstrate effectiveness of the specific use. **Point open ->** regarding the need for nozzle**.** c. Agreement that appropriate efficacy data are required. Regarding non-prof/prof there are various views: BE and CH: agree that spot applications for flying insects cannot be authorised for non-professionals. BE is even of the opinion that spot application is not relevant for flying insects at all (best-case is barrier). DE is of the opinion that non-prof use can be authorised, if a nozzle if part of product packaging. SE stated that each MS may apply national risk mitigation measures without consensus from the other cMS or the refMS. Hence, this issue can be member state specific in their opinion (?)

	Point proposed to be closed -> efficacy data required to demonstrate effectiveness of the specific use. **Point open ->** regarding the need for nozzle**.**		
2.	Bed bugs for household The table now states that "The WG considered this scenario rather to be relevant only for professional users". Does this mean that we use for professionals always the surface area for large buildings? **Proposal**: Professional uses can also be in households. As stated in the TAB 2.1 (ENV 147) a surface area of 5.9 m^2 can be used in the risk assessment if supported with efficacy data in which a limited fraction of the available surface area is treated resulting a sufficient efficacy.	**NL: Point proposed to be closed.** Professional uses can also be in households. As stated in the TAB 2.1 (ENV 147) a surface area of 5.9 m2 can be used in the risk assessment if supported with efficacy data in which a limited fraction of the available surface area is treated resulting a sufficient efficacy**.** **TEG conclusion:** Please refer to the discussion of this item under Part 2. It was noted that the correct treatment area is 22 m², the 5.9 m² refer to the area of wet cleaning.	Proposed to be closed.
	Background (e-consultation): Agree that professional uses can perform bed bug treatment in households and to follow the ENV147. BE (appropriately) refers to the recent e-consultation by FR on this scenario. In addition, BE includes that use in house and large buildings should be summed up for professionals. Furthermore, SE stated that even when unacceptable risks are shown using default values for the scenario, each MS may apply national risk mitigation measures without consensus from the other cMS or the refMS. Please refer also to Appendix 2 of the DT, with the TAB 2.1 table and NL comments.		
3.	Moths – scenario and refinement The table included in TAB 2.1 states that the treated area is 3.75 m3 (based on the average of 2.5 wardrobes per household and a volume of 1.5 m3 per wardrobe) and that the wet cleaning area is 38.5 m^2. The ESD does not include a scenario for moths/wardrobes, but in TAB 2.1 (2019 - ENV 150) some default values for treatment of wardrobes are included, which relate to number of wardrobes per household, fraction to floor, cleaning efficiency and simultaneity	Ad a: Point was closed bilaterally (with BE) by further clarifying the scenario. Ad b: The TEG agreed that the cleaning of cloth is considered negligible and should not be assessed. Ad c:	Proposed to be closed.

	factor. In addition, under Remarks of the table it is stated that refinement for smaller number of wardrobes is possible. a. Why is the wet cleaning/floor area for a whole house used, instead of the floor area for wardrobes? **Proposal:** a wardrobe with a volume of 1.5 m^3, may have a floor area of for example 1 m^2. With 2.5 wardrobes per household, the total wardrobe wet cleaning (floor) area is 2.5 m^2. b. Regarding a scenario for treatment of wardrobes, only fraction to floor is included in the TAB (ENV 150), however, should the scenario also include treated surfaces - clothes which are washed after treatment? **Proposal:** Fraction to clothes is 0.9 and cleaning efficiency is 1. c. What information would be needed for the refinement; to conclude that only a smaller number of wardrobes is treated? **Proposal:** Remove this statement from ENV 150. Refinement is always possible, if valid information is provided, but adaptations of scenarios should be harmonised and agreed upon.	**NL: Point proposed to be closed.** Statement on refinement of smaller number of wardrobes should be removed from TAB ENV 150. **TEG conclusion ad c:** The concerned ENV entry is ENV A21. The TEG agreed that the statement can be removed.	
	Background (e-consultation): Ad a: We reckon that we misunderstood the wardrobe scenario. As we now understand from the responses that this should be implemented in the 'diffuser scenario' as discussed in the ESD for PT18. Hence, size of the wardrobe is not relevant, but (as explained by BE) 'an amount of product used in the wardrobe is diffused within the wardrobe. Each time the wardrobe is opened, it is assumed that an amount of this diffused product falls on the floor of the bedroom (Ffloor = 0.1); which is then wet cleaned with a 100% efficiency (FCE = 1)". Using the below formula, the daily emission to waste water can be calculated [kg/d]: • Emission from one wardrobe $E_{application,\ floor,6} = Q_{prod,6} \times F_{AI} \times \frac{T_{Dur}}{T_{Max}} \times F_{application,\ floor,6} \times 10^{-3}$		

	• Emission from one house: $$E_{ww,house} = E_{application,floor,6} \times N_{diffusers-efficacy} \times N_{dwellers}$$ • Local emission to wastewater: $$E_{local,STP} = E_{application,floor,6} \times N_{diffusers-effic} \times N_{dwellers} \times N_{house} \times F_{simultaneit}$$ Here NL assumes that for the emission from one house Ndiffusers is the number of diffusers per wardrobe and Ndwellers is the number of wardrobes per house (which is stated in TAB – ENV 150 and should be 2.5 wardrobes per household). DE also discussed the use of a "default" factor of 0.296 as ratio between wet cleaned areas and treated areas in domestic premise, as discussed at the 2nd PT18 EG-Meeting in 2017. Ad b: Various opinions: SE agrees. BE: 20% more realistic. CH and DE: emission from clothes negligible. Ad c: All agree that the statement on refinement as discussed in the table included in TAB2.1 (PT18 scenario overview) should be removed. Please refer for further details also to Appendix 2 of the DT.		
4.	<u>Ants large buildings - outdoor</u> a. Ants – outdoor (large buildings): Perimeter treatment - refinement for window/door-only possible? **Proposal:** apply factor 5 (on the default values for households). TAB agreement for window/door treatment is 5 m^2 (10m x 0.5m) for households. Hence, large buildings would then be 50 m x 0.5 m = 25 m^2 b. Ants – outdoor (large buildings): Spot treatment - Terrace area the same as for households. Should you expect a larger terrace area for larger buildings? **Proposal:** The agreed terrace surface for households is 30 m^2 (3 sides 17 m) and a receiving soils surface of 8.5 m^2. When a factor of 5 is applied for large buildings this results in 150 m2 terrace (15m x 10m), 3 sides = 40m x 0.5=20 m^2. Regarding the number of bait boxes for large buildings, again a relation	Ad a: This concerns only the scenario for large buildings in a city with release to the STP. The majority of TEG members agreed in principle to use the factor of 5 as proposed by NL. DE noted that a factor of 2 would be more realistic since it is based on the extrapolation of the circumference of a house to a large building, therefore the factor of 5 is too high. **Action**: NL will provide the reasoning for the factor of 5 before the AHEE meeting. Ad b: The majority of TEG members agreed that for large buildings in a city releasing to a sewer system an additional scenario for terraces is not needed since the perimeter treatment would somehow also cover terraces. BE and NL consider a specific scenario for terraces for large	Point open (AHEE-5).

	with households can be used. However, the factor of 5 on the number of bait boxes (4 for households) would result in 20 bait boxes for large buildings. This seems quite high for a terrace of 150 m^2. Therefore, a different relation is used: the receiving soil relating to the number of bait boxes is 8.5 m^2 soil/4 bait boxes ≈ 2.1 m^2 soil/bait box. The receiving soil for large buildings is 20 m^2 and then the number of bait boxes for large buildings should be (20 / 2.1 ≈) 10 bait boxes for 20 m^2. Resulting in a similar risk for soil for large buildings as for around the house treatment, with difference that the use around large building also will emit to sewer.	buildings in a city however as relevant.	
	Background (e-consultation): Ad a: SE and CH agree. BE refers to TAB ENV35 and states that this relates to brushing and questions if brushing is a realistic application method for large buildings. DE also refers to TAB ENV35 and also to TAB159, and proposes to use 20 m instead of 50 m as 'treated length'. Ad b: Differing views: • CH: scenario for a 30 m2 terrace covers both households and large buildings and would propose not to add another calculation/scenario. • BE: Agrees, but prefers worst-case use of 20 bait boxes. • SE: Suggested scenario only applicable when the surface is restricted to non-permeable e.g. concrete or asphalt ground • DE: Most larger buildings will only need a treatment around the building. According to ESD PT18, 4.3.1.3 (Treated and untreated surfaces), the treated area around a building is 50 cm wide. Considering a perimeter of 100 m (see answer to question 4.1), the treated (paved) area would be 51 m2, the untreated (receiving) zone 53 m2. Based on the treated area the number of bait boxes/spot applications could be calculated. Please refer for further details also to Appendix 2 of the DT.		
5.	Risk mitigation measures: Conclusions changed over the course of earlier discussions (during expert group meetings) and in the latest versions were rather confusing. Therefore this issue is broad up again: If there is an unacceptable risk (to aquatic and sediment dwelling organisms), can RMMs be used to mitigate the risk? 1. Can the RMM for crawling insects "use only in areas/on	*SECR note: This item should in general be forwarded to the CG meeting for further discussion. An exchange on points 3 and 4 can however take place.* Ad 3 and 4: NL and other TEG members questioned if the RMMs under 3 and the proposed non-wet cleaning by non-professionals described under 4 are applicable to non-	Proposed to be closed – to be forwarded to CG.

	surfaces that are not routinely wet cleaned (or wet cleaned at all) such as corners, behind and under the furniture, under the fridge, under the kitchen sink, under the oven or stove, under the water heater, areas of skirting boards, doors, areas of ventilation ducts and central heating pipes where insects usually hide" be applied to mitigate the risk? 2. Can an RMM for flying insects, restricting applications to locations not routinely wet cleaned where insects usually settle (e.g. on walls or ceilings), be applied to mitigate the risk? 3. Can we expect non-professionals to use impermeable sheets to cover floor (sufficiently)? 4. Can it be expected that non-professionals know not to wet clean treated areas, after treatment by professionals? **Proposal:** RMMs 1, 2, and 4 should be country specific, as it depends on the national standards for information professionals provide to non-professionals after treatment. RMM 3: the use of impermeable sheets to cover floor only for professionals.	professionals and can be followed by them. Different views have been noted by MS during commenting and also during the TEG meeting. The comments received will be forwarded to the CG for further discussion. *Description of discussion at TEG meeting to be provided for CG:* *NL asked these questions because they have these claims in their authorisations. However, NL asks especially for non-professionals if these RMM can be applied in a sufficient way.* *SE noted on 4 that if the RMM is only applied in areas which are not wet cleaned, as if the area is wet cleaned, then this condition has already been discussed in the CG 2018 and it has already been agreed that professionals can apply RMM. SE further noted that these substances are very toxic and should not come in contact with people. Authorisation of products should be done according to article 19.1 and article 19.5, e.g. if a treatment is needed against bed bugs including a barrier treatment and risks for environment and human health is identified, then the product needs to be authorised only under 19.5 for professional users.* *NL doesn't agree with 4, it should be a case by case decision by MS.* *ASOs questioned if it is always clear to the applicant what is a use instruction and what is a RMM.* *DE is of the opinion that this is not a suitable RMM for non-professional users.* *BE noted 3 is unrealistic and expressed some doubts on 4; people that clean surfaces routinely, e.g. in a larger building, may not know how to clean after a treatment.*	

		SE stated that professionals are responsible for providing clear cleaning instructions to the personnel of the company e.g. cleaning a larger building.	

Background (e-consultation):

- SE and BE agree that RMM 1, 2 and 4 should be country specific (each MS may apply national risk mitigation measures (without consensus from the other cMS or the refMS) and on case-by-case basis).
- DE does not agree that RMM 1 and 2 should be country specific. In addition, DE propose to adjust the RMMs regarding (not-/)wet cleaning areas to avoid further confusion: "rephrase the agreed SPC sentence (N-1) accordingly, e.g. "Do not apply to areas susceptible to (routine) wet cleaning" or replace it with "The application is restricted to areas that are not wet cleaned"."

a. RMM for crawling insects:
   - BE think that this RMM depends on the type of crawling insect and that this RMM cannot be used for non-profs.
   - CH think that this is not RMM but use instruction and can therefore not be used to reduce risk.
   - DE agree with this RMM

b. RMM for flying insects:
   - BE disagrees with this RMM, as flying insects are quite mobile.
   - CH state that this RMM cannot be used for non-profs.
   - DE agree with this RMM

c. Various opinions on the RMM on use impermeable sheets to cover floor:
   - SE are of the opinion that the RMM can also be used for non-professionals (with information and sheet provided with the product).
   - CH and DE agree that the RMM is only for professionals.
   - BE does not approve of the RMM at all, also not for professionals, as there is not scientific support.

d. RMM on wet-cleaned areas:
   - CH and DE: can also be used for non-profs (with information on SPC/by professional).
   - BE: RMM only for professionals

	• Please refer for further details also to Appendix 2 of the DT.		
6.	Flies/mosquitoes – outdoor (large buildings) The table states that "Refinement for 25 % fraction of the wall covered (based on UK experience)". **Question**: Is this not product specific? Hence, shouldn't this require additional efficacy data/testing is required for the product?	*SECR note: This point should not be re-opened, since it was agreed by the ENV WG.*	Proposed to be closed.
	Background (e-consultation): BE: do not agree twith25% refinement. For flying insects, a standard surface/barrier treatment scenario is more relevant, with 50% cleaning efficiency as stated in ESD PT18. CH and DE: such refinements can only be considered if confirmed by efficacy data (CH: never acceptable risk for such a use, regardless of 25% or 100% for (organic) insecticide). Please refer also to the table in Appendix 2 of the DT.		
7.	RMMs for wasps/hornets a. **Wasps/hornets – indoor**: Possible RMM of floor covering indoors to prevent emissions to floor from spot treatment? For professionals only? **Proposal:** RMM covering surfaces below a wasp/hornet test is relevant for professionals only (as we do not expect non-professionals to follow RMMs like these). b. **Wasps/hornets – outdoor**: RMM of covering the soil during application not considered feasible due to high pressure sprays/ dust application and possible significant outdoor spray drift. Spray drift is not included in the scenario for wasp nests. Hence, additional information (on area etc.) required to include spray drift? **Proposal:** The ESD indicates that drift will end up 3 meters from the source. We presume that this is the radius. Therefore the surface area is 29.6 m2, taking the depth of 0.5 m result in a soil volume of 14.8 m^3. And assuming that $F_{spray,nest,deposition}$	*Ad a: RMM related item, to be forwarded to the CG for further discussion.* Ad b: The TEG clarified the interpretation of the ESD. It was noted and confirmed that spray drift is not relevant for this kind of treatment, only deposition should be considered. It was further noted that the text in the ESD is not clear and this should be corrected (Table 4.3 should note 50 cm diameter instead of 3 m). *SECR: For AHEE meeting add description of the ESD in the background section for further clarification.*	Proposed to be closed – point a) to be forwarded to CG.

	remains 0.3. Thus the Csoil can be calculated.		
	Background (e-consultation): Ad a: Different views: • CH, DE and BE: agree – for profs only. (BE: data required from APCP on the spraying pattern) • SE: for non-profs also (when sheet and information is included with product) Ad b: Different views: • CH: (For professionals only) cover a minimum surface of 3 m2 below the nest. • BE and DE: Agree that RMM of covering soil during outdoor application is not feasible and spray drift should be considered. • DE and SE both refer to ESD. Please refer also to the table in Appendix 2 of the DT.		
8.	<u>Spiders</u> The table states that for spiders spot application may be used in risk assessment. *Please note that this use was discussed with one of our experts, who indicated that against spiders often whole walls are treated, because generally a product against spiders is used to prevent the creation of spider webs (on any part of the wall) and not for example to remove one spider(web).* **Question**: Is a barrier or whole wall treatment not more relevant for treatment of spiders?	The TEG agreed that the extent of the area treated (spot, barrier, whole wall) depends on the efficacy claim/tests provided. If e.g. efficacy was only shown for a limited area, only this limited area would need to be assessed in the risk assessment. Use instructions on how the product should be used however they need to be clear also for non-professional users.	Proposed to be closed.
	Background (e-consultation): Different views: • DE: in general – a widespread use of biocides against spiders seems not justified for DE. Indoor treatment is not considered necessary. Outdoor treatment to prevent webs on walls could be tolerated/approved. DE agree that whole wall has to be treated (based on efficacy		

	input). • SE: all types of application patterns could be applicable (spot/barrier/surface).BE agree that surface /barrier treatment is more relevant. • CH: it was common practice in CH to treat whole wall outdoors and MS-CH has restricted this to only punctual use in areas that are protected from rain (cracks and crevices) (experience: surface treatment will never lead to acceptable risk). Indoor spot application could be relevant. Please refer also to the table in Appendix 2 of the DT.		
9.	Nozzles/lances: When can nozzles/lances be included in the risk assessment (to reduce the treated surface area from a "whole" area treatment to a spot application or a reduced treated area): **Proposal**: (1) for professionals and (2) for non-professionals only when the product is sold with the nozzle/lance attached to the can and (3) supported with efficacy data (in which a limited fraction of the available area is treated).	*SECR note: the support by EFF data should be discussed by the EFF WG.* Please refer to the conclusions on item 1b and 1c above. **Action**: ASO will provide an overview on suitable devices to reduce the treatment area before the AHEE meeting (27. August).	Point open (i.e. defined Action)
	Background (e-consultation): CH: sprays should always be equipped with a suitable device e.g. nozzle/lance/capillary tube if they are used for spot treatment/crack and crevices application. This does not affect the risk assessment. SE: agree with 1 and 2. But do not agree that new efficacy studies are always needed in order to support the applicability for RMMs. BE and DE: support NL proposal. Please refer also to the table in Appendix 2 of the DT.		
10.	Cleaning efficiencies: In the ESD PT18 Table 3.3-8 (page 64) shows different cleaning efficiencies depending on formulation and use. a. What cleaning efficiencies to use? **Proposal:** For spot application and barrier applications, the cleaning efficiency can be either based on surface treatment (0.5 for spray) or on crack and crevices (0.25 for spray), depending on the intended uses. b. Why are there (quite large) differences between cleaning efficiencies for sprays (0.5 for surface / 0.25 for crack and	Ad a: **NL: Point proposed to be closed.** For spot application and barrier applications, the cleaning efficiency can be either based on surface treatment (0.5 for spray) or on crack and crevices (0.25 for spray), depending on the intended uses**.** **TEG conclusion ad a:** The TEG re-confirmed the proposed cleaning efficiency (see also TAB ENV 149, a reference to TAB ENV 149 should be added to the UK table in ENV A21).	Points a) and b) proposed to be closed, point c) to be cross-checked at AHEE-5.

	crevices) and RTU aerosols (0.2 for surfaces and 0.03 for crack and crevices)? **Proposal:** use the same Fce values for RTU as for spray (0.5 for surface / 0.25 for crack and crevices), unless supported with data. c. Can the cleaning efficiency be refined to 0.15 when the product is applied with a special crack and crevice extension/pin nozzle/lance. And can the application is restricted to a bandwidth of 0.1 m (professional users) to mitigate the risk? Can the refinements to cleaning efficiency and band width be applied only in the case of crack and crevice application or in the case of spot or barrier application to surface as well? **Proposal:** the refinement should be supported by efficacy data (in which a limited fraction of the available surface area is treated with specific target organisms) and is only relevant for crack and crevices. Also, the product can only be applied with specific equipment and should be for professionals only.	Ad b: It was agreed to currently not adapt the existing values. The values will however be looked at in the frame of the revision of the ESD for PT 18. Ad c: The discussion on efficacy data is not in the remit of the AHEE/ENV WG and should be discussed by EFF WG. The TEG agreed in principle to stick to the existing values in the ESD and TAB. **Action**: NL to check before the AHEE meeting why in some CARs the value was changed to 0.15 (check justification for the change).	

Background (e-consultation):

Ad a: All agree.

BE: please note that is already explained in TAB ENV 144 but a table such as proposed below, may clarify the emission scenario):

Spraying Application type		Cleaning efficiency
Spot	Normal	0.5
Spot	Crack & crevice	0.25
Barrier	Normal	0.5
Barrier	Crack & crevice	0.25

Crack & crevice cleaning must be clearly stated on the label.

	Ad b: Different views: • DE and CH: not in favour to adapt current values. However, no scientific reasoning seems to be behind these values. Moreover, DE UBA currently conducts a research project where the ESD PT18 for household and professional uses should be updated. • SE: Agree to use the same Fce Ad c: Various views: • DE: agree on need for efficacy data and authorised for profs only. But 'Why is the use of special equipment and its consideration in the exposure assessment not possible for surface applications?' • SE: efficacy data not always required. Refinement of bandwidth can also be used for barrier treatment, and can be used by both profs and non-profs. • BE agree with NL. Moreover, BE state "not with lance as it is not sure that the emissions from this device can be restricted to 0.1m only and no drift will happen". • CH: In our opinion, sprays (and RTU aerosols) should always be equipped with a suitable device e.g. nozzle/lance/capillary tube if they are used for spot treatment/ crack and crevices application Please refer also to the table in Appendix 2 of the DT.		
11.	Additional issues encountered by NL during product assessments: a. Can products be authorised with intended use in non-inhabited areas (such as a garage)? **Proposal:** Considering the generic use of insecticides - they are applied where the problem is, which may be also in "inhabited areas" - this is not an acceptable RMM. b. It was noted that a number of highly toxic products are sold to the general public as concentrates and/or large volumes. **Proposal:** These products should be sold as ready to use products in ready to use equipment with a maximum package size limited to 100-200 ml? (See also a proposal for PT8 products in Efficiency and practicability of risk mitigation measures for biocidal products - Wood preservatives and insecticides)	*SECR note: These questions should be discussed in the CG meeting (second item potentially by the TOX WG).*	Proposed to be closed – to be forwarded to CG.
	Background (e-consultation):		

	Ad a: Different views: • CH, DE and BE agree • SE: RMM to restrict to 'areas not wet-cleaned' (which includes garage) is possible. Ad b: BE, CH and SE agree. Moreover SE ask 'Should this point be forwarded to Coordination Group?' • DE agree in general. But If a product authorised for non-professionals needs a dilution step, clear instructions should be given and a dosing aid should be part of the packaging. And why the restriction to 100-200 mL for non-prof packaging?

Part 2: FR - Clarifications of the ENV147 scenario (TAB v2.1, 2019): Scenario for spraying application to treat against cat fleas or bedbugs (indoor, PT 18) - Version 2.0 (follow up of 8th July 2020)			
a) No	**b) Issue and background**	**c) PT 18 TEG conclusions**	**Comments/ Actions**
12.	POINT 1: Do you agree to have systematically the RMM (or the use instruction) "Do not use on regularly washed surfaces and textiles" when this scenario is applied? **Questions to the WG:** 1. For this specific scenario ENV147 described as covering the use of PT18 products on non-regularly wet washable surfaces as soft furnishings and carpeted areas to treat fleas and bedbugs infestations, does the WG agree to apply the use instruction "Do not use on regularly washed surfaces and textiles" as a condition of this scenario? 2. Is there a need to be more precise on 'regularly'?	Ad 1: **ENV WG conclusion**: The above noted sentence should be added to the SPC as use instruction in case of an acceptable risk. It should however be noted that this instruction cannot be used as risk mitigation measure to reduce an unacceptable risk. Ad 2: The majority of TEG members agreed that no further definition of "regularly" is needed – point related to point 2 and 3 below.	Proposed to be closed.

	Background - See Annex 1.
	
	Feedback of MS:
	
	- SE and DE do not agree to apply systematically the RMM/Instructions for use when this scenario is conducted. The 5.9 m² value represents the wet cleaned area for a classical barrier treatment.
	- **DE** mentions all the difficulties of using the RMM "Do not use on regularly washed surfaces and textiles" (the definition of "regularly", the definition of all the textiles that correspond to this criterion and the potential misunderstanding of the non-professional user). They consider the scenario suitable for indoor application on all surfaces (including soft and hard surfaces) potentially infested by pests mainly found on textiles.
	- **NL and BE agree to use the sentence as an instruction for use.**
	  - NL states that it cannot be used as an additional RMM in case of the risks are unacceptable.
	  - BE proposes that it could become a mandatory RMM if a barrier scenario is used in Tier 1 and leads to unacceptable risks. Then a Tier 2 scenario is conducted with scenario ENV147 and the RMM is applied.		

13.	<u>POINT 2: Do you agree with the proposed treated textile and surfaces covered by the TAB entry ENV147?</u> **Questions to the WG:** 1. Does the WG agree that hard surfaces cleaned regularly (including all types of floor except carpeted areas) are not covered by ENV147? 2. Does the WG agree that pet supplies washed regularly such as cover, blanket and soft basket are not covered by ENV147? 3. For the bed base and bed frame issue, see point 5.	Ad 1: The TEG agreed that hard surfaces are not covered by ENV 147. Ad 2: Point open. It could not be clarified if the release from this kind of treatments of pet soft furnishing items is covered by the assumed default values of wet cleaning area and FCE. Depending on the discussion on this item, POINT 1 may need to be revised (note that PONT 1 is meant as use instruction, not as RMM). **Action**: Can ASOs provide an overview on typical treated areas when products are applied against pet fleas before the AHEE meeting? Ad 3: Please refer to point 5.	Ad 1) proposed to be closed Ad 2) open (AHEE-5)

	Background - See Annex 1.
	
	Feedback from MS:
	- **SE** do not believe that stipulating exactly which area should be treated is needed. They remind that in Sweden, the treatment of bedbugs is only authorised for trained professionals as non-professional users cannot conducted an efficient treatment.
	- **NL** and **BE** agree with most of the proposed treated surfaces and textiles, and have suggestions:
	  ○ **NL**:
	  ▪ "Regularly wet clean" should be specified more clearly (is it once a week? More often?)
	  ▪ For the floor, it should be clarified that it includes all types of floor (tile, laminate, PVC floors…).
	  ○ **BE**:
	  ▪ ENV147 is not applicable to some of the pet supplies (cover, blanket and soft basket) as they can be washed regularly for odour and hair issue.
	  ▪ ENV147 is not applicable to hard surfaces cleaned regularly (parquet floor/baseboard). They also have some reservations regarding bed frame and bed-base		

	- **DE** did not comment this point.		
14.	<u>POINT 3: Do you think the scenario ENV147 covers more areas (especially for bedbugs)?</u> **Question to WG:** see header	The TEG agreed that the scenario can be used also for other species (e.g. lice), however it is meant exclusively for products used for the treatment of textiles and soft furnishing not regularly washed. **Follow up question for AHEE-5**: If a barrier treatment takes places in addition to the treatment of only soft furnishing/textiles, is it sufficient to assess only the scenario for barrier treatment since it covers also the other scenario? **Action**: SE and ASO to provide further information on bed bug treatment (areas treated, way of treatment, professional/non-professional users) before the AHEE meeting.	Proposed to be closed. Follow up question for AHEE–5.
	Background - See Annex 1. **Feedback from MS:** - **SE** remind that barrier treatment covers C&C treatment and this need to be clarified in the TAB. Moreover, mattresses, backs of headboards, divan bases, backs and underside of bedside furniture, skirting boards, wall/floor junctions, window and door frames etc. can be considered covered by barrier treatment. - **NL** and **BE** agree that ENV147 covers more area, BE precises that pet covers, pet blankets and soft basket should be added. - DE supports the use of the scenario for all products that control pests which are mostly in textile objects (dust mites, ticks, fleas, bedbugs). **Response to SE**: Please note that Barrier treatment refers to a scenario where AREAwetcleaned is 5.9m². It can be a Barrier treatment on surface (FCE = 0.5) or a barrier treatment in C&C (FCE = 0.25). A smaller AREAwetcleaned of 2m² is considered in a targeted spot application treatment. Again, it can be a spot application on surfaces or a spot application in C&C. Therefore, a barrier treatment in C&C covers a targeted spot application in C&C. • For the areas covered by the scenario, see discussion point 2. • For an extrapolation to other pests, see discussion point 9.		
15.	<u>POINT 4: How to describe the use in the authorisation documents? Is 'Treatment of soft furnishing and carpeted area' sufficient or do</u>	*SECR note: This items should be forwarded to the CG.*	Proposed to be closed – to

	we need a more detailed description of the treated articles? **Questions to the WG:** Do you agree that the phrase proposed by BE is sufficient and can be followed by non-professional users? We propose a slight modification: "Do not use on regularly washed surfaces and textiles. The product is not intended to be used on fitted sheet and mattress protector, covers of **duvet/cushions/sofa**, cuddly toy, soft basket, covers and blankets of pets. *For these furniture or other regularly washed textiles, a heat treatment should be carried out in a washing machine at 60°C for 90 minutes or in the freezer at -17°C for 10 hours*".		be forwarded to CG.

	Background - See Annex 1.
	
	Feedback:
	- **SE** do not believe that stipulating exactly which area should be treated is needed. In Sweden, the treatment of bedbugs is only authorised for trained professionals and for them, the following phrases can be applied: *'The product should only be used as part of an integrated pest management (IPM) system' and 'Apply according to EU code of practice for bed bug control that may include mattresses, backs of headboards, divan bases, backs and underside of bedside furniture, skirting boards, wall/floor junctions, window and door frames etc'.
	- **NL** and **BE** believe that a more detailed description is preferable,
	  ○ However, **NL** wonders how it can be interpreted and followed by non-professional users,
	  ○ **BE** proposes a phrase where the textiles known to be frequently washed (clothes, sheets) are not detailed: "Do not use on regularly washed surfaces and textiles. The product is not intended to be used on fitted sheet and mattress protector; covers of duvet, cushions and sofa); cuddly toy; soft basket, covers and blankets of pets. For these furniture or other regularly washed textiles, a heat treatment should be carried out in a washing machine at 60°C for 90 minutes or in the freezer at -17°C for 10 hours".
	- **DE** prefers to link the scenario to the pest than to the treated surfaces.		

16.	POINT 5: The bed frame or bed-base treated in case of bedbugs infestation are not textiles or soft furnishing but more hard surfaces (i.e. wood). In this case, how to describe this use in relation with the scenario?	Point open. The point is related to the follow up defined for AHEE-5 under POINT 3.	Point open (AHEE-5).

	Question to the WG: Are bed frame and bed base considered non-regularly washed and covered by the ENV147?		
	Background - See Annex 1. **Feedback of MS:** - **SE** remind that for trained professionals, the sentence of point 4.* can be applied - **BE** believes that ENV147 does not cover hard surfaces and that a separate assessment should be performed (classical barrier scenario on surfaces) if they are part of the claimed use. Both scenarios should be summed up. In that case, a special instructions should also be added "Apply to bedding and on bed frame/headboard" Moreover, some parameters of the ENV 147 scenario should be discussed and revised if necessary: o Fapplication,treated = 0.85, o Fapplication,floor = 0.11, o AREAwet,cleaned = 5.9 m². - **NL** suggests to describe the use on bed frame or bed-base 'associated furnaces' or 'regularly wet-cleaned furniture and textiles' - **DE** prefers to link the scenario to the pest than to the treated surfaces and believes that ENV147 AREAtreated/AREAwetcleaned take into account soft and hard surfaces that could be treated. Therefore, this question is not necessary. For the point on a separate assessment, see point 6. For the discussion on ENV147 parameter modifications, see general comment, French position.		
17.	POINT 6: Can the treatment of bedbugs be entirely evaluated with ENV147 scenario only or should it be cumulated with a classic scenario in crack and crevices (or other)? **Questions to the WG:** 1. If hard surfaces are part of the claimed use for the bedbug treatment, does the WG agree that ENV147 is not sufficient and additional emission calculations should be added?	Point open. The point is related to the follow up defined for AHEE-5 under POINT 3.	Point open (AHEE-5).

	2. Which scenarios must be added to cover hard surface in the case of this specific pest?		
	Background - See Annex 1. **Feedback from MS:** - **SE** believes that the classical barrier scenario already covers the treatment of bedbugs. They also remind that barrier treatment covers C&C treatment and this need to be clarified in the TAB. - In the assessment of bedbugs products, **NL** and **BE** agree to cumulate the ENV147 scenario with another scenario which presents smaller AREAtreated. - **DE** prefers to link the scenario to the pest than to the treated surfaces and believes that ENV147 AREAtreated/AREAwetcleaned take into account soft and hard surfaces that could be treated. Therefore, no cumulative assessment is needed. **Response to SE**: See response point 3.		
18.	POINT 7: Do you agree to inform the user that regularly washed textiles should undergo cold or heat treatment? **Question to the WG:** Does the WG agree to systematically inform the user to conduct a cold or heat treatment on regularly washed textiles?	*SECR note: This items should be forwarded to the CG.*	Proposed to be closed – to be forwarded to CG.

	Background - See Annex 1.
	
	Feedback from MS:
	- **SE** confirms that heat treatment is already a part of the integrated pest control strategy for bedbugs treatment by trained professionals and that it does not need to be specified in the SPC. However, it could be added for fleas products.
	- **BE**, **NL** and **DE** agree that heat treatment can be an interesting option, however they have questions and suggestions:
	  ○ **NL** requires efficacy data on these treatments and proposes to rephrase the instructions,
	  ○ **DE** wonders if we have a sufficient mandate within the framework of the Biocide Regulation for such an information on biocides products labels,
	  ○ **BE** believes that it may also be specified that the treated surface / textiles must not be washed directly or soon after treatment, for efficacy reasons.
	Response to NL: You proposed to rephrase the instructions as follows: "*Do not use on regularly washed surfaces and textiles. For **washable***		

	textiles, use a heat treatment instead (machine wash at 60°C for 90 minutes). Alternatively, apply a cold treatment (freezing at -17°C for 10 hours)". This is exactly what we meant, thank you for the correction. **FR remark**: Heat treatments are already used in Sweden by professional users. In France, mechanical treatments are also strongly recommended by the Health authorities to complete chemical treatments. In other section (efficacy…), the following RMMs can already be applied: - "Adopt integrated management methods such as a combination of chemical, physical and other public health control methods, taking into account local specificities (climatic conditions, target species, conditions of use, etc.)." - "Consider the use of other protective measures in combination with a biocidal repellent. " We believe that the heat treatment is the same type of instructions and that we have the mandate to apply them.		
19.	<u>POINT 8: RMMs and/or instructions for use in case of acceptable or unacceptable risks - What do you think about the above proposal?</u> **Question to the WG:** 1. Which RMM can be proposed in case of unacceptable risks from treated surface releases (to set $F_{application\ treated}$ to 0)? 2. Which RMM can be proposed if the emissions due to the floor and the applicator clothes lead to unacceptable risks (to set $F_{application\ floor}$ to 0)?	Ad 1: **ENV WG conclusion**: No RMM was agreed on. *SECR note: item 1 to be forwarded to the CG.* Ad 2 **ENV WG conclusion**: It was agreed that for professional users the following RMM could be applicable: "Protect the adjacent surface during application with a non-washable impermeable film". It is noted that the impermeable film does not cover cloth.	Proposed to be closed – to be forwarded to CG.

	Background - See Annex 1.
	
	Feedback from MS:
	- **SE** reminds that such discussions on the applicability of RMMs have already been closed during Minutes for WG-1-2018 and that MS should follow the agreement.
	- **BE**, **NL** and **DE** disagree to use the RMM "Protect the adjacent surface during application with a non-washable impermeable film" in case of unacceptable risks.
	- **NL** believes that these RMMs cannot sufficiently used to result in acceptable risks.
	- If risks become acceptable with:
	  ○ No emission from treated surfaces, **BE** proposes to use the RMM "Vacuum cleaning / Dry cleaning only for treated surfaces".
	  ○ No emission from floor (beside the treated surfaces), **BE** proposes various RMM but seems to favour a RMM which restrict the use to crack and crevices area.
	  ○ No emission from treated surfaces, DE proposes to use "Do not apply on wet washable or cleanable surfaces"		

20.	<u>POINT 9: Do you agree that ENV147 scenario covers the use on other textile pests such as lices, dust mites?</u> **Question to the WG:** Do you agree that ENV147 scenario covers all products that control pests which are mainly found in textiles objects (for instance ticks, but other organisms could be proposed)?	The TEG agreed that the scenario could be used for the textile pests like lice, the possibility for the use on dust mites and ticks was not clear. **Action**: ASOs will collect further information specifically for ticks and dust mites before the AHEE meeting.	Point open (AHEE-5).
	Background - See Annex 1. **Feedback from MS:** - **SE**, **BE**, **NL** and **DE** agree that ENV147 scenario also covers the use on lice, - **SE**, **NL** and **DE** agree that ENV147 scenario also covers the use on dust mites. **BE** believes that these organisms are widespread throughout the house and that a standard surface scenario seems more relevant. - **DE** proposes that ENV147 scenario covers all products that control pests which are mainly found in textiles objects (for instance ticks, but other organisms could be proposed). **Conclusions:** It has been agreed that ENV147 can be applied to cover uses on lice.		
21.	**POINT 10: Does the recommendation about the cold or heat treatment can be applied effectively for these pests?** **Question to the WG:** *For the points on efficacy data and the sufficient mandate within the framework of the Biocide Regulation, see point 7*	*SECR note: This items should be forwarded to the CG (related to POINT 7).*	Proposed to be closed – to be forwarded to CG.

	Background - See Annex 1.
	
	Feedback from MS:
	- **SE**, **BE**, **NL** and **DE** agree that heat treatment can be an interesting option.
	  ○ **NL** and **SE** requires efficacy data on these treatments,
	  ○ **DE** wonders if we have a sufficient mandate within the framework of the Biocide Regulation for such an information on biocides		

	products labels. **Conclusions:** It has been agreed that heat treatment is an interesting option.

Human Health WG-II-2020

Final minutes

15 September 2020

Minutes of Human Health WG-II-2020

9-11 June 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 42 members registered, of which 9 were (alternate) core members. Three stakeholder representatives and six stakeholder experts 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 noted that especially for Secure Webex, it is crucial to respect the deadlines as it is not possible to accept additional last-minute participants joining the meeting.

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-I-2020

The minutes were agreed without further changes.

6. Discussion of Active Substances

6.1 Alpha-bromadialone, PT 14 (eCA FR)

The WG agreed on the read-across between alpha-bromadiolone and bromadiolone. It was not possible to conclude on the ED properties according to the ECHA/EFSA guidance because it is technically not possible to perform the relevant testing. There are however no indications of ED properties with regard to human health in the available information. The WG agreed on the reference values proposed by the eCA. For details, please refer to the minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.2 Chlorine dioxide – Genotoxicity assessment, PT 9 (eCA DE)

The discussion concerned the testing proposal for genotoxicity assessment, where the WG agreed on the testing approach. For details, please refer to the minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicants in R4BP 3.

6.3 ADBAC/BKC – ED assessment, PT 3, 4 (eCA IT)

No discussion took place. The WG agreed with the evaluation made by the eCA.

6.4 DDAC – ED assessment, PT 3, 4 (eCA IT)

No discussion took place. The WG agreed with the evaluation made by the eCA.

7. Discussion of Union Authorisations

7.1 UA for product containing clothianidin and pyriproxyfen, PT 18 (eCA NL)

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

7.2 Harmonisation of assessment among applications for UA containing lactic acid (eCA FR)

Closed session for MSCAs only

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

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.

8.2 Quantitative risk characterisation for sensitisers

SECR presented the meeting document explaining that it was drafted in light of the discussion at the WG-I-2020 and having further analysed the REACH guidance. In the document, the SECR considered that there is for the time being no agreed methodology to quantitatively assess the risk of sensitisation, that the current scientific understanding does not enable a sufficiently protective assessment, and that in the current state of science it is not possible to develop reliable guidance to quantitatively assess the risk for sensitisers. The SECR therefore proposed following the scientific developments and reconsidering the possibility of developing guidance at a later stage, with possible involvement of experts from REACH and Cosmetics Regulations. The problem regarding the availability of in-can preservatives was however recognised as a serious concern. As it is not possible to develop reliable guidance, action would be required at the policy level. The members were asked whether they agreed with this interpretation of the situation and the proposed way forward.

An ASO representative presented a room document in which it was proposed that a quantitative risk assessment for active substances that are skin sensitisers can only realistically be carried out at product authorisation stage, when elements that can affect the bioavailability of the active substances are known (e.g. the use pattern or the exact product formulation). Accordingly, also the necessary restrictions that might be the result of this assessment would be taken into account at the product authorisation stage and not at the active substance approval. The ASO representative also informed that a proposal for a policy approach has been submitted for the BPC-35.

The members agreed with the SECR interpretation and the proposed way forward, considering that the SECR proposal reflects the discussion held at WG-I-2020 and that more information would be necessary for guidance development, which at the moment is not seen as a possibility. Regarding the ASOs proposal, it was noted that assessing sensitisation only at product authorisation would mean that treated articles would be disregarded in the assessment. The members highlighted that the development of a QRA approach for skin sensitisers would require resources and the support from the stakeholder organisations would be welcomed.

The document proposed by SECR was unanimously agreed. Guidance development is not considered possible at this stage.

8.3 Revising ECHA guidance Vol III Part A

The information requirements for biocidal active substances and biocidal products are being changed in the revision of Annexes II and III to the BPR. The guidance on

information requirements (ECHA Guidance Vol III Part A) will be updated to reflect these changes. During this revision, the guidance will also be reviewed to bring it up to date with regard to the scientific development.

ECHA will provide drafting to cover the changing data requirements, while the members were requested to identify where the guidance should be changed even though the data requirements are not changing. The proposals should be justified with references provided, if relevant. The input should be provided by 7 August 2020 in the following S-CIRCABC Newsgroup: https://webgate.ec.europa.eu/s-circabc/w/browse/e3bd04fd-5620-4144-9d48-d180fa0a3369.

8.1 Revising the WG recommendation on in situ generated substances

SECR informed of the task group activity on revising the WG recommendation on in situ generated substances. The document is available in S-CIRCABC to members and associated stakeholder organisations.

9. Any other business

9.1 Other information & lessons learned

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

Meeting organisation

The WebEx meeting was held on three days although timewise it could have been done in two days. This decision was based on experience and on the input received during and after WG-I-2020, as full-day WebEx meetings are perceived as exhausting and because for virtual meetings, there is no pressing need to reduce the number of days. SECR asked for feedback regarding this approach to better prepare future meetings. An overwhelming majority supported the current organisation, i.e. to have virtual meetings during a larger number of days and thereby have shorter meeting days.

Communication

SECR informed of miscommunication that took place during trilateral discussions, as the responses were provided to commenting MSCA via R4BP 3 where this input was not seen in time. SECR proposed to always ensure by e-mail that the recipient is aware of sharing any information.

Endocrine disruption (ED) in discussion tables

SECR reflected that after the ED criteria became applicable, SECR always included the ED conclusion in the discussion table in the same way as e.g. the reference values for agreement by the WG. In general, other issues are included only when there are open points in the RCOM.

Having gained some experience, SECR proposed the following principles when there are no open points:

- When the eCA proposes that the active substance is not an ED, the ED conclusion is not in the discussion table
- When the eCA proposes that the active substance is an ED, the ED conclusion is in the discussion table

The members agreed on this approach.

Endocrine disruption (ED)

SECR informed that the ED Expert Group meetings for 2020 are provisionally scheduled as follows:

- 29 September - 1 October: virtual
- 17-19 November: virtual[1]

Next WG meetings

SECR informed of the provisional timing of the next meetings:

- 7-18 September 2020: virtual (exact days to be established)
- 16-27 November 2020:virtual[1] (exact days to be established)

9.2 Report on follow-up actions of the active substance action plan (ASAP)

SECR updated the WG on the progress on the active substance action plan (ASAP) and specifically regarding the activity on improving the WGs effectiveness. The presentation is available in S-CIRCABC.

[1] At the meeting, the November EG meeting and WG meeting were expected to be physical, but this information is updated here to reflect the current knowledge.

Annex 1 – Human Health WG attendees

Core/Alternate members
MIKOLAS Jan (CZ)
HOLTHENRICH Dagmar (DE)
HERRMANN Kristin – Alternate (DE)
ARAPAKI Niki (EL)
NIKOLOPOULOU Dimitra (EL)
AUBIN Aurelie – Alternate (FR)
MAXIMILIEN Elisabeth (FR)
BOS Carina (NL)
LEŠER Vladka (SI)
Rapporteurs
PEISER Matthias (DE)
RAT Benjamin (FR)
VAILLANT Vincent (FR)
Mantovani Alberto (IT)
Flexible members
HAUZENBERGER Ingrid (AT)
HOELZL Christine (AT)
AZZOPARDI Charline (BE)
TORDOIR Charlotte (BE)
GRÜNIG David (CH)
ROSSIER Nadine (CH)
SCHNEIDER Heiko (DE)
BOYE PETERSEN Annika (DK)
HÄMÄLAINEN Anna-Maija (FI)
HYVÄRINEN Tuija (FI)
RYDMAN Elina (FI)
VÄLIMÄKI Elina (FI)
BELLINGARD Valérie (FR)
KOSE Serif (FR)
REY Marion (FR)
BALDASSARRI Lucilla (IT)
DEKOVI Edlira (IT)
ANDERSEN Hilde (NO)
GAUSTAD Astrid (NO)
LÅSTBOM Lena (SE)

LITENS KARLSSON Sabina (SE)
PETTERSSON Emma (SE)
ČEBAŠEK Petra (SI),
ROMAN Olha (SK)
Advisors
KIRKEGAARD Maja (DK)
RIME Soyub (DE)
ECHA Staff
AIRAKSINEN Antero
DAMSTEN Micaela
ANTAL Diana
ESTEVAN MARTINEZ Carmen
FRANKEN Stefan
MULLER Gesine
OLIVERO Roberto
PAPADAKI Paschalina
RUGGERI Laura
VAN DER LINDEN Sander
VASILEVA Katya
Applicants
Brenntag Holding GmbH
Ecolab
Linnunmaa Ltd
Lipatech
Lonza
Micro-Pak Europe
Nouryon
REACH Monitor SL
Sumitomo UK
TCDO Produktionsgesellschaft mbH
Stakeholders
VAN BERLO Boris (CEFIC)
LEROY Didier (CEPE)
POHER Aliénor (EUsalt)
Experts: KERN Petra, KVERNSTUEN Johnny, MASSEL Arnaud, SPANG Guenter, STAHL Vinzenz, WATT Ian