WG-V-2017

Final minutes

15 May 2018

Minutes of WG-V-2017

14 November - 24 November 2017

Meetings of the Analytical methods and physico-chemical properties, Human Health, Efficacy and Environment Working Groups of the Biocidal Products Committee

Minutes of Analytical methods and physico-chemical properties WG

WG-V-2017 (14-15 November 2017)

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. CEFIC was registered as accredited stakeholder organisation (ASO) for this meeting.

Participants of the working group were informed that the meeting is recorded, but solely for the purpose of drafting the minutes and that the recording will be destroyed after the agreement of the minutes. The recording is not released to anybody outside ECHA and any further recording is not allowed.

2. Administrative issue

A presentation on the administrative matters was provided by ECHA for information.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the working group members to include any additional items under any other business (AoB).

The following items were added to the agenda:

- Union authorisations of iodine containing products
- The possibility to replace shelf-life studies by efficacy data
- 5-batch analysis is not possible due to annual production of one batch only
- CLP classification applied for biocidal products

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

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

5. Agreement of the draft minutes from WG IV 2017

Comments on the draft minutes were received as follows:

Naming of active substances

Carbenazim

Sodium metabisulphite releasing sulphur dioxide

Active chlorine

Empenthrin

The draft minutes have been updated accordingly and the working group members agreed on the modifications. No comments on the other parts of the minutes have been received.

The minutes of WG IV 2017 have been agreed by the working group members.

6. Follow up of previous working group meetings and e-consultations

6.1 Follow-up of e-consultations

6.1.1 e-consultation on Union authorisation discussed at WG meeting IV 2017

The Chair presented the summary of received comments and the conclusion and action points. The working group members agreed on this summary.

6.1.2 e-consultation on analytical information required for C12-14-alkyldimethylamides-N-oxides

The Chair presented the summary of received comments and the conclusion and action points. The working group members agreed on this summary.

6.1.3 e-consultation on the definition of hydrocarbons

The Chair presented the summary of received comments. The working group members agreed that the definition of hydrocarbons covers substances and their components of the chemical elements carbon and hydrogen only but not any of their derivatives.

The test on surface tension of liquid biocidal products is a data requirement and shall be conducted at the highest in use concentration. The test on surface tension of liquid biocidal products as formulated containing ≥10% hydrocarbons as stated in the information requirements guidance is now obsolete, since Directive 1999/45 is now replaced by the CLP Regulation.

6.2 Follow-up of previous working group meetings

The Chair presented for each member state an overview of open information that should be or should have been provided. The working group members reported back on the state of affairs. The Chair reminded the working group members to follow-up frequently on open issues and inform ECHA in case deadlines are not kept.

7. Technical and scientific issues

7.1 CHED – naming and requirements on physico-chemical tests

All open issues were discussed and agreed by the working group members. The substance name was agreed.

7.2 Definition of 'in situ' on the example of chlorine dioxide

All open issues were discussed by the working group members.

7.3 Residue of distillation of peracetic acid

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

8. Discussion on active substances

8.1 Salicylic acid

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

The reference specification and reference source were agreed.

8.2 Didecyldimethylammonium chloride (DDAC)

All open issues were discussed. An ad-hoc follow up e-consultation is to be launched on the acceptability of the publicly available analytical methods for monitoring in food and feed and on the information on the starting materials to be submitted by the applicants within 10 days following the working group meeting.

The reference specification and reference source were agreed.

8.3 Alkyldimethylbenzylammonium chloride (ADBAC/BKC)

All open issues were discussed. An ad-hoc follow up e-consultation is to be launched on the acceptability of the publicly available analytical methods for monitoring in food and feed and on the information on the starting materials to be submitted by the applicants within 10 days following the working group meeting.

The reference specification and reference source were agreed.

8.4 Chlorfenapyr

All open issues were discussed. An ad-hoc follow up e-consultation is to be launched on the reference specification to be drafted by the eCA based on the newly submitted 5-batch analysis.

The reference specification and reference source could not be set and were not agreed.

8.5 Silver zeolite

All open issues were discussed.

The reference specification and reference source were agreed with modifications.

8.6 Silver copper zeolite

All open issues were discussed.

The reference specification and reference source were agreed with modifications.

8.7 Silver sodium hydrogen zirconium phosphate

All open issues were discussed.

The reference specification and reference source were agreed.

9. Any other Business (AoB)

- **Union authorisations of iodine containing products**
  An overview on the processing of the applications was given. It was highlighted that the same data as for the already discussed iodine-containing products will be requested from the applicant.

- **The possibility to replace shelf-life studies by efficacy data**
  It was reported that under the approval of a biocidal product used as a rodenticide, efficacy could be demonstrated after 24 months but no further chemical or physico-chemical data have being provided after 24 months. The question was raised whether data should be requested and if yes what kind of data. The working group members agreed that a long-term storage stability test including analysis of degradation products/metabolites should be provided.

- **5-batch analysis is not possible due to annual production of one batch only**
  It was explained that an application of a new active substance was submitted, that includes analytical information about the active substance produces at a pilot plant. A complete 5-batach analysis could not be provided as the applicant manufactures one batch per year only. The reference specification was set on the data of the pilot plant. It was agreed that the company has to apply for the assessment of technical equivalence to ECHA when 5 batches are available. Nevertheless, the set reference specification has to be matched.

- **CLP classification applied for biocidal products**
  It was explained that applications for the authorisation of biocidal products not always follow the test guidelines / criteria described in the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixture (CLP). Hence, it was asked whether these tests should be requested form the applicants. The working group members agreed that the tests on physical hazard shall be provided according to the CLP criteria but already existing tests (not following CLP) may be acceptable after expert judgement.

Minutes of Human Health WG

WG-V-2017 (21-23 November 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 26 members registered, of which 7 were core members. One stakeholder observer was present. 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 gave a brief presentation on housekeeping and administrative issues. The presentation is available to MSCAs in the meeting folder in S-CIRCABC[1].

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 the draft minutes from WG-IV-2017

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 ADBAC (eCA IT) PT 03, 04

This agenda item was discussed together with the 6.2. Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.2 DDAC (eCA IT) PT 03, 04

This agenda item was discussed together with the 6.1. Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.3 Salicylic acid (eCA NL) PT 02, 03, 04

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

[1] Path: /CircaBC/echa/BPC-WG/Library/Confidential/03. WG - Human Health/Meetings 2017/WG-V-2017 (21-23.11.2017)

https://webgate.ec.europa.eu/echa-scircabc/w/browse/192f00c7-491c-44d1-bf3a-c54768452b52

6.4 Chlorfenapyr (eCA PT) PT 18

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

6.5 Silver sodium hydrogen zirconium phosphate (eCA SE) PT 02, 04, 07, 09

This agenda item was discussed together with 6.6 and 6.7. Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.6 Silver copper zeolite (eCA SE) PT 02, 04, 07, 09

This agenda item was discussed together with 6.5 and 6.7. Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.7 Silver zeolite (eCA SE) PT 02, 04, 07, 09

This agenda item was discussed together with 6.5 and 6.6. Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.8 Early WG discussion: Sodium metabisulphite releasing sulphur dioxide (eCA DE) PT 09

This agenda item was discussed together with the 6.9. Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

6.9 Early WG discussion: Sulphur dioxide generated from sulphur by combustion (eCA DE) PT 04

This agenda item was discussed together with the 6.8. Please refer to the confidential minutes provided to Member State Competent Authorities in S-CIRCABC and to the applicant in R4BP 3.

7. Technical and guidance related issues

7.1 Update on guidance development

SECR presented the current status of several guidance-related documents which are at different stages of development, including general documents as well as those developed in the context of the ad hoc Working Groups on Human Exposure (HEAdhoc) and Assessment of Residue Transfer to Food (ARTFood). The identified needs for further guidance development were also included. The document presented is available in S-CIRCABC to members[1] and associated stakeholder organisations[2].

[2] Path: /CircaBC/echa/BPC Working Groups (non-confidential)/Library/Meetings 2017/WG-V-2017/TOX WG

https://webgate.ec.europa.eu/echa-scircabc/w/browse/311191de-5216-483c-ba4f-66901beea0c2

7.2 Recommendations of HEAdhoc

a) Harmonisation PT 14 exposure assessment

The SECR presented the background for the discussion and noted the legal discussion ongoing on the use of data from a protected study. A request has been made to the data owner to use the study and once the use of the study has been confirmed, further discussions will follow within HEAdhoc.

A member proposed to use the same protection factor for both plastic and paper sachets. Another member raised the issue of the compliance with the instructions of use indicating that the sachets should not be opened for consumers.

Since the discussions will continue once the legal issue has been clarified, the comments received during the meeting will be taken up in the next version of the document.

b) Alignment of HEAdhoc Recommendation 11 to Efficacy WG agreement

SECR provided the background for the revision of the document. It was clarified that the Recommendation indicates that the application rate used in the risk assessment should be efficacious but its scope is not to provide guidelines on how to perform the efficacy studies.

A member noted that by the time the Recommendation will become applicable, applicants will have to perform the efficacy tests with application rates that are realistic. The WG members agreed with the revision of the Recommendation 11.

Several WG members requested to include in the cover note of the Recommendation the dates of the publication and entry into force of the revised Recommendation. It was also requested to publish the previous versions of the document in the ECHA website. SECR informed that the process for publishing superseded guidance is starting.

7.3 Iodine background in milk and iodine dietary intake

The following agreements were confirmed:

Background iodine value in milk

The value 200 µg/L of iodine in milk as a background level in milk was agreed, based on monitoring data (EFSA Journal 2013;11(2):3101)[3].

Iodine dietary intake for sources other than milk

The iodine dietary intake for dietary sources other than milk was set at 185 µg/day for adults and 96 µg/day for toddler, based on data from the UK survey[4].

[3] EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). Scientific Opinion on the safety and efficacy of iodine compounds (E2) as feed additives for all species: calcium iodate anhydrous and potassium iodide, based on a dossier submitted by HELM AG1. EFSA Journal 2013;11(2):3101

[4] Retail survey of iodine in UK produced dairy foods, FSIS 02/08, 16 June 2008. http://webarchive.nationalarchives.gov.uk/20120403220603/http://www.food.gov.uk/multimedia/pdfs/fsis0208.pdf

7.4 Toxicological relevance of metabolites in groundwater

SECR introduced the document on whether the SANCO guidance could be used in assessing the toxicological relevance of metabolites in groundwater. The document included a proposed answer.

The members in general agreed that the SANCO guidance could be used for biocides as well. It was seen useful to apply the same guidance as applied for pesticides.

The following notes were made however:

- Some member states have their own legislation in place which might not be compatible with that described in the SANCO Guidance
- Other member states follow the SANCO Guidance but having their own national guidance on the interpretation of the SANCO Guidance
- One member indicated that the drinking water directive is being revised and this would trigger changes in the guidance as well
- The data requirements to be triggered would have to be clarified
- The current TTC (threshold of toxicological concern) values could be taken into account
- The water consumption of 2 L in step 4 could be questioned
- It should be clarified whether the assessment to be performed according to the guidance would also cover toddlers
- It should be further reflected whether e.g. clearly higher AEL values could be taken into account in the assessment
- The classification triggers would have to translated to CLP classification
- The drinking water directive 98/83/EC does not take into account biocides appropriately
- It has to be clarified whether the classification concerns only harmonised C&L or also C&L proposals

In addition, the members considered that further guidance would be necessary to interpret the guidance.

SECR will provide a revised document based on the input.

7.5 Local risk assessment – proposals for new TAB entries

SECR introduced the document which contained three proposals for new entries (a-c) for the TAB (Technical Agreements for Biocides).

a) Is local risk assessment necessary for substances that are classified for local effects but are present at concentrations that do not trigger classification of the product?

SECR proposed principles for performing local risk assessment (LRA) when classification of the product is not triggered.

The members considered that more guidance should be provided on selecting an appropriate NOAEC, keeping in mind that the dosing in the study should be relevant for human exposure (e.g. amount, concentration, frequency and duration).

The members discussed the relevance of the NOAEC to the product. Most commenting members considered that the NOAEC should be used for the product unless there is information showing that it will not be relevant in a specific case.

SECR will provide a revised proposal, taking into account a number of specific comments made.

b) Should dermal AEC values be derived based on local dermal effects?

SECR proposed that no dermal AEC values should be derived.

The members in general agreed with the proposal, while some members suggested that an AEC could be useful for some cumulative effects.

SECR will provide a revised proposal, taking into account the specific comments made.

c) Should systemic risk characterisation (RC) be performed for substances that have only local effects?

SECR proposed that to ensure a precautionary approach, systemic RC should always be performed.

Some members did not agree on performing a systemic RC if no systemic effects are seen because experience has shown that a systemic RC is problematic for such substances. Reference was made to the guidance which requires an assessment to demonstrate that local effects are clearly more critical than systemic effects "*if it can be shown by a first tier systemic risk assessment that local effects are much more critical than systemic effects; higher tier assessments for systemic effects could be omitted, if full justification is provided*".

Other members agreed with the proposal, arguing that the absence of systemic effects could be concluded only if limit doses have been tested. Otherwise there would be no knowledge on effects above the tested concentrations, and this could encourage companies not to test at sufficient doses. One member also pointed out that it has earlier been agreed that the top doses would be considered as NOAELs.

Some members suggested that when any doubt remains on whether there are systemic effects, systemic RC should be performed. Thereby local RC would be sufficient if it can be convincingly concluded that there are no systemic effects whatsoever. There could however always be doubt in this sense, at least when limit doses have not been tested.

Considerations regarding oral and dermal absorption were suggested to be included in the text.

SECR will provide revised proposals, taking into account the specific comments made.

8. Any other business

8.1 Update on Union Authorisation (ECHA)

SECR presented an update on Union authorisation to present an overview of the current status of the applications in the ECHA pipeline, an outline of the ongoing activities, the planning for the discussions at the upcoming Working Group and BPC meetings, and some considerations on the experience acquired so far with Union authorisation applications. The presentation is available to MSCAs in the meeting folder in S-CIRCABC[1].

8.2 Other information & lessons learned

The presentation is available in S-CIRCABC to MSCAs[1] and to associated stakeholder organisations[2].

Template for reference value information

SECR reminded of the agreement at WG-V-2016 that the eCAs should provide a document on human health reference values and absorption values. It would be most helpful if the document could be provided together with the CAR or with the RCOM, but it should be submitted at the latest together with the updated RCOM (step 15 of working procedure). This document should be provided by filling in Chapters 14.1 *Critical endpoints* and 14.2 *Reference values* of the draft CAR template.

Superseded guidance

Noting that new guidance does not always apply immediately to applications, it is often necessary to refer to previous versions of the guidance. A new web page (https://echa.europa.eu/superseded-biocides-guidance-documents) is now available for replaced/updated guidance and a link to this page is in the BPR Guidance page (https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation).

Endocrine disruptors – guidance and implementation

SECR informed that the ED criteria were published 17 November 2017 (COMMISSION DELEGATED REGULATION [EU] 2017/2100) and will enter into force in December 2017, 20 days after publication. The application date is 6 months after entry into force.

Problems in reference specifications

The reference specification is a key element of the assessment and should be the starting point for the evaluation. There are several recent examples of substances with complications due to problems in the reference specification. These problems have been mostly related to the identification of relevant impurities and to the question whether the reference specification is supported by the toxicity testing. SECR asked the evaluating CAs to take this experience into account in ensuring, as far as possible, that the assessment is performed according to the current standards before submitting the CAR for peer review.

Early WG discussions

SECR asked the members to proactively consider requesting for an early WG discussion at least if it is unclear whether the risk characterisation should be systemic and/or local, and if there is extensive waiving in the dossier.

Next WG meetings

The timing of the next Human Health WG meetings is provisionally planned as follows:

- UA – virtual WG meeting: 4-5 December (Monday-Tuesday)
- Human Health WG-I-2018: 23-24 January (Tuesday-Wednesday)

Ad hoc follow-ups

Avoiding ad hoc follow-ups

Based on SECR proposals to avoid ad hoc follow-ups, the members agreed that the eCAs should always provide the document on human health reference values and absorption values (as agreed at WG-V-2016) and always provide all information together with the updated RCOM.

Similarly, the members agreed that SECR should always prioritise AS discussions over guidance and early WG discussions. Furthermore, the members agreed that SECR would provide further proposals for closing points in the discussion tables.

SECR asked whether the points that are always discussed (e.g. ref values) could be indicated as "provisionally closed". This could be done only when there are no open points in the RCOM and SECR sees no specific need to discuss the values. If agreed, these points would be closed only provisionally, i.e. they could still be raised at the WG meeting. The members in general supported the approach but instead of indicating the points among the provisionally closed ones (below the main discussion table), they should be presented in the main discussion table.

Managing ad hoc follow-ups

The members agreed that as a general rule, ad hoc follow-ups should be closed in teleconferences. SECR would verify the availabilities of the appointed members by e.g. Doodle, and the teleconference would take place when the largest number of appointed members are available. Those members who cannot join the teleconference would be able to appoint a substitute.

SECR clarified that in some cases the approach would mean that some appointed MSCAs might not be represented in a teleconference. This was accepted as a practical consequence of finding a workable way forward.

In preparation for a teleconference, written commenting can be applied as a preparatory step where considered necessary or useful.

Minutes of Efficacy WG

WG-V-2017 (15 – 16 November 2017)

1. Welcome and apologies

The Chair welcomed all participants to the 19th Efficacy WG meeting. There were 7 core and 1 alternate member who participated in the meeting. In addition, 10 flexible members, 2 rapporteurs and 1 ASO expert attended the EFF WG meeting.

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

2. Administrative issues

SECR gave a brief summary on the administrative issues.

3. Agreement of the agenda

The Chair introduced the agenda items.

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

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

5. Agreement of the draft minutes from WG-III-2017

The Chair informed that comments for the minutes of WG-IV-2017 had been received from FR and NL. The draft minutes version (without part related to UA-APPs) was amended in relevant parts and agreed by the EFF WG. The part related to UA-APPs will be agreed at the EFF WG-VI-2017.

6. Discussion of active substances[5]

6.1 ADBAC (eCA IT)

During the EFF WG meeting it was noticed that the open point related to biostatic claim of DDAC is also relevant for ADBAC even though it was not mentioned in the RCOM table. The relevance of this issue to ADBC was confirmed by the eCA and therefore it was agreed to apply the conclusion of the discussion on DDAC also to ADBAC.

6.2 DDAC (eCA IT)

There was one open point in the discussion table. In order to make MSs aware, that there is a risk of development of resistance with quaternary ammonium compounds, the EFF WG agreed to include in the CAR information that products with cidal activity should be priviledged, even though static activity can be obtained.

6.3 Salicylic acid (eCA NL)

There were no open points for discussion. However, at the beginning of the meeting the eCA reopened a point related to the presence of specific co-formulant in the formulation with salicylic acid. The EFF WG was not able to conclude on this point during the meeting, therefore an ad hoc follow-up will be launched.

[5] The details of the substance discussions are considered restricted. Only the non-restricted conclusions are reported here.

6.4 Chlorfenapyr (eCA PT)

There were two open points in the discussion table. The EFF WG agreed that the submitted efficacy data are sufficient to prove efficacy of the representative biocidal product at the active substance apporaval stage. During the discussion of the second open point the EFF WG conluded that additional information is needed in order to support the efficacious dose used for risk assessment. Ad hoc follow-up will be launched.

6.5 Silver sodium hydrogen zirconium phosphate (eCA SE)

There were four open points in the discussion table. The EFF WG noted that currently there is no common agreement on how to assess potential development of resistance, and discussed about the mechanisms of potential resistance/tolerance of bacteria against silver. The WG agreed to add a general sentence on development of resistance/tolerance to the CAR.

The EFF WG agreed that innate efficacy for PT 2 and PT 7 is not demonstrated with the submitted studies. The WG concluded that in case there is a need to control microbes on dry surfaces in PT 2 use it should be a fast cidal effect. For preservatives (PT 7 and PT 9) microbes need to grow in order to cause a problem and therefore growth in controls needs to be shown.

6.6 Silver copper zeolite (eCA SE)

There were three open points in the discussion table. The EFF WG noted that currently there is no common agreement on how to assess potential development of resistance, and discussed about the mechanisms of potential resistance/tolerance of bacteria against silver. The WG agreed to add a general sentence on development of resistance/tolerance to the CAR.

The EFF WG concluded that innate efficacy for PT 2 is not demonstrated with the submitted studies, but the provided efficacy studies are sufficient to prove efficacy against bacteria in PT 9.

6.7 Silver zeolite (eCA SE)

There were three open points in the discussion table. The EFF WG noted that currently there is no common agreement on how to assess potential development of resistance, and discussed about the mechanisms of potential resistance/tolerance of bacteria against silver. The WG agreed to add a general sentence on development of resistance/tolerance to the CAR.

The EFF WG concluded that innate efficacy for PT 2 is not demonstrated with the submitted studies, but the provided efficacy studies are sufficient to prove efficacy against bacteria in PT 9.

6.8 Sulphur dioxide generated from sulphur by combustion – early WG discussion (eCA DE)

The eCA explained that the wood particles present in the wine barrels have disturbed the determination of microbes in the tests performed, and therefore qualitative rather than quantitative data has been obtained. The WG agreed that the applicant should describe more clearly the claim, i.e. the problem, the intention of the treatment, and the expected outcome. The WG also concluded that more information, preferably quantitative data, is needed.

6.9 Sodium metabisulphite releasing sulphur dioxide – early WG discussion (eCA DE)

Testing needed to show efficacy of stickers attached to the insides of shoeboxes was discussed. The WG concluded that the two test set ups presented are sufficient for showing efficacy at active substance approval stage.

7. Technical and guidance related issues

7.1 Update on guidance development (ECHA)

ECHA gave a usual update on guidance development. All details are available in the working document: WGV2017_EFF_7-1_Update on guidance development.

7.2 PT18 – Clarification on tests needed for a general claim against 'Other arthropods' (ECHA)

The question referred from CG SECR to ECHA for support from the EFF WG was discussed. The clarification was needed on what efficacy data is necessary for a general claim against "other arthropods".

EFF WG members agreed that a general claim "other arthropods" is not possible. It was indicated that for this particular general claim it is not possible to define the representative species, considering a broad spectrum of different target organisms (e.g. spiders, harvestmen, millipedes, centipedes, woodlice, scorpions) with variable body size, biology and consequently different sensitivity on the biocidal product application rate is expected.

EFF WG agreed that the general claim following by specific species is also not possible in this particular case.

Therefore, the claim needs to be restricted only to the organisms that have been tested, and only organisms tested should be mentioned on the SPC.

The EFF WG proposed to discuss and agree on test methods which would be applicable for each organism. The proposal will be made and discussed in the near future.

7.3 Information on virucidal claims – recommendation for the EFF WG website (AT) – closed session

There was a misunderstanding between the EFF WG members related to last agreements made during EFF WG-IV-2017. The Chair clarified that the EFF WG agreed to include information and explanation on virucidal claims (full virucidal claim, claim against enveloped viruses, limited spectrum virucidal claim) into ECHA Efficacy WG site. A link to this site can then be provided in the SPC. This will allow consumers (non-professional users) and professional users an easy acces to this information. Draft proposal will be made by AT and discussed further at upcoming meetings.

In addition the EFF WG needs to discuss which example viruses (names) should be eventually listed into the SPC. The e-consultation is already ongoing and the outcome will be further discussed.

8. AoB

8.1 Efficacy testing in PT6, 11 and 12: range of dosage recommendations – closed session

The EFF WG member raised the questions for the EFF WG on the wide ranges of dosage recommendations used in UA application for product family (PT 6, 11 and PT12) as well as the related efficacy data acceptance for PT11 and 12. The question on how to inform user to determine effective dose for their matrix/location/system was also introduced.

During the discussion different views were expressed by the EFF WG members. Some members expressed their agreement with the eCA approach to accept the simulated use test without the necessity to request additional field tests.

The EFF WG members could not conclude on the discussion points indicating that more time is needed, considering also information from national authorisation cases. An e-consultation will be launched to solve this issue.

8.2 Room disinfection - how to ensure the proper use (NL) – post WGIV2017 comments

The comment provided by ASOs on the draft conclusion was discussed related to the meaning of the used term "validation". Clarification was needed whether the validation of the test method should be done or the validation of the process.

The NL explained that the intention is to give an advice for user that it is necessary to validate process of the room disinfection in the particular product place of use. It should be considered that different requirements can be applied in different rooms, e.g. hospital rooms, food industry facilities etc. It was also commented, that the efficacy of the product can be effected on a several variables, .e.g. volume of a room, exposure time, product amount, surface size, used furniture and textile in the room. Therefore, for each type of room the instruction for use needs to be validated in order to ensure that necessary efficacy level is achieved in the particular use conditions.

DE pointed out that while the devices themselves are not subject to the authorisation procedure, the following sentence should be reflected in the SPC: *"The user shall always carry out a biological validation of the disinfection in the rooms to be disinfected (or in a suitable "standard room" if applicable) with the devices to be used after which a protocol for disinfection of these rooms can be made and used thereafter."*

The EFF WG agreed, that for biocidal products used as room disinfectants, the recommendation for validation of the process should be included in the use instruction of the SPC.

The presented document was agreed by the EFF WG members and the solution will be included in the TAB.

8.3 Textile disinfection (NL) – post WGIV2017 comments

The comments provided by ASOs on the draft conclusion were discussed. The following agreements were reached:

1) The NL clarified that the changes are introduced in the document in order to clarify sentence regarding the approach that should be taken for biocidal products used as disinfectants in combination with detergents: *"….in principle all claimed disinfectant/detergent combinations and various conditions….."*.

2) During the discussion on the efficacy testing for the washing process, it was still supported that for main-wash the dirty test conditions need to be used as not always the pre-wash is applied.

   In more general note, the industry informed that they will continue discussion about the possible intermediate level of soil which can be proposed for main-wash for future discussion.

3) Considering the discussion on information of test organisms and temperature, the EFF WG agreed to precise the information in Table 2, including the following changes:

(a) in the second row: 40 **≤** Temp <60°C and in the third row: Temp **≥** 60°C.

It was also agreed that CEFIC will communicate with CEN on the necessity to develop the test methods for high temperature uses.

The presented document was agreed by the EFF WG members with the minor changes (indicated above). The solution will be included in the TAB.

8.4 Update on Union Authorisation (ECHA)

An update on Union authorisation was given by the SECR to present:

- an overview of the current status of the applications in the ECHA's pipeline;
- an outline of the ongoing activities;
- the planning for the discussions at the upcoming Working Group and BPC meetings;
- some considerations on the experience acquired so far with Union authorisation applications.

8.5 Other information & lessons learned (ECHA)

The EFF WG members were informed about next meetings. The detailed information is provided in the working document: WGV2017_EFF_8-5_Other info.

On request of FR an issue related to conditions of tests to be performed for PT1 disinfectants in food industries and for farmers was raised. The EFF WG members were not able to conclude on it, e-consultation will be launched.

In addition SE informed that the available formats for CAR and PAR should be improved as currently available versions causes difficulties when they are filled in. This information will be forwarded to the responsible persons in Biocides Unit.

Minutes of Environment WG

WG-V-2017 (22 November - 24 September 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 20 participants present, of which eight were core members (one represented by alternate) and five flexible members in addition to two advisor and four rapporteurs. One representatives from accredited stakeholder organisation was. 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 gave a brief presentation on housekeeping and administrative issues:

The eCAs should close the 'Evaluation' task in R4BP3 only after the positive accordance check, a resubmission of IUCLID file necessary to update the CAR can be requested by the eCA.

For new declarations a simplified procedure will be applied (templates can be found on the ECHA website). The RoPS will be updated accordingly.

The eCAs were invited to review the memberships and the information needed from members leaving eCA.

ECHA will start using ELM tool for sending the WG-invitations and registration to the meetings from WG-I-2018 onwards. Examples of invitations and registration pages were further presented.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. The agenda was agreed.

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

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

The Deputy Chair declared an interest with two of the substances of the agenda, which was considered as conflict of interest. The Deputy Chair did not participate in the discussion of these substances.

5. Agreement of the draft minutes from WG-IV-2017

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Chlorfenapyr (eCA PT) – PT 18

Six points related to effect/hazard assessment and five points related to the exposure assessment were discussed. All points but three were closed, the three open items will be followed up by an ad hoc follow up.

Actions:

- Ad hoc follow ups to be initiated by SECR (eCA to prepare the respective background documents).

- TAB entry: The WG agreed that for $Fspray_{wash\text{-}off}$ a value of 0.5 should be used, i.e. 50% of the total amount applied is washed off. No further reduction of this factor taking into account spray drift or run-off should take place.

6.2 Salicylic acid (eCA NL) – PT 2, 3, 4

Two points related to effect/hazard assessment and four points related to the exposure assessment were discussed. All points were closed during the meeting and the Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee.

6.3/6.4 ADBAC/DDAC (eCA IT) - PT 3, 4

Three points related to effect/hazard assessment and nine points related to the exposure- and risk assessment were discussed. All points but four were closed, the four open items will be followed up by an ad hoc follow up (three of them will be combined in one single follow up).

Actions:

- Ad hoc follow ups to be initiated in sequence by SECR (eCA to prepare the respective background documents).

6.5/6.6/6.7 Silver sodium hydrogen zirconium phosphate/ Silver copper zeolite/ Silver zeolite (eCA SE) - PT 2, 4, 7, 9

One general item related to the CAR template, three points related to effect/hazard assessment and ten points related to the exposure assessment were discussed. All points were closed, one point however only provisionally. The need for an ad hoc follow up will be decided based on the outcome of the assessment of the eCA as follow up of the WG Meeting discussions.

Actions:

- Ad hoc follow up to be initiated by SECR (eCA to prepare the respective background documents), if relevant.

- In case of a future update of the CAR template, redundant information should be deleted from the template.

7. Technical and guidance related issues

7.1 Update on guidance development, issues identified for the AHEE (ECHA)

SECR presented the status on guidance development, issues identified for the AHEE and e-consultations. Updates from WG members during the meeting have been included after the WG meeting (see updated table in Appendix 1 below).

7.2 Information, consultation of the PBT EG (ECHA)

SECR explained the update of the recommendations for consulting the PBT-EG and made the WG aware that some changes will be made to the working procedure for active substance approval. In general, SECR reminded the WG that is under their remits to conclude on PBT properties and the PBT-EG should be consulted if time allows. Several members expressed their concern in relation to the outcome received from the PBT-EG as they consider it would be much more beneficial to have a final conclusion from the group which could be afterwards easily used in the context of BPR. They also shared some deception by the fact that there are no detailed minutes of the discussion to which to refer to. SECR reminded that the PBT-EG is an expert consultation group which provides advice on PBT properties of a particular case and on topics related to approach development but is not within their remits to conclude or issue opinions on the PBT properties.

8. AOB

8.1 Other information & lessons learned

The following "Other information" was provided:

Next WG meetings: The ENV session of WG-VI-2017 (UA-PF 20) takes place as virtual meeting on 4 December 2017 (start: 14:00 Helsinki time). The ENV session of WG-I-2018 takes place as physical meeting on 23-25 January 2018. The uploading-deadline are as follows:

- Discussion tables: 15 December 2017 according to the timelines for AS approval
- Other meeting documents (e.g. guidance related): 12 January 2018

No substances are under commenting in process flow (PF) 22, leading to the WG in March 2018. If there are no substance discussions, the meeting will be virtual. A potential renaming of WG meetings starting 2018 was further announced.

File naming: To be harmonised between WGs. Changes in file naming of minutes to be agreed at the subsequent WG:

- If there are no pending ad hoc follow-ups: "Final minutes"
- If there are pending ad hoc follow-ups: "Agreed minutes"

A disclaimer will be added to indicate that the pending ad hoc follow-ups may cause changes in the agreements. These minutes will be renamed as "Final minutes" once the ad hoc follow-ups are finalised.

Superseded guidance ("guidance repository"): New guidance does not apply immediately. Agreements of the CA meeting and of the BPC. During the transitional period, it is necessary to refer to previous versions of the guidance

New web page for replaced/updated guidance: https://echa.europa.eu/superseded-biocides-guidance-documents.

ENV WG related items discussed at BPC-22:

- Remits of the ENV WG when discussing RMM

The BPC concluded: "*…the WG should discuss RMMs as far as they are in their area of competence with a focus on providing input on RMMs necessary and foreseen to achieve an acceptable level of risk. RMMs will be agreed by the BPC. It was further noted that awareness should be raised to the BPC where the competence of the ENV WG ended, i.e. where only limited discussion of RMMs took place.*"

Three items raised by BPC members concerning RMMs during the e-consultation were further discussed:

⇒ Harmonisation applicable RMMs among MS to facility mutual recognition: should take place as much as possible, the primary scope is however outside the remit of the WG
⇒ Who should submit data on RMMs: data should be provided by the applicant
⇒ Collection of quantitative information on how RMMS reduce emissions or otherwise reduce risk: If applicant provides quantitative information/measures, first the EFF WG should evaluate effects on efficacy. The ENV WG should evaluate the consequences on the risk assessment but only after the conclusions of the EFF WG is available (i.e. on the relevance of the proposed RMM and the implication on the dose)

- Definition of trigger values for updating the LoEP

The BPC concluded: "*…an update of the LoEP should take place in general only in exceptional cases, e.g. if the new information would trigger a significant change in the outcome of the risk assessment. No further triggers were proposed*."

Agreed actions: COM/SECR/MS to check procedure under PPP for updating LoEP after AS approval.

ENV WG related items discussed at 74th CA meeting:

- BPR Annex VI, Art 68: Relevant metabolites in groundwater: No conclusion drawn at CA meeting. Some MS noted that relevant metabolites = major metabolites, some MS agreed that for groundwater the primary focus should be on human health. COM called for comments by 20 October. Additional background requested from the Human Health WG.

Agreed actions: ECHA to contact EFSA to have feedback on the experience with the practical application of the SANCO guidance for PPP. D1 to organise a discussion at the WG Human Health on the applicability of the SANCO guidance for biocides (scheduled for TOX session at WG-V-2017)

- BPR Annex VI, Art 69: Comparison of $PEC_{surfacewater}$ with limits of 98/83/EC: No conclusion drawn at the CA meeting. COM acknowledged the differences between the BPR and the PPP regulation.

ED criteria: Agreed at CA meeting on delegated act on 12 July 2017, no extension of the scrutiny period asked by Parliament. The ED criteria were published 17 November 2017: COMMISSION DELEGATED REGULATION (EU) 2017/2100) will enter into force in December 2017 (20 days after publication), application date in May 2017 (6 months after entry into force). Related links:

- https://ec.europa.eu/health/endocrine_disruptors/next_steps_en
- http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2100&from=EN

ESD spreadsheets – state of play:

PT 8, PT9-rubber and PT 13 have been published.
The following draft spreadsheets will be circulated for comments before Christmas:

- PT 6: draft almost ready; doubts on the ESD to be clarified by DE
- PT 10: commented once by the MS; comments were implemented but the scenario in situ spraying is now being adapted according to PT 8 (as decided at WG-IV-2017)
- PT 12: draft ready

PT 18 (households, animal housing and manure storage) and PT 11 are in preparation.
PT 3 is to be started as soon as possible.

EUSES „Quick fix": Only biocides are involved, it consists of three subtasks.

- Subtask 1: Update of release module based on ESD Excel sheets and inclusion of links to the "Degradation and transformation input".
- Subtask 2: Update of result sheets, i.e. inclusion of PEC and PEC/PNEC values covering direct release.
- Subtask 3: Update of the implemented SimpleTreat module (→ new version 4.0).

EUSES update: REACH and Biocides involved.

A Workshop is planned for 10-11 April 2018 at ECHA premises, the objectives of it are:

- Agree among stakeholders from REACH and biocides on the update needs
- Prioritisation of the update needs
- Discuss a proposal for the update process

Note that this may trigger also an update/harmonisation of REACH and biocides guidance. Participants of the workshop: Regulators, Industry and consultants working on/with EUSES, Academia (working with multimedia/ fate & transport models). The kick off meeting of the organising group took place on 13 November 2017.

General items: Vol V Technical Equivalence update: Drafting is in progress, the PEG consultation planned for Feb/March 2018 and publication foreseen in 2018.
MS were invited to provide emission estimation related items pending that need clarification/harmonisation in the dedicated AHEE Newsgroup and inform SECR by 15 December 2017 (a "thought starter" document to be provided by 12th of January 2017).

The following **"Lessons learned"** were shared:

Problems in reference specifications ("necessary repetition" of previous WG meetings)**:** The reference specification is a key element of the assessment and should be the starting point. There are several examples of substances with complications due to problems in the reference specification. Therefore eCAs should not submit a CAR before the reference specification is clear.

General items: Ad hoc follow ups (AHF) concluded by the WG can only be discarded following a WG meeting agreement and if justified. A substance cannot proceed to the BPC without finalisation of the AHF.

Revised reference values (PNEC) always need confirmation by the WG, they should be indicated as open point in the RCOM, even if not commented by any MS

In case of deviation from agreed emission scenarios/default values it is recommended to consult upfront with the WG either via an early WG meeting or an e-consultation

Proposals to manage ad hoc follow-ups (AHF) to be presented for the TOX WG was also shared with the ENV WG. The ENV WG is in favour to continue with written commenting, only if no conclusions can be drawn the option of a teleconference should be used.

8.2 Update status on Union Authorisations

An update on Union authorisation was given by the SECR to present: an overview of the current status of the applications in the ECHA's pipeline; an outline of the ongoing activities; the planning for the discussions at the upcoming Working Group and BPC meetings; and some considerations on the experience acquired so far with Union authorisation applications.

Appendices:

Appendix 1:

Agenda item 7.1: Update on guidance development, issues to be sent to the AHEE

Note:

- Issues unchanged since WG-IV-2017 are highlighted in grey shading.
- Closed issues are ~~stroke through~~.

1. Guidance related documents

No.	Title (current leader)	Status
~~1.1~~	~~Scenario for freshwater marinas (**NL**) / PT 21 PA manual (**UK**)~~ ~~**Urgency for freshwater scenarios**~~	~~The PT 21 PA manual prepared by UK was endorsed at WG-I-2017, some items were forwarded to the 70th CA meeting.~~ ~~A written procedure on wet surface area of recreational boats was initiated with a deadline for providing comments of 15th September 2017. NL will present the freshwater scenarios for confirmation at the September CA meeting.~~ ~~**The document including the Excel sheets have been uploaded to the ECHA webpage.**~~
1.2	2nd EU Leaching Workshop for PT 8 (**ECHA**)	*Reminder:* ***Members*:** Start to perform a risk assessment for the new TIME2 (= 365 d), however not using it for decision making. Send the risk assessment to SECR via CIRCABC. ***SECR*** opened a Newsgroup on CIRCABC[6] in order to collect the data and perform an impact assessment as soon as sufficient data is available (target: in one year). **SECR** to include additional time also in the Excel sheet for PT 8 currently under preparation.
1.3	Fish net scenario (**ECHA**): discussion on the usefulness of the new version of MAMPEC to be initiated	Discussion was started by NO. **Possible inclusion in MAMPEC discussed with Deltares at AHEE-1, funding to be clarified by SECR (=> potentially in 2018)**.
~~1.4~~	~~1st revision of Vol. IV Part B (active substance) + new biocidal product part including SoC) (**ECHA**)~~	~~1st revision: First update to Part B (active substances) to address outstanding issues from publication of version 1.0 + update to add risk assessment of biocidal products and Annex for Substances of Concern (SoC) and to add Part C Evaluation to create~~

[6] **Path:** /CircaBC/echa/BPC-WG/Newsgroups/ENV WG Impact assessment for PT 8 - new TIME scheme
Browse url: https://webgate.ec.europa.eu/echa-scircabc/w/browse/97974dd4-2b7c-411b-99c1-9f8de5090990

No.	Title (current leader)	Status
		~~joint document "Assessment and Evaluation (Parts B+C).~~ ~~• CA consultation closed – no comments received~~ ~~• Publication is foreseen for September/October 2017~~ ~~**The document was published on the ECHA webpage.**~~
1.5	Guidance on aggregated exposure assessment (**DE**)	The discussion of the draft guidance is re-scheduled for an electronic procedure, to be started in Q1 2017. Documents were provided by DE to ECHA, SECR initiated e-consultation after the WG meeting. **Document planned for a final discussion at WG-I-2018.**
1.6	TAB (**ECHA**): Technical Agreements on Biocides	Version 1.3 was published on the ECHA webpage. The agreed items at WG-IV-2017 will be included in TAB v.1.5 since version 1.4 (containing updates of the APCP part) is already at MS commenting stage. **TAB v1.5 is scheduled to be distributed for commenting in Q1 2018 (to capture also the conclusions of WG-I-2018).**
1.7	ESD for PT 6 (**DE**)	DE has revised the ESD following comments received. **The ESD was endorsed at WG-I-2017, DE provided the draft final version to SECR, final check is ongoing together with DE.**
1.8	Evaluation of ESD PT 14 (**DE**)	Shortcomings of the current emission scenario document for rodenticides (ESD PT14) became obvious within the national product authorisation of rodenticides. UBA Germany has initiated a research project to review the described scenarios and assumptions. The project is scheduled from January 2016 to November 2017. A commenting round was started on 11th September 2017 with ad deadline for providing comments of 13th October 2017. **First discussion planned at WG-I-2018.**
~~1.9~~	~~Manual of instructions to eCAs for evaluation of active substances used in disinfectants~~	~~The final version has been provided by the consultant; finalised by SECR in August 2017. Publication expected during September 2017.~~

2. Issues identified for the AHEE (related to exposure assessment)

No.	Title (current leader)	Status
ASSIGEND ITEMS		
2.1	How to use market share data in order to derive a market	A discussion of specific items took place at WG-IV-2015 and at AHEE-1.

No.	Title (current leader)	Status
	penetration factor different from default values? ⇨ *WG-I-2015 – item 6.2 + WG-II-2015 – item 7.3 WG-II-2014 – item 6.4 (pulp and paper processing fluids)*	One item (collection of tonnage data) was discussed at BPC-17 and was forwarded to the 70th CA Meeting, where the collection of tonnage data was not agreed. **A summary of the agreed times will be prepared by SECR and provided for information to the ENV WG at WG-I-2018.**
2.2	PT 3: Scenario for disinfection in aquaculture ⇨ *Disinfection project/EMA visit*	ECHA contracted out the preparation of a first proposal. First discussion took place at WG-I-2017, comments received during the commenting period to be added. **Revised version will be provided for discussion/agreement at WG-I-2018 or WG-II-2018.**
2.3	Clarification on DT50 values according to the FOCUS guidance to be used for modelling purpose and as trigger value (for higher tier studies/PBT assessment) ⇨ *WG-I-2016 – item 6.3b*	**DE/UK** volunteered to take over the item (update of PBT guidance to be taken into account). Timing to be defined.
~~2.4~~	~~PT 21: How to use data on background concentrations in the env. risk assessment~~ ~~⇨ *WG-IV-2015 – item 6.3 (reference below the DTs to the respective RCOM table entries)*~~	~~**FR** volunteered to take over the item.~~ ~~*Following feedback from FR, this item is no longer relevant since covered by the substance specific Excel Sheets developed by UK/NL for marine and freshwater marinas.*~~
2.5	PT 11: Which fraction should be used to calculate the PEC in soil following deposition from air? ⇨ *WG-IV-2016 – item 6.3*	**NL** volunteered to take over the item. Timing to be defined.
2.6	PT 4: Is splitting up the release from on-site/off-site STP in the case of large breweries relevant and is the proposed percentage (on-site = 33% / off-site = 67%) realistic? ⇨ *WG-V-2016 – item 6.1*	**NL** volunteered to take over the item. Timing to be defined.
OPEN ITEMS (priority indicated in colours: high = red, yellow = medium, green = low; prioritisation based on the time lines provided in Annex III of the RPR)		
2.7	PT 18: How to derive values for the cleaning efficiency FCE (=> Release and exposure estimation of the biocidal product during cleaning step) ⇒ *WG-III-2015 – item 6.4*	AHEE member to take over item to be assigned.
2.8	PT 8: Use of a standard transfer factor (38 or 40) for transferring an application rate per volume to an application rate per surface (leaching rate assuming 100% leaching) or	*Item was solved in the frame of item 8.3 of the WG-IV-2017, therefore no longer relevant (a factor of 40 was agreed).*

No.	Title (current leader)	Status
	use of a specific transfer factor based on the dimensions of wooden commodity per scenario (of OECD ESD PT 8). ⇒ *WG-IV-2015 – item 6.3*	
2.9	PT 6: Development of an emission scenario for the preservation of unrefined fuels ⇒ *WG-V-2015 – item 7.3*	AHEE member to take over item to be assigned. *This item may by send to the ENV WG for an early WG meeting discussion in the frame of an UA case.*
2.10	Development of RTU/small scale application scenario for PT 18 (household and professional use) ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.11	Development of a proposal on how to use Fsim in an aggregated exposure assessment for PT 18 ⇒ *WG-II-2016 – item 6.2*	AHEE member to take over item to be assigned.
2.12	Refinement options for PT 11 once through and large recirculating systems ⇒ *WG-II-2016 – item 6.8/6.9*	AHEE member to take over item to be assigned – document form industry awaited.
2.13	PT 21: AHEE consultation - consideration of the PT8 ESD for accumulation and degradation processes (equation 3.11), and the emission pattern for soil exposure (batch-wise vs. continuous release). ⇨ *WG-III-2016 – item 6.4 (AHF)*	SECR to initiate.
2.14	PT 8: Proposal for emission scenarios on how to assess short term antisapstain treatments *WG-III-2016 – item 6.7/BPC-17*	AHEE member to take over item to be assigned.
2.15	PT 7: Revision of the ESD (inclusion of the formulation step, alignment of equations with A/B tables) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.16	PT 9: Definition/revision of fixation factors for PT 9 – leather applications ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.17	PT 10: Removal processes ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.

No.	Title (current leader)	Status
2.18	PT 9: Concentration in soil in PT 9 rubber-roof membrane scenario ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.19	Focus SWASH: Use of the model for calculation of PEC in sediment (PT 3, run-off from soil) ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.20	PT 19: review of default value for Fsim (worst case to apply the Fsim of PT 18 to PT 19?) ⇨ *BPC-19 – AP 07.05*	AHEE member to take over item to be assigned.
2.21	Development of guidance for bees and non-target arthropods ⇨ *CG (2017)*	AHEE member to take over item to be assigned. *Note: DE and CH have initiated national projects to collect information which could be the basis for a future guidance document.*

List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
WEBER Philippe (FR) alternate
MÜHLE Ulrike (DE)
MARAGOU Niki (EL) alternate
POUWELS Marianne (NL) alternate
HUSZAL Sylwester (PL)
WARBURTON Anthony (UK)
Flexible members
THANNER Gerhard (AT)
CORDUA Birgitte (DK)
ILMARINEN Kaja (EE)
KARHI Kimmo (FI)
KORKOLAINEN Tapio (FI)
IGAUNE Ieva (LT)
HELGERUD Trygve (NO)
Rapporteurs
CATALDI Lucilla (IT) - flexible
MARTINS DE ALMEIDA Ines (PT)
ÖSTERWALL Christoffer (SE) - flexible
Advisor
KRUIDHOF-AKERBOOM Sabine (NL)

ECHA Staff
KREBS Bernhard (Chair)
GLANS Lotta
MATTHES Jochen
Applicants
US-ISC consortium
Lonza
EQC consortium/AkzoNobel
Buckman International
TSGE Consulting
Salicylic Acid Consortium
JSC International Limited
BASF

Human Health WG

Core members
MIKOLAS Jan (CZ)
MAXIMILIEN Elisabeth (FR)
DE SAINT-JORES Jérémy (FR)
HOLTHENRICH Dagmar (DE)
SCHUMACHER David (DE)
BARRON Thomasina (IE)
BOS Carina (NL)
Flexible members
HAUZENBERGER Ingrid (AT)
HAVSLAND Stine (DK)
KIRKEGAARD Maja (DK)
HANSEN Max (DK)
WIWEL Maria (DK)
HÄMÄLÄINEN Anna-Maija (FI)
PALOMAKI Jaana (FI)
RYDMAN Elina (FI)
UJMA-CZWAKIEL Monika (PL)
BIRGANDER Pernilla (SE)
ROSSIER Nadine (CH)
Rapporteurs
PEISER Matthias (DE)
CRESTI Raffaella (IT)
WELTEN Angelique (NL)
BORGES Teresa (PT)
HAHLBECK Edda (SE)
Advisors
SUMBEROVA Hana (CZ)
CASIMIRO Elsa (PT)

ECHA Staff
AIRAKSINEN Antero (Chair)
ESTEVAN MARTINEZ Carmen
RUGGERI Laura
PAPADAKI Lina
MYÖHÄNEN Kirsi
DAMSTEN Micaela
ANTAL Diana
SCHAKIR Yasmin
Applicants
US-ISC consortium
Lonza
EQC consortium/AkzoNobel
Salicylic Acid Consortium
JSC International Limited
BASF
AFEPASA/EBRC
Stakeholders
WIETOR Jean-Luc

Efficacy WG

Core members
HAMEL Darka (HR)
ATTIG Isabelle (FR)
ESCH Daniel (DE)
GIATROPOULOS Athanasios (EL)
GERRITSEN Lonne (NL)
MARCU Horatiu (RO)
DUH Darja (SI)
SMITH Ryan (UK)
Flexible members
ZUTZ Christoph (AT)
WENNERMARK Henrik (DK)
VOGEL Birte Fonnesbech (DK)
ILMARINEN Kaja (EE)
KAUKONIEMI Sanna (FI)
RYDMAN Elina (FI)
NIEMINEN Timo (FI)
HUSZAL Sylwester (PL)
DAN Marius (RO)
GURBA Alexandre (CH)
Rapporteurs
BALDASSARRI Lucilla (IT)
MARTINS DE ALMEIDA Ines (PT)
FRANK Ulrike (SE)

ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
STASKO Jolanta
SCHAKIR Yasmin
Applicants
US-ISC consortium/Lonza
Lonza
EQC consortium/AkzoNobel
Salicylic Acid Consortium
JSC International Limited
Klarusconsulting
BASF
Afepasa
EBRC
Stakeholders
ASHWORTH David (CEFIC expert only for non-confidential items)

Environment WG

Core members
CHRISTENSEN Anne Munch (DE)
CHION Béatrice (FR)
ALEXANDRE Stéphanie (FR)
PETERSOHN Eleonora (DE)
REDMOND Aisling (IE)
LANE Clare (UK)
PEPPER Catherine (UK)
Flexible members
PUERGY Reinhild (AT)
PASANEN Jaana (FI)
PENTTINEN Sari (FI)
HOLTHAUSE Karlijn (NL)
HADAM Anna (PL)
JURASZEK Magdalena (PL)
BOQVIST Pernilla (SE)
MARCA A Maria (CH)
Rapporteurs
MARCHINI Silvia (IT)
ORRÙ Maria Antonietta (IT)
OKKERMAN Petrus (NL)
VIANA Bruno (PT)
HAHLBECK Edda (SE)
Advisors/Experts
MARTIN MADARIAGA Bárbara (PT)

ECHA Staff
SCHIMMELPFENNIG Heike (Chair)
NOGUEIRO Eugenia?
GUTIERREZ Simon
LAITINEN Jaana
LIPKOVA Adriana
SCHAKIR Yasmin
Applicants
US-ISC consortium/Lonza
Lonza
EQC Consortium/AkzoNobel
Akzonobel
BASF
Salicylic Acid Consortium
JSC International Limited
Stakeholders
WIETOR Jean-Luc (CEFIC)