WG-III-2017

Final minutes

15 September 2017

Minutes of WG-III-2017

29 May - 2 June 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-III-2017 (29-30 May 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:

- Analytical methods for substances of concern (SoC)
- IUCLID problems with annotations

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 II 2017

Comments on the draft minutes were received as follows:

Accelerated storage stability: Denmark and Germany

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 II 2017 have been agreed by the working group members.

6. Follow up of previous working group meetings

6.1 HPT and MBO

The working group members were informed about the outcome of the e-consultation held on quality control data that was provided to the eCA by the applicant following WG II 2017.

6.2 Cholecalciferol

The working group members were informed that the composition has been updated.

6.3 Copper

The eCA informed about the outcome of the e-consultation held for the APCP, Human Health and Environment working groups following the discussions on the active substance at WG V 2016.

7. Technical and scientific issues

7.1 Redefinition of polymeric betaine

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

7.2 Ethanol outcome of the e-consultation

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

7.3 Substance identification of silver substances

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

7.4 Biocidal Product Families

The working group members discussed the term ‘similarity of composition’ in the context of biocidal product families and how ‘similarity of composition’ is applied in the member states for national authorisations. The discussion was general and no conclusions on the different discussion points were made. In this context, it was highlighted that the coordination group has established a working party, which will deal with the same or similar issues. Therefore and for avoiding parallel discussions, further discussions should be coordinated and managed by this working party.

7.5 Carbon dioxide generated in situ outcome of the e-consultation

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

7.6 Prallethrin outcome of the e-consultation

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

7.7 Guidance on *in situ* generated active substances

The working group members welcomed the improvements of the updated version of the document. Nevertheless, the working group members discussed the following matters:

- 3. Terminology and definitions
  - The definitions of ‘Reaction by-product’ and ‘impurity’ should be combined. The reaction by-products are regarded as impurities, therefore they should not be listed separately but under the heading of ‘Impurities’. ECHA agreed to modify the document accordingly.
  - Unreacted precursors: (unreacted) precursors may be active substances on their own. Therefore expert judgement is needed to decide whether unreacted precursors contribute to the efficacy of the technical active substance generated *in situ*. A remark will be included in the document to make this clear.

- 4.1.2 Precursor
  - A sentence will be added to the document highlighting that it is the responsibility of the applicant to provide a justification why the precursor(s) may be regarded as a “commodity chemical”.
- 4.1.3 Generation process
  - It was suggested that the “Device description if devices are required for the generation” should be removed from the information requirements. However, there have been reservations expressed as the device may have an impact on the composition of the technical active substance.
- 4.3 Physical and chemical properties
  - A reference to the ‘Guidance on Biocidal Products Regulation; Volume I: Identity/physico-chemical properties/analytical methodology – Part A: Information requirements’ will be added.
- General
  - Working group members expressed concerns on the proposed terminology without providing alternative proposal. Therefore it was agreed to provide further comments and proposals for the terminology by 21 June 2017.

7.8 Use of literature

ECHA presented a document on the use of literature as the use of certain literature was challenged in previous working group meetings when discussing active substances. It was highlighted by the working group members that the ‘Guidance on Biocidal Products Regulation; Volume I: Identity/physico-chemical properties/analytical methodology – Part A: Information requirements’ includes already criteria for the use of literature:

“Public literature data can be used in the assessment if the following conditions are fulfilled:
a.
The data comply with the BPR Annex II, III introduction points 5-9.
b.
The identity, purity and the impurities of the substance have to be defined in the publication and to be comparable with the substance addressed in the application.
c.
The reporting of the study allows evaluation of the quality of the study. If conditions a - c are met the applicant can claim that adequate data is publicly available. Providing that the quality of public data fulfils the criteria, it can be used as key studies.”
The following decision was made on the different types of literature with regard to physico-chemical properties:

- Journals can be used if
  - The exact method is given
  - The purity of the test substance is indicated
  - The results are given and discussed
- Handbooks can be used for none critical endpoints (density, melting- and boiling point)
- Safety Data Sheets (SDS) are not accepted to be used

Further, it was highlighted if different literature sources have conflicting results/data for an endpoint a test and study on this endpoint will be needed.

Literature referring to analytical methods can be used as long as it includes complete and sufficient information on the validation and its parameters.

7.9 Definitions used and applied

ECHA introduced a compilation of definitions which may be applied for active substance approval and the authorisation of biocidal products. These definitions have been taken over from the REACH Guidance for Annex V – Exemptions from the obligation to register. The aim of this compilation is to get a common understanding of terminology used for additives or co-formulants. The presented compilation should be regarded as a "living document" which can be extended by further definitions. If the definitions are agreed they may be included in the SPC editor. The working group members welcomed the document but suggested some modifications and additions. No further discussion on the document took place but an e-consultation will be launched for providing comments with the deadline of 22 July 2017.

7.10 Naming of active substances

ECHA introduced a document that aims to clarify the naming of active substances in cases when the strict application of the REACH guidance for identification and naming of substances results in a not appropriate name of the substance, e.g. the name of the active constituent in the substance would not be considered for the substance' name. In this context it was highlighted that the member states agreed at the CA meeting in March 2007 to use the REACH guidance. A brief discussion took place whether the REACH guidance needs to be applied with more flexibility and whether the considerations outlined in the presented document should be considered or not. No conclusion has been made so far but an e-consultation will be held to receive more consideration. The document will be revisited in a future working group meeting. The deadline for providing comments via the e-consultation is 22 July 2017.

8. Union authorisation

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

9. Discussion on active substances

9.1 Azoxystrobin

All open issues were discussed and agreed by the working group members. The reference specification and reference source have been set.

9.2 d-Allethrin

All open issues were discussed and agreed by the working group members. The reference specification and reference source were not set at the meeting but will be followed up by the eCA.

9.3 Esbiothrin

All open issues were discussed and agreed by the working group members. The reference specification and reference source were not set at the meeting but will be followed up by the eCA.

9.4 PHMB (1415; 4.7)

All open issues were discussed and agreed by the working group members. The reference specification and reference source have been set.

9.5 Chlorophene

All open issues were discussed and agreed by the working group members. The reference specification and reference source have been set.

9.6 Peroxyoctanoic acid – early working group discussion

An early working group discussion on the substance identity of peroxyoctanoic acid took place. The eCA will revise the draft CAR based on the conclusions.

10. Any other Business (AoB)

10.1 Analytical methods for substances of concern (SoC)

A brief discussion took place on whether analytical methods for substances of concern are required. It was clarified that no analytical method is needed if the SoC is not formed during the storage of a biocidal product. This conclusion will be added to the technical agreements for biocides (TAB).

10.2 IUCLID problems with annotations

The working group members expressed their frustration about the IUCLID format and the lack of support by the ECHA helpdesk. Some member states have experienced problems with annotations, which were not saved after closing the application. The chair promised to highlight this problem in ECHA so that the member states receive an appropriate support by the ECHA helpdesk.

Minutes of Human Health WG

WG-III-2017 (30 May – 1 June 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 26 participants present, of which nine were core members and one alternate core member. Two stakeholder observers were present, one for all agenda items and one for the non-confidential agenda items. 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.

Invitations to applicants will be sent only via R4BP 3 from WG-IV-2017 onwards. The contact details of the case owners need to be updated in R4BP 3. The evaluating CA will have to provide the applicant contact details to SECR for substance related agenda items where there is no specific case in R4BP 3 (e.g. early WG discussion).

The WGs are constantly growing. The MSCAs were asked to inform SECR also when colleagues are leaving their position. In addition, the MSCAs were encouraged to consider the role of 'advisor' as a lighter approach to being a flexible member.

Some participants have included in the webropol form specific requests for having an agenda item discussed on a certain day. Such requests are not expected in the webropol and they may be unnoticed. For such requests, MSCAs should contact SECR directly by sending an e-mail to BPC-WGs@echa.europa.eu.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. No additional items to the agenda were proposed. 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-II-2017

The minutes were agreed without changes.

6. Discussion of active substances

6.1 Chlorophene (eCA NO) PT 2, 3

The discussion points mainly concerned the effects on the reproductive system, reference values derivation, and human exposure assessment. Points regarding reference value derivation, the batches tested and proposed specification, as well as some human exposure estimations will be closed in ad hoc follow-ups.

6.2 Azoxystrobin (eCA UK) PT 7, 9, 10

The discussion concerned the interpretation of the toxicity studies, the reference value derivation and human exposure assessment. An ad hoc follow-up will close the points regarding the batches tested and proposed specification, the relevance of some impurities, dermal absorption and inhalation exposure assessment.

6.3 PHMB (1415; 4.7) (eCA FR) PT 1, 2, 4, 5, 6

The discussion points concerned the reference value derivation, absorption values, human exposure assessment, dietary risk assessment and animal safety. Reference values derivation and one human exposure scenario will be closed in an ad hoc follow-up.

6.4 d-Allethrin (eCA DE) PT 18

The discussion concerned the interpretation of the toxicity studies, the reference values derivation and human exposure assessment. An ad hoc follow-up will close the points regarding the batches tested and proposed specification, the relevance of some impurities and the sufficiency of toxicity information for certain endpoints.

6.5 Esbiothrin (eCA DE) PT 18

This item was discussed together with agenda item 6.4.

7. Discussion of Union authorisations

7.1 Early WG discussion on UA applications for product families containing Iodine/PVP-Iodine – WebEx

The discussion points concerned use patterns and application rate of PT3 products, milk consumption and possible post-authorisation data. All points were closed.

8. Technical and guidance related issues

8.1 Update on guidance development

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

8.2 Recommendations of HEAdhoc

a) *Default human factor values for use in exposure assessments for biocidal products (revision of HEEG Opinion 17)*

Due to time constraints, this agenda item was discussed in a separate follow-up WebEx.

The WG suggested including a clarification in Appendix B regarding the age categories and the data from which the values for each category are derived. The WG members agreed with the proposed revision of HEEG opinion 17.

b) Proposal for harmonising the assessment of human exposure to repellents (PT 19) – (revision of HEAdhoc recommendation 11)

Due to time constraints, this agenda item was discussed in a separate follow-up WebEx.

Different views were presented at the meeting on the definition of normal outdoor clothing for a realistic worst-case scenario of exposure to repellent products. The considerations included in the proposed revision for the exposed body surface area were not agreed by the WG and further discussions will take place within HEAdhoc on this point before bringing the document back to the WG meeting.

8.3 WG discussions on issues related to classification and labelling

The WG agreed on the document presented to the WG with minor changes.

8.4 Data requirements for precursors of in situ generated active substances

The WG agreed on the document presented to the WG.

The terminology will still be updated based on the agreements of the APCP WG. An updated version of the document will be provided following the availability of all the APCP WG agreements.

8.5 Product residues from paper used for food/feed packaging (PT 12)

The WG agreed on the following approach:

- **Biocidal residues in food packaging**: it is proposed to estimate the biocidal active substance transfer from food packaging to food using data if available, and otherwise by a theoretical worst case scenario. This proposal should be seen as an interim approach until a more clear procedure will be defined by the Commission.
- **Biocidal residues in feed packaging**: it is proposed to estimate the biocidal transfer from packaging to feed using data if available, and otherwise by a theoretical worst case scenario.

8.6 Definition of relevant impurities

SECR intends to clarify the definition of relevant impurities in the revision of the guidance on technical equivalence (*ECHA Guidance on the Biocidal Products Regulation Volume V, Guidance on applications for technical equivalence*). The current guidance is considered to allow two different interpretations of the definition of a relevant impurity.

The definition is not clear on whether the concentration of the impurity plays a role in deciding on the relevance of an impurity. The question is whether it is only the hazard properties of the impurity (in comparison with the hazard profile of the active substance) that determines the relevance, or whether the concentration of the impurity should be taken into consideration. Both views had support among the members.

SECR will include examples to illustrate the consequences of the possible approaches and will provide a revised document for commenting by the members and stakeholders.

8.7 Dermal absorption of anticoagulant rodenticides

Due to time constraints, this agenda item was discussed in a separate follow-up WebEx.

FR presented the document proposing a way forward with regard to re-evaluating the dermal absorption studies and the pro rata approach.

Regarding the applicable procedures, SECR clarified that the WG would not be able to decide but this would likely be for either the CA meeting or the BPC to decide. The majority of the members were however of the opinion that the re-evaluation of the dermal absorption studies would be necessary for the product authorisations.

The applicability of the pro rata approach to anticoagulant rodenticides was questioned. The majority of the members considered the pro rata approach not applicable to anticoagulant rodenticides, but no conclusion was made as it was considered necessary to assess the available relevant information before concluding.

SECR has collected the available dermal absorption studies performed on rodenticides. Some MSCAs have also provided re-evaluations of the studies using the EFSA guidance on dermal absorption (2012). Following the WG discussion, these were made available to the MSCAs in S-CIRCABC.

It was agreed that a commenting period should be launched to identify the questions that need to be solved and to try to harmonise the application of the EFSA Guidance on dermal absorption.

9. Any other business

9.1 Other information & lessons learned

Accordance check

The template/checklist used by ECHA in the accordance check is available in S-CIRCABC with the name *Template extended accordance check*:

- Path: /CircaBC/echa/Biocidal Products Committee (BPC)/Library/Non Confidential Folder/01. Procedural Documents/02. Active substance approval
- https://webgate.ec.europa.eu/echa-scircabc/w/browse/2333a050-9cdd-4514-99e3-f7e59fbfecc2

ECHA will use this from process flow 18, which means using it in the currently ongoing accordance checks.

The eCAs are asked to fill in the checklist from process flow 19, where CARs are submitted by 17 March.

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 together with the updated RCOM (step 15 of working procedure). This document would be provided by filling in Chapters 14.1 *Critical endpoints* and 14.2 *Reference values* of the draft CAR template.

It was agreed at WG-V-2016 that this practice should start from process flow 17, where the deadline for the updated RCOM and the document on reference values is 13 February 2017.

SECR thanked SE for providing this document already for the current meeting.

Public consultation of EFSA dermal absorption guidance

SECR informed that a new draft guidance is available, and a public consultation is ongoing until 24 February 2017 (http://www.efsa.europa.eu/en/press/news/161222). Noting that this guidance is used for biocides, the impact of the revision will require further discussions at the WG at a later stage.

Dermal absorption of anticoagulant rodenticides from formulations

SECR informed that the derivation of reference values has not been progressed because of concerns expressed by COM and CEFIC. The concerns relate to data protection and the ability to use studies submitted in deriving reference values. The SECR will inform the members of any developments.

SECR will clarify the possible ways forward and whether re-evaluated dermal absorption studies of anticoagulant rodenticide active substances and products should be collected in S-CIRCABC.

Combined CAR/CLH template

The template applicable for both CLH and biocides processes was finalised by the task force and is currently being commented by the members of BPC, RAC and CARACAL. Pending on the nature of the comments, the publication is expected to take place in February 2017.

Documents for discussion at WG

SECR reminded the members that any member may suggest an agenda item for discussion at the WG. For such items, the member suggesting the item would normally be expected to provide a document for discussion. Depending on the nature of the item, a commenting period could also take place, possibly followed by a discussion table for the meeting.

Minutes of Efficacy WG

WG-III-2017 (31 May – 1 June 2017)

1. Welcome and apologies

The Chair welcomed all participants to the 17th Efficacy WG meeting. There were 6 core and 1 alternate member who participated in the meeting. In addition, 8 flexible members, and 1 ASO representative (2 experts only for the non-confidential agenda items) 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. Members agreed on the proposed agenda.

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

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

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

The Chair informed that comments for the minutes of WG-II-2017 had been received from AT and FR. The draft minutes version was amended in relevant parts and agreed by the EFF WG.

6. Discussion of active substances[1]

6.1 Chlorophene (eCA NO)

There were three open points for discussion. For the first point the EFF WG agreed with the eCA that the new studies submitted by the applicant show mycobactericidal activity of chlorophene. The EFF WG concluded that innate activity of the active substance is sufficiently proven, and that additional data may be requested at product authorisation stage. It was further noted that discussion on the essentiality claim is not within the remit of the EFF WG.

The second and third open point were connected. Taking into account the ECHA document "Introducing new information during the peer review process_Jan_16", the EFF WG concluded that the new studies submitted by the applicant are not needed to prove the innate activity of the active substance.

6.2 Azoxystrobin (eCA UK)

There were no open points concerning efficacy for discussion in the RCOM table, so the discussion table was only provided to record the agreement/disagreement of the WG.

The EFF WG agreed on the evaluation of the eCA.

6.3 d-Allethrin (eCA DE)

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

There were no open points concerning efficacy for discussion in the RCOM table, so the discussion table was only provided to record the agreement/disagreement of the WG.

The EFF WG agreed on the evaluation of the eCA.

6.4 Esbiotrin (eCA DE)

There was one open point for discussion remaining in the RCOM table related to one efficacy study submitted by the applicant in conjunction with the values mentioned in the intended use table (Appendix II). This point was included in the discussion table prepared for the meeting, but shortly before the WGIII2017 the eCA informed the Chair of the EFF WG that this point is bilaterally closed with CH. Thus this point was not discussed by the EFF WG. The explanation was given by the eCA during the meeting, and respective clarification will be added in the CAR.

6.5 PHMB (eCA FR)

There were four open points for discussion remaining in the RCOM table related to the new efficacy studies submitted by the applicant during the peer-review phase. The applicant submitted new studies, information and additional uses for most of the PTs (1, 2 and 4). Therefore the discussion was started with a question "Does the WG agree that new information provided by the applicant are required?" The question was included for discussion in accordance with the approach described in ECHA document "Introducing new information during the peer review process_(January_ 2016)[2]".

The open points were related to resistance, new challenge test (PT6) and new efficacy study (PT5).

Based on the eCA literature review the concern of resistance was highlighted for PHMB with bacteria at the low dose. To be consistent with the previous EFF WG agreements where the occurrence of resistance was identified at active substance approval stage, the eCA proposed to include relevant information into the CAR and address this issue at the product authorisation stage. The information regarding resistance will be rewritten in the draft CAR according to the eCA proposal in order to indicate the risk of resistance and cross-resistance of PHMB.

Regarding the submitted new challenge test (PT6), the eCA pointed out that from the efficacy point of view, the existing study included in the dossier is sufficient, and there is no necessity to take into account the new study. Regarding the new study (PT5) the eCA indicated that after brief evaluation some deviations from the guidance were recognised in relation to soiling conditions and target organisms.

Finally the EFF WG agreed that the new studies provided by the applicant for open points are not required for the assessment of the efficacy, and should therefore not be taken into account.

6.6 Cyphenothrin (eCA EL)

There were two open points for discussion related to the new efficacy field and laboratory studies submitted by the applicant. In both cases the EFF WG agreed with the eCA without any additional comments or questions.

6.7 Copper sulphate (rapporteur FR)

In January 2017 ECHA received a request from the Commission for an Article 75(1)(g) opinion regarding the status of copper sulphate pentahydrate in the "representative

[2] https://echa.europa.eu/documents/10162/4221979/peer_review_info_jan2016_en.pdf/7fbb63d5-b7e8-472b-b166-5ced176af87d

biocidal product" [3] for PT3. The Commission requested an opinion on the following questions:

1. Does copper sulphate pentahydrate act as an active substance in the "representative biocidal product" referred to by the applicant for product-type 3?
2. If it acts as an active substance:
   a) What is the mode of action of copper sulphate in the "representative biocidal product"?
   b) Is this the same mode of action as for copper sulphate used in PT2 biocidal products, which was notified in 2003 and already approved by Regulation (EU) No 1033/2013?
   c) Is this the same mode of action as other active substances notified and included in the review programme in 2003 for PT3, and currently under review or already approved?

The function of copper sulfate pentahydrate in the representative product is clearly described and justified, nevertheless the study performed by the applicant on Salmonella Thyphimurium was not sufficient to conclude whether copper sulphate pentahydrate acts as an active substance in the "representative biocidal product", especially in relation to soiling conditions and target organisms. Appropriate test conditions, like soiling, temperature, and contact time for intended use should be taken into account.

The test should be performed with the "representative biocidal product" without copper sulphate pentahydrate in order to demonstrate that such product is capable of producing the required biocidal effect.

The EFF WG agreed with the Rapporteur that the additional efficacy test should be performed and submitted for the Rapporteur consideration.

Therefore, the applicant needs to:

(a) agree with the Rapporteur on test conditions taking into account appropriate soiling, temperature and contact time for intended use.

(b) inform the Rapporteur and ECHA regarding the timelines for the new test performing and data submission.

7. Discussion of Union Authorisations

7.1 Early WG discussion on UA applications for product families containing Iodine/PVP-Iodine- WebEx

There were three open points for discussion. For the first open point on the phase 2 step 2 testing the EFF WG discussed of the different approaches that applicants have taken to perform testing. It was noted that the majority of the tests performed according to the draft phase 2 step 2 test proposed in the Statement Paper of the IRG PT3 sub-group (see WGIII2016_EFF_8.1) are within acceptable limits, and variable results have only been obtained in a few studies. The EFF WG concluded that in the absence of a validated standard, Phase 2 step 2 studies with variable results or obtained with modified EN 1499 and EN 1500 tests can be accepted, provided that reasoned justification is made by the

[3] The precise product name indicated in the the Commision request is presented here as "representative biocidal product".

applicant. Justification may be provided e.g. by referring to literature studies, experiences of products being on the market, or other appropriate information.

The second open point concerned bridging studies with different soiling (BSA and skimmed milk) and different test organisms (bacteria and yeast). The opinion of the EFF WG was that for more reliable assessment of Phase 2, step 1 tests exact log reductions instead of lower than (<) values should be given. The EFF WG concluded that since bridging studies between different organisms are problematic, the applicant should provide for the pre-milking claim either a new study or reasoned justification.

In the discussion of the third open point the EFF WG agreed that products in one meta-SPC having multiple PTs can have a specified virucidal claim only for one PT.

8. Technical and guidance related issues

8.1 Update on guidance development (ECHA)

ECHA gave an overview of the EFF guidance. As a general information ECHA informed that the new diagram showing the re-organised structure of the Guidance has been published on the Biocides Guidance webpage. With reference to Transitional Guidance (TG) the EFF WG was informed that seven TG documents on Efficacy have been removed from the TG webpage; they are incorporated into Volume II B+C published in February.

Projects in progress planned for 2017:

1. Vol II Part A - update to align with B+C
   - Drafting/revisions by WG in progress: to be agreed at Sept WG
   - Initiate Guidance consultation in October 2017 with publication foreseen in March 2018

   At the moment written procedure is planned for Part A, in case some major issues will arise a standard PEG procedure including WebEx meeting will apply.

2. Vol II B+C update to Section 5/PT8 to add appendix on "Annex A of EN-599"
   - PEG consultation to be launched by end of May
   - Written procedure with publication foreseen in Nov/Dec 2017

   With reference to the proper interpretation of Use Class 2 possibly a footnote will be added to the current version of section 5.5.8.2.2.3 Treatments of solid wood (EN 599-1 Standard). The date of applicability has to be clarified with the COM.

3. Vol II B+C update to PT5 following completion of ECHA Disinfectants project
   - PEG consultation planned for July/August 2017
   - PEG meeting planned for October; provisional date 11 October 2017 (Post-WG comment: new provisional date 9 November 2017)
   - Publication foreseen in February 2018

   Call for nomination of PEG members is ongoing, in addition two external experts may be nominated by ECHA.

4. Vol II B+C update to PT11/12, and PT19
   - Drafting/revisions by WG in progress
   - Consultation planned for 2017/2018

   Work on the PT11/12 guidance is ongoing, COM decision related to borderline between PT11 and 12 is awaiting and then the discussion at WG level will be continued.

With reference to Volume II Parts (B+C) published in February 2017 on ECHA website the EFF WG raised the issue related to ‘old’ versions of the efficacy guidance published previously as ‘Transitional guidance’ (TG), which have been removed from the website. As the applicability of the new version is two years for dossier prepared for biocidal products the ‘old’ version should be still available and accessible for potential applicants and eCAs.

ECHA informed that the old versions will be placed during summer time on a dedicated page on ECHA website. As many changes were done in this TG in the past it is impossible to identify all of them by ECHA. At best the identification from when specific changes apply has to be done by the EFF WG members and then placed on the same dedicated page as TG. On the 2nd page of new guidance the document history is listed in a table, and all changes will be recorded there. On the third page in a section related to the Applicability of Guidance explanation is given that different documents should be taken into account in relation to active substances and biocidal products.

8.2 Revision of Volume II/B+C:PT19

The Chair informed the EFF WG that due to limited time only a brief discussion is foreseen for this agenda item. DE informed that a workshop dedicated to PT19 efficacy guidance revision will take place 19-20 October 2017 in Berlin.

Slightly revised combined commenting table (CCT) was provided as a room document together with the presentation focusing mainly on the new structure of the guidance and issues to be addressed in the new version (highlighted in purple in the CCT). As a way forward ECHA proposed to agree during the meeting on the new structure, then the new draft version of the guidance will be prepared by ECHA including all editorial comments (highlighted in green in the CCT). The remaining technical/scientific comments (highlighted in orange in the CCT) will be discussed during the workshop in Berlin.

At a first instance the EFF WG agreed on the new structure of the guidance. The current version of PT18 and 19 will be divided into two chapters: PT18 Insecticide, Acaricides & other biocidal products against Arthropods and PT19 Repellents and attractants. PT19 chapter will consist of two sub-chapters:

1. Repellents and attractants: arthropods
    1.1. Repellents
    1.2. Attractants
2. Repellents and attractants: non-arthropods
    2.1. Repellents

The same structure will be kept in both sub-chapters.

The general introduction part should be revised to be more PT19 specific. Section 5.6.4.1.3.8 in the current guidance: The distinction between professional and consumer products will be deleted and section 5.6.4.1.3.11: Residual treatments may also involve the use of palatable baits will cover only to attractants. In addition section concerned general claims will be removed as not appropriate for repellents and attractants.

In each sub-chapter the target organisms will be listed in alphabetical order. Regarding arthropods bed bugs and ticks will be kept only in repellents section. Flies for the time being will not be divided into separate groups like sandflies or biting flies, possibly they can be divided into biting and non-biting flies. Lice will be added as target organism, however confirmation from COM is needed that they are within the scope of the BPR. Litter beetles and wasps will be moved to the new section: Other arthropods, which will be added at the end of this sub-chapter. Spiders will be added to the repellents section only.

Birds, cats, dogs, martens, moles, rabbits, snakes, jellyfishs will be listed as target organisms in the Repellents and attractants: non-arthropods sub-chapter.

Other non-arthropods section will be added as well to this sub-chapter to cover some other target organisms e.g. deer, rodents.

The EFF WG agreed also that information obtained during e-consultation concerning maximum end storage efficacy test (e-consultation for EFF WG on shelf life of bait products October 2016) or during WG discussion (WGIV2015_EFF_7-4 and WGV2015_EFF_7-5: Efficacy evaluation of repellents – field test) should be taken into account.

Decision to include monitoring traps containing attractants to insects into this guidance will be based on Commission implementing decision pursuant to Article 3(3) of the BPR.

EFF WG members and ASOs are invited to share the information concerning repellents and attractants on national markets.

8.3 Revision of Volume II/A

The revised versions of Volume II, Part A and relevant sub-sections of Volume I Part A – information requirements were discussed based on the comments submitted by the EFF WG members.

The respective sub-sections 7.1/7.2/7.3/7.4/7.8 of Volume I Part A will be incorporated in the Volume II Part A. An EFF WG member questioned whether the sub-sections 7.5/7.6/7.7/7.10 will also be incorporated into Vol II, Part A guidance. The EFF Chair informed that this point will be clarified and EFF WG members will be informed.

During the discussion Cefic was invited to provide text to Vol II Part A section 7.9 “Proposed instructions for use”. It was agreed that Cefic will discuss internally with the Cefic members and inform the EFF WG Chair about the possibility to give the input for this section development.

The EFF WG also questioned whether the appendix on resistance could be published as ECHA transitional guidance. The EFF WG Chair informed that this needs to be consulted with Guidance unit, and it will be done by ECHA.

Section related to user categories will be aligned by ECHA with the CA document concerning respective user categories.

As a more general note, it was proposed to add into this guidance a table including all relevant definitions for the major terms used. This is a topic for future update of the guidance following the agreement of relevant bodies.

The updated version of the guidance will be prepared by ECHA and possibly endorsed in September 2017.

As an additional note it was indicated that the appendices of Vol II Part B+C should be revised in the future.

9. AOB

9.1 Other information & lessons learnt

The presentation was given by ECHA. The EFF WG members were informed about timelines and deadlines related to the EFF WGIV2017 meeting. Next physical meeting is planned to take place in Helsinki (6-7/09/2017). The reminder concerning IUCLID training for in-situ substances was given. It is planned as a separate WebEx workshop for Member States on Wednesday, 21th June 2017. To facilitate the accessibility to the information gathered during e-consultations ECHA prepared a proposal for the EFF WG consideration. Due to lack of time this proposal will be discussed during next EFF WG meeting. The presentation is available on S-CIRCABC.

Minutes of Environment WG

WG-III-2017 (31 May - 2 June 2017)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 22 participants present, of which seven were core members and nine flexible members in addition to two advisors and two rapporteurs. Representatives from accredited stakeholder organisation were present for agenda item 8 and 9. 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.

Invitations to applicants will be sent only via R4BP 3 from WG-IV-2017 onwards. The contact details of the case owners need to be updated in R4BP 3. The evaluating CA will have to provide the applicant contact details to SECR for substance related agenda items where there is no specific case in R4BP 3 (e.g. early WG discussion).

The WGs are constantly growing. The MSCAs were asked to inform SECR also when colleagues are leaving their position. In addition, the MSCAs were encouraged to consider the role of 'advisor' as a lighter approach to being a flexible member.

Some participants have included in the webropol form specific requests for having an agenda item on a certain day. Such requests are not expected in the webropol and they may be unnoticed. For such requests, MSCAs should contact SECR directly by sending an e-mail to BPC-WGs@echa.europa.eu.

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 were declared.

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

The minutes were agreed without further changes.

6. Discussion of active substances

6.1 Azoxystrobin (eCA UK) – PT 7, 9, 10

Two points related to effect/hazard assessment and two points related to the exposure assessment were discussed. One point related to effect/hazard assessment (more specifically on classification and labelling) was presented for information only (not discussed). All points were closed but in case the endpoint for the PNEC derivation changes a written procedure will be take place (point 1 of the discussion table).

There were two follow up actions agreed for the SECR (see below).

Actions:
- Possible written procedure in case the endpoint for the PNEC derivation changes;
- SECR to seek clarification from the BPC on toxicological relevance of metabolites (does this supersede Art. 68 of Annex VI in the BPR?);
- SECR to add an entry to the TAB on the possibility to use of different DT50 values for PECsoil and PECgw assessment for substances where degradation is pH dependent (approach outlined in FOCUS guidance);
- SECR to follow up with the author of the city scenario on the inconsistency between the emissions estimation for application and service life and assess whether there is a need to revise this scenario.

6.2 Chlorophene (eCA NO) – PT 2, 3

Four points related to effect assessment and ten points related to exposure assessment were discussed. One point remained open, for which an ad-hoc follow up was triggered.

Actions:
- Ad hoc follow/up on point 8 depending on the outcome of the recalculations.
- Ad hoc follow/up on point 12: eCA will recalculate the cases where only one application occurs. eCA will add further refinements like using Focus SWASH for surface water (Participants: UK, DE, NL, FR, eCA, Applicant, SECR).

6.3/6.4 d-Allethrin / Esbiothrin (eCA DE) - PT 18

Three points related to effect assessment and three points related to exposure assessment were discussed. Three points remained open, for which respective ad hoc follow up were triggered.

Actions:
- eCA to prepare the documents for the ad hoc follow ups and SECR to initiate the ad hoc follow ups.

6.5 PHMB (1415; 4.7) (eCA FR) - PT 1, 2, 4, 5, 6

Two points related to effect assessment and seven points related to exposure assessment were discussed. The two related effect points remained open, for which an ad hoc follow up was triggered.

Actions:
- eCA to prepare the documents for the ad hoc follow up and SECR to initiate the ad hoc follow up.
- SECR to update the TAB with the conclusions noted for point 7 of the discussion table.

7. Discussion of Union authorisations

7.1 Early WG discussion on UA applications for product families containing Iodine/PVP-Iodine

Two points related to exposure assessment were discussed. The Working Group members agreed on the evaluation of the eCA. The eCA can proceed with the preparation of the CAR.

8. Technical and guidance related issues

8.1 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).

8.2 Proposal on exposure assessment of metabolites in the terrestrial compartment (DE)

DE presented the second version of the concept "Proposal on exposure assessment of metabolites in the terrestrial compartment". The document aims to harmonise the quantitative risk assessment of relevant metabolites in the terrestrial compartment for indirect exposure via sewage sludge application, including ground water refinement with FOCUS PEARL. The document was previously discussed at AHEE 1 2016 (AHEE-1 AP5 9) and BPC-WG-V—2016 (WGV2016_ENV_7-2c).

Conclusion: Following open points were agreed and closed:

A. Terrestrial exposure assessment, the WG agreed to follow the approach proposed for the calculation of the metabolite concentration in soil due to 10 years of continuous deposition (Cdepsoil_10_metabolite).

B. Choice of formation fraction (fij) and degradation coefficient of the metabolite (kmet), the WG agreed to use the same values of fij and kmet for both the soil and the groundwater assessment (including the refinement with FOCUS PEARL).

C. Additional agreements in case several soils are tested, the WG agreed:
   - To the strategy (key aspects 1-4) proposed for choosing f_{ij} and k_{met} for the soil and the ground water assessment (including the refinement with FOCUS PEARL)
   - To follow the averaging procedure as described by DE in key aspects 5 and 6 and not the alternative average procedure described under the discussion point (key aspects (5) and (6)).
   - To Key aspect 7
   - To Key aspect 8. It was highlighted that in deviating cases (see case 2), case-by-case decision are possible as already stated in the document prepared by DE.

Action: DE to provide the final version of the document to SECR for inclusion in the next TAB version.

8.3 Simplification of the exposure assessment (all PTs) for biocides (ECHA)

Please refer to the detailed minutes to the document in Appendix 2 below.

Action: SECR to extend the document including the discussions at the WG meeting and draw conclusions on concrete proposals. These to be confirmed with the MSs by written procedure/a discussion at a later WG meeting.

8.4 Applicability of the AHEE recommendation for PT 18 to PT 3 (ECHA)

SECR presented a proposal for the applicability of the AHEE recommendation for PT 18 (2015) to PT 3. FR noted that their impression is that the AHEE recommendation for PT18 can be applied without changes but deeper look at the issue is needed. SECR proposed that comments would be preferably collected via an e-consultation.

Action SECR: An e-consultation of the document will be initiated after the WG meeting. If needed the document will be tabled again at WG-IV-2017.

8.5 Data requirements for precursors of in situ generated active substances (ECHA)

SECR presented the changes in the final version of the document proposed in line with the conclusions of the WG-II-2017 and WG-V-2016. The SECR also noted that the section on terminology is pending the agreement of the APCP WG. NL asked for clarification regarding the confirmation of the composition of the *in situ* generated substance in order to perform environmental risk assessment. The SECR clarified that it is assumed that normally this would need to be confirmed where relevant by an early APCP WG meeting case by case.

APCP WG would use the estimations and calculations provided by the Applicant as a starting point.

Conclusion: The WG adopted the document as proposed.

8.6 Ongoing developments related to PT 21 (NL, UK)

a) Revision of the default value for the underwater surface area of pleasure craft (NL)

NL presented the document highlighting the most important elements.

Q1: Do MS experts agree that the existing default value of 30.7 m^2 (corresponding to an average boat length of 9.2 m) for the wet surface area of pleasure craft can be replaced by the value proposed for NL: 23.5 m^2 (average boat length 8.9 m)?

Conclusion: The members in general wondered if the change in this parameter would affect the saltwater scenario and were reluctant to make such a change at this point in time for saltwater. Some members (UK and DE) commented that they could share some national data on this topic which could better support the change in the parameter so the new value was not agreed. UK also mentioned would also like to some time to review the underlying data. DK emphasized that the change in the value will only affect freshwater.

Action: The point should remain open. DE and UK to provide their data bases to NL. NL will check the database and revise the value proposed if needed. The potential revised value can be agreed via an e-consultation. It was agreed that any changes should relate only to freshwater scenarios.

Q2: If Q1 is answered with no, are MS experts able to submit data (as described above) that would enable the calculation of wet surface area value for pleasure craft for their country (Member State)?

Action: Item is covered by the conclusion on the first question

b) Update/discussion on the development of harmonised scenarios for freshwater: pleasure craft and commercial ships (NL)

NL went through the document highlighting the most relevant issues. They explained some of the reasons that explain why some of the scenarios tested had given exposure values of zero and one of the reasons could be that DOC was set to zero in some marinas. NL highlighted that time is running and there is an urgent need to have a harmonized method for assessing freshwater marinas.

Q1: Only two regulatory, single marina scenarios were available to compare PECs with the distribution of 50 EU marinas. Do MS have a national scenario available that can be modelled in MAMPEC (i.e. fully parametrised) that should be added or are MS content with the provided comparison?

DE wondered why the OECD was not used. NL explained that the OECD was mainly developed as a saltwater marina which differs from the freshwater.

Conclusion: The WG agreed that no additional scenarios are available to be added.

Q2: Are MS content with current underlying data set and results, and if so, do MS support the further development of substance specific Excel calculation tools?

Conclusion: The WG is content with the current underlying data set and results, the further development of substance specific Excel tools is supported.

Q3: Are MS able to invest time in the further development of Excel calculation tools? These tools should ultimately be finalised in the coming month. The process of generating these tools would be comparable to that for saltwater pleasure craft marinas.

Conclusion: Some members questioned how much time is needed for the exercise and NL clarified that the work mainly implies checking the calculations all the rest of the work will or has been done by NL. DE, FR, CH and UK offered their help in order to continue.

Action: NL will coordinate the work

Q4: Do MS agree that Risk Managers should be consulted over the choice of proposed method and appropriate percentiles to use for regulatory decision making?

Conclusion: Some members considered necessary that risk managers are consulted and some didn't consider it necessary. The NL commented that it would be good to specify in the consultation that we are suggesting the same approach as for salt water.

Action: SECR will clarify with the COM is consultation is needed.

c) Update on the situation for marine waters/marinas - feedback from the 70th CA meeting (UK)

UK went through the document that was provided for information.

Note on commercial ships in freshwater:

NL reported back on the item as it was part of their work plan. They asked which MS could be interested in the development of a scenario for commercial ships in freshwater and FR and De were interested but were not able to provide data. In addition DE indicated that antifouling paints are not used in commercial ship for freshwater in DE. In the meantime, NL had internal discussions and have decided to put the development of the scenario on-hold. NL mentioned that at the AHEE meeting in Amserdam, Industry mentioned that commercial boats in fresh water do use antifouling paints but the boats are not treated in DE or NL.

8.7 Definition of relevant impurities (ECHA)

SECR presented the agenda item and the WG members were asked to provide feedback on the two options given. It was noted that, based on the comments received, the document will be revised and SECR aims to present the final version at WG-IV-2017.

It was requested by several MS and by CEFIC to have an opportunity to provide written comments and it was agreed that SECR will launch an e-consultation. However, NL, DK and FR tentatively expressed their preference for Option 1.

NL stated that in their opinion the current definition of relevant impurity is clear and they did not see a need for further clarification. Furthermore, NL suggested that the statement in the item document regarding impurities with PBT/vPvB properties could be explained more extensively.

Action: SECR to launch e-consultation in order to collect comments on the Option 1 and Option 2.

8.8 Specific items identified in the revision of Vol. IV Part B for WG follow up (ECHA)

The SECR presented the status of the ongoing 1st revision of the guidance as well as the list of topics sent back by the Partner Expert Group to the WG for further elaboration. The

SECR also clarified its plans for the 1st revision of the Volume IV part A and 2nd revision of Vol IV part B and C. NL asked for clarification on the applicability of TAB agreements in particular where they were included in the revised guidance. The SECR noted that existing TAB agreements entered in a guidance are exempt from six month applicability period applicable to the guidance document as such (as stated in the BPC document on the Applicability time of new guidance and guidance-related documents in active substance approval). A question was also raised on the progress of the SECR in preparation of a plan for testing of mixture toxicity and substance of concern guidance (as an integral part of the mixture toxicity guidance). The SECR noted that time is needed to gain experience with the new guidance to be able to share ideas (through a workshop most likely to be organised in 2019). Therefore, it was not possible to give more details on the planning of the testing at this stage.

8.9 Application of $F_{weatherside}$ for PT 8 (groundwater assessment) and other PTs (DK/ECHA)

Following questions and trilateral discussions with two other MS, SECR provided the following clarification on the application of $F_{weatherside}$ in different PTs:

Use of $F_{weatherside}$ for groundwater assessment in PT 8 and other PTs

$F_{weatherside}$ should be applied in the groundwater assessment for PT 8 (according to the Supplement to Appendix 4 of the revised OECD ESD for PT 8) and for other relevant PTs, if the groundwater assessment is conducted according to the revised OECD ESD for PT 8.

Use of $F_{weatherside}$ for the city scenario (PT 6, 7, 9, 10)

At WG-II-2015 in the frame of an active substance it was concluded that the $F_{weatherside}$ should not be used for the city scenario. It was commented that $F_{weatherside}$ refers to the fact that not all sides are exposed to rain equally, however the value of 0.5 for $F_{weatherside}$ was accepted for houses in the countryside. In cities, buildings are taller and closer to each other so the effect on biocides reaching the environment is different. It was further stated that with regard to the cities, turbulence, direction of rain is different.
$F_{weatherside}$ should therefore not be applied in the city scenario.

Action: SECR to include clarification in the TAB.

8.10 How to use Fish Enbryo Actue Toxcity (FET) Test Guideline (OECD 236) to fulfil information requirements under different regulation (ECHA)

SECR made the presentation to give an overview of the current on-going discussions on the topic and to raise awareness that the topic may be in the near future discussed under biocides. The presentation was well received by the members who showed interest in the topic and agreed with the SECR that further actions will be needed in order to have a common approach to this test method.

Conclusion: The members agreed that the WG should wait for the proceedings of the workshop held by ECHA and UBA. Also the members agreed that in principle, the conclusions drawn in terms of applicability for REACH could also apply to biocides, but further analysis may be needed

Action: SECR will make available to the members the proceedings from the workshop when they become available.

8.11 Outcome of the e-consultations initiated in Q1 2017 (ECHA)

SECR provided feedback on the discussion at the CA meeting regarding the collection of tonnage data. It was concluded at the CA meeting that it was not possible to establish at EU level a systematic collection of data at this stage. It was noted that private companies might collect this type of data which could be bought. Industry representatives were invited

to reflect on the possibility to buy such data and submit them to the ECHA and the Member States, as it is on their first interest to have refined market penetration factors.
SECR will update the recommendation on Fpen taking into account this conclusion.

SECR informed that the following consultations triggered by the ENV WG will be discussed at the next BPC meeting:

1. Remits of the ENV WG when discussing risk mitigation measures - WG-I-2017 (item 6.3)
2. Number of safe scenarios for FOCUS groundwater in the case of Union authorisation - WG-I-2017 (item 7.6)
3. New study endpoints after approval of an active substance triggering an update of the list of endpoints - WG-IV-2016 (item 8.1)

SECR provided in addition an overview on items that have been included in the newsgroup (on open items on ESD). Items related to PT 18 had been send to the PT 18 EG meeting. The remaining items were mainly related to PT 8.

9. AOB

9.1 Assessment of Endocrine Disruptors – update on status

SECR presented the agenda item and went through the presentation. Some of the members made some questions in relation to the scientific guideline by ECHA-EFSA and how prescriptive will be for the assessment of biocides. One of the concerns expressed in this regard was to have principles when requesting further data from the applicants. There were also some questions in relation to the difference in assessment for substances submitted before and after 1 Sept 2013. NL made a comment in relation to the substitution criteria and how the comparative assessment should be performed. SECR emphasised that MSCA should start looking at the guidance whenever it becomes available for them and that resources need to be put in place to be ready for the assessments.

9.2 Other information & lessons learned

The following lessons learned were presented:

With regard to **procedural items concerning MS** the following was noted:

MS were reminded again to keep the timelines, specifically for trilateral discussions and providing the updated RCOM table. Timelines are provided on the ECHA webpage: https://echa.europa.eu/documents/10162/4221979/revised_timeline_as_app_en.pdf/ba57583d-b081-4b6e-8632-3d8a5bfe0028

In the RCOM table, exchanges between applicant and eCA that took place before submitting the draft CAR should not be included. Such information should be taken into account in the CAR. It was further noted that the Ad hoc follow up document should be prepared by the eCA (see Working Procedures for active substance approval for relevant step/description). It was recommended that if WG meeting documents are send to any ECHA FMB, the chair should be set always in copy.

With regard to **procedural items concerning SECR**, to enable disagreeing to closed points, SECR to take care internally that the updated RCOM is moved from submission folder to the correct place in S-CIRCABC in time.

Concerning **reference specifications**, the following was highlighted:

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 to ECHA, before the reference specification is clear.

The following information were provided:

Starting from September, **two week WG meetings** are planned with ENV discussions taking place in the second week. eCAs for the substances in September were asked if it is helpful to exceptionally delay provision of update RCOM table (and consequently provision of discussion table) by one week after summer break. This concerned BE, SK, UK, PT, FR. It was agreed to keep the original timelines as provided in the document referred to under the lessons learned, however some flexibility will be allowed, if the updated RCOM is provided few days later (however not more than five days). Note that all other timelines remain unchanged.

Concerning the **timelines for uploading non-active substance related meeting documents** the following was clarified: Documents "for agreement" or "for discussion/agreement" to be uploaded at least 10 days before the meeting. Documents "for information/discussion" to be uploaded 10 days before the meeting, however a certain flexibility is applied (since not for agreement). Documents "for information" to be uploaded 2 days before the meeting, presentations "for information" can be provided still at the meeting.

The following updated on the development **of ESD spreadsheets** was provided:

- **PT 6,7&9, PT 7 and PT 9 leather** – published in April
- **PT 8** and **PT 13** – first draft commented by MS; a final draft will be circulated before publication
- Previously circulated spreadsheets:
    - **PT 9 rubber**: commented twice by the MS; to be finalised and published
    - **PT 10**: commented once by the MS; comments to be implemented and re-circulated for confirmation
- **PT 11**, **12** and **PT 18 households** – new date: August 2017
- **PT 18 animal housing** and **PT 18 manure storage** – new date: September 2017
- Preparation of **PT 3** and **PT 6** planned to start in August 2017
- Update of published spreadsheets is a priority (e.g. alignment with new TAB entries)

A **IUCLID training** for in-situ substances as separate WebEx workshop for MS will take place on 21th of June, 12:00 – 14:00 (Helsinki time). The following topics will be covered: Introduction to IUCLID 6 – where are we now; components of the Biocides dossier – how to browse a dossier, how to understand table of contents, how in-situ generated substances should be reported; Dossier comparison; How to use and share annotations in IUCLID 6; How to search in ECHA database. Note that the training will be recorded.

The **Read-across framework (RAAF)** – Environment was introduced: Objective of the RAAF is to provide framework and guidance for consistent evaluation of read-across predictions with an output suitable for regulatory consideration

Related documents are the Read-across assessment framework (Appendix ENV-A to ENV-F for the Environment Scenarios 1-6) (*March 2017*), Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across. A presentation by SECR planned for the next WG meeting where a description of the ENV RAAF in more detail with an example case will be provided.

The following **general items** were provided:

Feedback from BPC meeting: if a literature search was concluded at WG meeting level, the outcome should be taken into account in the assessment

An update on Union Authorisation can be found on S-CIRCABC: https://webgate.ec.europa.eu/echa-scircabc/w/browse/9b34e8bd-8b0d-47e1-ba88-69b7fcdfbd7f.

SETAC 2018 will take place 13 – 17 May 2018 in Rome, WG members were invited to provide items for a biocide session by mid of August. ECHA is internally discussing a session on modelling tools (REACH/Biocides).

Appendices:

Appendix 1:

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

Note:

- Issues unchanged since WG-II-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**	Intention for scenario preparation presented at TM IV 2013. NL has started discussion with IND and has received information from industry. NL has compiled the reactions from the e-consultation on PT 21. Outcome was included in the PT 21 PA manual discussed at AHEE-1. The PT 21 PA manual was endorsed at WG-I-2017, some items were forwarded to the 70th CA meeting. **NL/UK presented the status at WG-III-2017.**
1.2	Leaching to groundwater from paint, coatings and plaster (**NL**)	The document was discussed at WG-II-2015. NL agreed to make some clarifications in the document for better readability. The document was distributed for commenting after WG-II-2015, no comments have been received (commenting period ended on 8/5/2015). DE commented directly to NL during the physical meeting. **The document will be updated and NL will explain the method in more detail**.
~~1.3~~	~~Evaluation of the model SimpleTreat (**DE**)~~	~~DE did not yet receive the final report and the announced manual for the new SimpleTreat version. DE is currently clarifying some open points with the provider of the tool; the final report will be provided to WG members as soon as these are solved.~~ ~~**The document was endorsed at WG-I-2017 and was included in the TAB 1.3.**~~
1.4	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[4] in order to collect the data and perform an impact assessment as soon as sufficient data is available (target: in one year).

[4] **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
		SECR to include additional time also in the Excel sheet for PT 8 currently under preparation.
1.5	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 (=> most likely in 2017)**.
1.6	1st revision of Vol. IV Part B (active substance) + new biocidal product part including SoC) (**ECHA**)	1st revision: definition of subjects for first revision and assignment of volunteers taking over the subjects were agreed at WG-I-2016, revised text parts have been provided by 15 June 2016. After discussion of some items at WG-IV-2016. The PEG consultation was initiated in December 2016. Discussion of the revised text will take place in the frame of the PEG. PEG meeting takes place on 16 March 2017. **An update on the status/further steps was provided at WG-III-2017.**
1.7	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 to be sent for final agreement to WG-IV-2017.**
1.8	TAB (**ECHA**): Technical Agreements on Biocides	Version 1.3 was uploaded on 12 April 2017 for a six week commenting period. Deadline for providing your comments: 24th May. **The TAB v1.3 will be published in the first weeks of June.**
1.9	ESD for PT 6 (**DE**)	DE has revised the ESD following comments received. **The ESD was endorsed at WG-I-2017, DE to provide the final version to be placed on the ESD webpage.**
1.10	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.**
~~1.11~~	~~Guidance on mixture toxicity (**DE**)~~	~~Will be presented at WG-II-2017 for information and to a certain extend discussed in the frame of the PEG meeting on the revised Vol. IV Part B (PEG meeting).~~
1.12	Manual of instructions to eCAs for evaluation of active substances used in disinfectants	The final version has been provided by the consultant; currently being finalised by SECR. Publication expected during summer 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 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)*	AHEE consultation ended on 28 August 2015. Based on the comments received the proposal will be revised and then re-commented/confirmed by AHEE. A discussion of specific items took place at WG-IV-2015 and at AHEE-1. 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 items will be prepared by SECR and provided for information to the ENV WG at WG-IV-2017.**
2.2	Proposal on exposure assessment of metabolites in the terrestrial compartment ⇨ *WG-II-2016 – item 6.4*	DE will prepare a proposal for discussion. Discussion at AHEE-1 and WG-V-2016. An e-consultation was initiated after the WG meeting to close points 3 to 7. **The item was discussed and agreed at WG-III-2017. DE to provide the final version to SECR.**
2.3	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-V-2017.**
2.4	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.
2.5	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. Timing to be defined.
2.6	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.
2.7	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)		

No.	Title (current leader)	Status
2.8	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.
2.9	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 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*	AHEE member to take over item to be assigned.
2.10	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
2.11	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.
2.12	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.
2.13	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.
2.14	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.
2.15	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.

No.	Title (current leader)	Status
2.16	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.
2.17	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.
2.18	PT 10: Removal processes ⇨ *WG-IV-2016 – item 7.3*	AHEE member to take over item to be assigned.
2.19	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.
2.20	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.
2.21	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.
2.22	Development of guidance for bees and non-target arthropods ⇨ *CG (2017)*	AHEE member to take over item to be assigned. *For information: DE will start a research project (basic questions), the outcome could be the basis for a future guidance document.* *CH is also considering start of a related project.*

3. ENV WG e-consultations on items that came up during product authorisation / mutual recognition or AS evaluation

Agreed procedure for items that came up during product authorisation at WG-V-2016: the CA who initiated the e-consultation on a specific item should prepare the summary and conclusion of the consultation which will then be presented by the CA at the subsequent WG meeting for information (not for re-discussion or agreement). If relevant, it will be noted in the minutes of the respective WG meeting if the conclusion should be reflected in the TAB or if further actions are required.

No.	Title (current leader)	Status
~~3.1~~	~~PT 18: Aircraft disinsection (**UK**)~~	~~Deadline for commenting is 31 January 2017.~~ ~~**UK will report outcome at WG-II-2017/WG-III-2017**~~
~~3.2~~	~~Simplification of exposure assessment (all PTs); initiated post WG-V-2016, relevant for~~	~~Deadline for commenting is 3 February 2017.~~ ~~**Item will be scheduled for discussion at WG-III-2017.**~~

No.	Title (current leader)	Status
	~~PA authorisation/AS approval (**SECR**)~~	

Appendix 2: Item 8.3 - Possibilities to simplify the environmental exposure assessment

Detailed minutes on the discussion on concrete proposals:

A. Harmonised exposure assessment tools

The development of Excel sheets was emphasised by several WG members. It simplifies the calculations preformed for active substance and biocidal product. The same sheets should be used by all MS and they should be attached to the CAR/PAR in order to allow an easy check of calculations performed.

One WG members proposed to prevent implementation of new ESDs until there are validated / agreed / peer reviewed and easy-to-use Excel calculation tools available. If every PT had an agreed Excel tool for the majority of major use patterns, it would save significant time for MS and costs for industry. Furthermore, the emissions outcomes will be reproducible by any party in a format that is transparent so input values can easily be checked. The outputs would then represent the EU harmonised approach for use in the environmental risk assessment.

The same approach could be applied to any new scenarios, refinements or additions to existing ESDs – the leading MS has to produce a calculation tool as part of the process of getting it accepted.

Comments WG-III-2017:
NL showed appreciation of the development of the emission estimation Excel sheets. NL raised a question whether fate and distribution models could be added to theses sheets in order to be able to calculate PECs in one go. NL suggested also to add tables in the Excel sheets that could be directly copied and pasted in CARs with the relevant outputs. FI showed support for the NL suggestion.
The Chair explained that these Excel sheets were originally developed to support the future update of EUSES. If it is decided that ECHA takes over development of EUSES, integration of the fate and distribution models into the Excel sheet would be done in vain. Therefore, such a decision can be made only once the future of EUSES has been clarified.

B. RMM

A number of assessments always result in environmental risk and subsequently RMMs are applied. For these areas (e.g. industrial application and storage of impregnated wood) RMM's should be applied per default so that no calculations are needed.

Comments WG-III-2017:
CH was against application of RMM by default as the RMM may not be necessarily correct and particular RMM does not reduce risk sufficiently. DE was of the view that this proposal is not appropriate for AS approval. DE suggested that it is necessary to have an idea on how the substance is emitted in the environment and what the risk would be. FR concurred with DE adding that releases of different uses need to be described, studies need to be provided in order to quantify the risks. FR suggested that RA could be skipped when the question is of standard RMM agreeable to all. UK noted that PT 18 bait boxes and PT 8 industrial sealed storage are good candidates for this approach. DK proposed that this proposal should be relevant for product authorisation only. NL further elaborated that in such case one should assume that the use subject to product authorisation has been covered in the CAR. In case of new uses, it would need to be assessed whether the RMM is needed or possible. NL suggested a discussion on the common uses where MSs should agree on default RMMs.

C. Acceptance of local risk

It was proposed to discuss if it is acceptable under certain, very specific, conditions to accept risk locally for a certain use. For example in situations where recolonization would be possible.

Comments WG-III-2017:
DE noted that efforts should be made to develop guidance on the interpretation of the BPR with regard to the uses such as ant bait boxes used in gardens. It would need to clarify which parts of the garden are covered by "use around the building" and if there should be different views on protection goals for gardens and for wider environment. DE would be interested in the development of such guidance. NL concurred with DE that this has to do with the definition of protection goals and it needs to be clarified if recolonization could be a part or risk assessment. The SECR noted that this would potentially add a step to the process and that the acceptability of local risk is up to the risk managers. FR suggested that in such case this should be rather addressed at BPC level. Nevertheless, FR would be interested to cooperate with DE on the aspects of recolonization. NL reminded that a restricted risk assessment is used for exposures "around the building" by using 50 cm depth instead of 10 cm. NL suggested to consider focusing on uses where emissions can be reduced. DK questioned the assessment of recolonization, noting recolonization would need to be shown by a test that may not exist. DK also noted this may not necessarily reduce the workload. DE noted that in the absence of guidance, they would not accept the approach. DE proposed that instead of recolonization, they would exclude treated area from the risk assessment. NL supported the view of DE.

D. Risk envelop approach

The use a risk envelope approach was proposed, in which small uses are covered by one or two major uses. For each PT it should be checked if exposure calculations are unnecessary as other scenarios are covering the worst case for the environmental compartment of concern, e.g.:

- PT08: use only the house scenario for direct emission to soils, only bridge over pond for direct emission to water, etc.
- PT06 and 07: Emission from paints covers emission from sealants, glues, etc.;
- PT10: emission from plasters covers fillers and mortars;
- PT04: large kitchens and canteens as a surrogate for (professional) kitchens etc. and slaughterhouses as a representative for large scale applications in the food industry.

In the same line, the introduction of a much simpler Tier 1 approach at review stage could result in greater numbers of RMM being triggered (and potentially even cause over-regulation and over-labelling). One MS asked if other MS could provide advice, practical guidance and analysis of the existing ESDs so that only the worst case scenarios are calculated at Tier 1. If Tier 1 passes, there is no need to present the other scenarios since covered by the risk envelope.

A separate project could be initiated to rate the different uses or product types.

Comments WG-III-2017:
DK expressed its support for the idea. DK asked about the possibilities to include this in ESDs. The Chair noted that the possibilities to revise ESDs are limited and therefore it would be rather resolved with a TAB entry. ESD PT 8 does however already contain the information. The SECR further noted that MSs may have even better possibilities to look into the issue considering that more scenarios are assessed at product authorisation level than at active substance approval. FR, NL, DE, CH, DK and SECR volunteered to participate in the exercise. The ESD would be split between the MSs. FR noted that working with concrete examples would make this work easier. DE reminded that the underlying work has been done for PT 18 through the expert group.

E. Substance properties

The substance properties should act as a starting point for deciding whether a "light exposure assessment" can be performed, rather than the amount of substance (i.e. a tonnage based approach) or the origin of the substance (i.e. plant materials). A lighter exposure assessment could be performed if a defined set of specified environmental criteria, e.g. based on rapid degradation and a low environmental hazard profile, are met.

For these substances, it could also be argued that also at product evaluation, there would not be a need for an extensive exposure assessment (unless the biocidal product contains other active substances or substances of concern which warrant a more thorough assessment – but in that case full exposure assessments should anyway be available for the other active substances). Simplified exposure assessments are already performed for substances with low environmental concern, e.g. the substances in category 6 of Annex I.

Comments WG-III-2017:

DE reminded that for substances that degrade rapidly the possibility of formation of metabolites must be kept in mind. FR concurred and noted that this could be relevant also for substances of concern when evaluating products. NL noted that this is again possibly not a simplification, nevertheless it may speed up the process. NL highlighted the need for an agreed harmonised list of endpoints to be used in calculations, in particular for substances of concern. The Chair reminded of the discussions on in situ generated active substances, where harmonised assessment of reaction by-products was proposed and the activities of the APCP WG with the aim of creating an overview of metabolites that are relevant for several active substances. DK was of the view that agreed risk assessment needs to be performed for all active substances with the exception of those that are to be included in the Annex I list. DK would rather prefer simplification of exposure scenarios that would result in reduced requirements.

F. Use of already existing scenarios for new uses

In the event that a new use is identified, the possibility that the use is covered by an already present scenario should be carefully assessed before creating a new scenario.

The use of many different non-harmonised exposure scenarios should be avoided. Screening of products on the market (with the a.s. under evaluation and in the relevant PT) at the time of the active substance dossier submission would be helpful. The need for new harmonized exposure scenarios could then be decided on a relatively early stage and would enable the start of developing these. When harmonised tools for performing exposure assessments are missing (e.g. exposure scenarios for uses outdoors) this may lead to different solutions for different substances although the use is the same/similar and also different solutions between member states on product level. To make this process work, companies need incentive to participate with their expertise in the development of exposure scenarios. At product level there is not much room for harmonisation of exposure assessment considering how resources, timelines and forums are organised today.

Another way is putting active substances and type of uses in perspective, in other words, does make sense to spend a lot of resources in a very limited or restricted use? We could think of a system by which we can decide what scenarios we should discuss and tackle or which ones can perfectly be covered by a scenario already available.

The generation of Product database including uses that have been assessed at national level could also be helpful.

Comments WG-III-2017:

The Chair summarised that in this case it is simply favourable to try to use existing scenarios also for any new uses and to limit the development of new scenarios as much as possible. Whenever a new scenario needs to be developed it should be discussed through e-consultation or early WG meeting. It needs to be checked whether the use is a major use, development of scenarios for niche uses should be avoided. NL suggested that it

should be discussed with the applicant at first if he really wants to proceed. The tricky part is when it is claimed that there are no emissions.

G. Cover more scenarios at AS approval stage

Risk characterisation in different scenarios already in the substance authorisation stage would allow the applicants on product level to get an approximate understanding of how to allocate resources for product development. Possibly this would result in submissions of more relevant applications for authorisation of biocidal products.

Another argument for performing exposure assessments on substance level in general is that the outcome of the evaluation effects the market in a more unison way than the evaluation on product level. An active substance under evaluation can be present in imported biocidal treated articles. If a specific use of this active substance is rejected in the active substance evaluation process, articles treated with this substance for the same biocidal use can no longer be imported. However, if a certain use is rejected on product level this has no effect on the import of biocidal treated articles.

In addition, calculations done at the a.s. level should be clear and ready to use. Potential solution could be to report the risk assessment clearly in concentration in the product (or alternatively MADe is the maximum allowed dosage that would not cause any risk in any environmental compartment (PEC/PNEC < 1) – currently proposed for discussion under UA) so products containing only one a.s. and for same uses wouldn't need to be assessed.

Comments WG-III-2017:

FR supported the proposal and further noted that very representative uses should be covered at the approval including those that were not safe. A clear overview of safe and unsafe uses should be presented in the opinion. This would allow the applicant to prepare the refinement options and RMMs for product authorisation. DK questioned the willingness of applicants to cover more than one safe use at the approval stage. The Chair however thought that that may depend on the applicant. Larger companies may find it a commercial advantage. Reinforcement options nevertheless may need to be developed.
UK suggested defining core uses for each PT that need to be assessed always in addition to the intended uses. This would simplify the process further down. The SECR noted that similarly the maximum allowed dosage would reduce resources at product authorisation while there would be no need to recalculate. FR supported these views and added that if all uses were looked at approval and aggregated exposure assessment would be done there would be no need for product authorisation. NL however questioned the use of the maximum allowed dosage as it is rather realistic situation when not all uses have been assessed at approval and new ones are coming up at authorisation. NL noted that from their experience this is not always very helpful approach. The Chair however explained that (1) the assessment of the core scenarios and (2) derivation of maximum allowed dosage from the core scenarios need to be performed stepwise. This is likely to simplify the assessment for products containing one AS and to some extent also the products containing more than one active substance. The approach is common in REACH (maximum tonnage).

H. Simplification of metabolites assessment

One proposal was to consider moving back to a simplification of the metabolite assessment. This could be based on hazard assessment at first tier – so if major metabolites are much less toxic than the a.s., then there would be no need to undertake full quantitative risk assessments on them (whilst this does not work for groundwater assessment, there are screening criteria already available to help with decision making).

Comments WG-III-2017:

FR noted that this should be relevant for the AS approval stage and not for the product authorisation.

Detailed minutes on formal/procedural aspects regarding CAR/PAR:

Several formal items concerning the CAR/PAR preparations were proposed in addition:

- Do not repeat complete ESDs in DOCIIB, but make references to the ESDs and TAB agreements applied and only publish the variables and possible deviations. It should be reproducible.
- Do not include model output files from PEARL and EUSES or ECHA calculation sheets as this leads to extensive documents. It is rather important to present all relevant input parameters for calculating exposure concentrations in a table.
- Do not deviate from defaults without any scientific substantiation even when risks has been identified unless sufficient information is available demonstrating that the applied methods are unrealistic for the current active substance and products.
- If it is necessary to deviate from default parameters and/or a new scenario must be applied, it is advisable to discuss this with the WG prior to the commenting phase.
- Combine DOC IIB and DOC IIC, i.e. tables with both PECs and PEC/PNEC ratios (results and discussion in a single document).
- For complex substances and/or substances with multiple PT's, it may be beneficial to discuss DOCIIA first and start with the risk assessment once agreement on endpoints is reached (this was done in the past for e.g. glutaraldehyde).
- The CAR is the backbone for future product authorisations. The document should be complete as possible and all crucial data gaps should be filled before product authorisation starts. Approval of an active substance based on a minor use (a use with negligible emission to the environment), while major uses could be expected may delay product authorisation. The same holds for substance approval based on one or two safe PEARL-scenarios while union authorisation are expected.

Comments WG-III-2017:
NL suggested further explanation of minor and major uses as a basis of approval with regard to what is being compared, which emissions constitute a use to be considered minor/major use. It was proposed that minor/major uses are described in qualitative manner (with signs).
DE noted that there is a CA decision saying e. g. that the output files from PEARL should be provided in the CAR. The SECR explained that the suggestion in this document was meant to propose that not full output files should be included. The input parameters and results instead should be provided.
FR pointed that it is a good idea to discuss DOC IIA as a first step. Nevertheless, in cases where the applicant submits a new study in order to refine risk assessment, it may turn out not to be a simplification.

Detailed minutes on concerns towards a simplification

Several WG members raised in the e-consultation concerns with regard to a possible simplification:

A reduced number of scenarios at a.s. evaluation could lead to an increased workload at the product evaluation stage.

It was highlighted that great care should be taken with simplification of the review dossier so that acceptance would be based in future on only one use pattern which is known to be safe. There is great danger in simplifying the process to this extent as the representative product becomes meaningless. It was questioned how to ensure that the data set agreed at WG matches all intended use patterns when only a fraction of the actual uses will be specified? Can MS be sure that uses are realistic and not just used to ensure Approved List

status? It is most relevant to consider the major use or even the worst use so that all others would be safer (and then rely upon a risk envelope approach rather than review each use in turn)?

Whilst slimming down the emissions assessment may indeed speed up the review program, it will bring product authorisation to a standstill. Most of the tricky use patterns are likely to be avoided at review and only be submitted at PA stage and there may not be agreed scenarios or mitigations or even sufficient endpoints / PNECs in the CAR to successfully perform a harmonised assessment. MS could then be required to undertake significant study evaluation, build non-standard models without proper consultation with OMS and create RMMs at a part of the regulatory process where limited time is available. Many of these national decisions may then be rejected at MR or Union authorisation so it is not clear how streamlining the process is of benefit. There are already examples of major issues arising at PA level due to incomplete decisions at review or conclusions based on one safe use / one pass in FOCUS groundwater modelling.

Concerning plant materials for which a light assessment was proposed by SECR, some WG members did not agree. The question was asked on what grounds would plant materials as a group are less harmful in general, than other substance groups? Extracts from plants should be assessed similar to chemicals as there are efficacious and therefore harmful to.

Concerning the use of a tonnage-based risk assessment to lighten the assessment proposed by SECR, some WG members did not agree. Tonnage data is to variable, focusses only on the concerning applicant and/or product, and is often confidential. Although consumption-based risk assess may overestimate emission for the concerning active substance(s) and/or product, it can be considered as a kind of aggregated risk assessment as it included substances from other applicants as well.

Comments WG-III-2017:

NL asked whether it would be possible to add the calculation sheets in the CAR/PAR. The Chair responded that MS had differing views on the issue. Nevertheless, it could be useful to do so in particular when harmonised sheets are used which allow quick check.

NL furthermore highlighted that input/output files from PEARL do not allow checking all settings chosen at AS approval which may be needed if reruns are needed at product authorisation. The Chair clarified that inputs should include also the settings, i. e. substance properties, application rate, plants and stages but not all the runs for 26 years or the recording of the concentration at every location at all layers.

PL noted that the new CAR template requires filing the same PEC and PNEC twice which causes it is very long. It is not easy to fill, neither to read. The Chair asked PL to provide the list of the problematic sections and address this issue separately.

List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MŰHLE Ulrike (DE) - Rapporteur
WEBER Philippe (FR) – Alternate
HUIZING Tjaart-Jan (NL)
HUSZAL Sylwester (PL)
WARBURTON Anthony (UK) - Rapporteur
GATOS Panagiotis (EL) - Rapporteur
MARAGKOU Niki (EL) - Alternate
CEBASEK Petra (SI)
Flexible members
KORKOLAINEN Tapio (FI)
KARHI Kimmo (FI)
CATALDI Lucilla (IT)
THANNER Gerhard (AT)
CORDUA Birgitte (DK)
ILMARINEN Kaja (EE)
ÖSTERWALL Christoffer (SE)
HELGERUD Trygve (NO) - Rapporteur
Rapporteurs
DONS Christian (NO)
BOITIER Caroline (FR)
Stakeholders
COGNAT Flore (CEFIC)
RANGGASAMI Nirmala (CEFIC expert)

Applicants
ECOLAB
LANXESS
JSC International
Syngenta
PAREVA
Rütgers Organics GmbH
ECHA Staff
KREBS Bernhard (Chair)
GLANS Lotta
MATTHES Jochen
SCHAKIR Yasmin

Human Health WG

Core members
MIKOLAS Jan (CZ)
MAXIMILIEN Elisabeth (FR)
DE SAINT-JORES Jérémy (FR)
HOLTHENRICH Dagmar (DE)
KNEUER Carsten (DE)
NIKOLOPOULOU Dimitra (EL)
ARAPAKI Niki (EL)
ROBINSON Julie (UK)
BRESCIA Susy (UK)
BOSMAN Saskia (NL) alternate member
Rapporteurs
BOITIER Caroline (FR)
HAUGSTAD Kjetil (NO)
HERRMANN Kristin (DE)
Flexible members
PETERSEN Annika Boye (DK)
WIWEL Maria (DK)
HAVSLAND Stine (DK)
HYVÄRINEN Tuija (FI)
PALOMÄKI Jaana (FI)
PUPIER Cindy (FR)
LORI Julia (FR)
GOTTLOB Kathrin (DE)
FRYDENLUND Jorid (NO)
UJMA-CZWAKIEL Monika (PL)
ROSSIER Nadine (CH)

ECHA Staff
AIRAKSINEN ANTERO (Chair)
ESTEVAN MARTINEZ Carmen
RUGGERI Laura
DAMSTEN Micaela
PECORINI Chiara
JANOSSY Judit
ANTAL Diana
Applicants
LANXESS
TSGE Consulting
PAREVA
Knoell
Sumitomo
Endura
Stakeholders
COGNAT Flore (CEFIC)
COREA Namali (CEFIC expert)
Advisors
VAILLANT Vincent (FR)
DONS Christian (NO)

Efficacy WG

Core members
GIATROPOULOS Athanasios (EL)
ATTIG Isabelle (FR)
HAMEL Darka (HR)
GERRITSEN Lonne (NL)
DUH Darja (SI)
LOW Andrew (UK)
Alternate members
GÜNNEWIG Kathrin (DE)
Flexible members
HORNEK-GAUSTERER Romana (AT)
BURMISTROVA Anastasia (BE)
VOGEL Birte (DK)
ILMARINEN Kaja (EE)
KAUKONIEMI Sanna (FI)
DOLINSKA Tatiana (PL)
FRANK Ulrike (SE)
ROSSIER Nadine (CH)
Rapporteurs
BOITIER Caroline (FR)
AAMODT Solveig (NO)
Experts
RYDMAN Elina (FI)
DONS Christian (NO)

ECHA Staff
SZYMANKIEWICZ Katarzyna (Chair)
PRIHA Outi
CIOATA Nadia
STASKO Jolanta
Applicants
Lanxess
Sumitomo
Endura
Pareva
Vitfoss/Stormoellen
Stakeholders
COGNAT Flore (CEFIC)
ASHWORTH David (CEFIC expert)
MORENO Mara (AISE expert)

Environment WG

Core members
CHION Béatrice (FR)
ALEXANDRE Stéphanie (FR)
PETERSOHN Eleonora (DE)
FREIN Daniel (DE) – Rapporteur
REDMOND Aisling (IE)
OKKERMAN Peter (NL)
LANE Clare (UK)
Flexible members
PUERGY Reinhild (AT)
MARCA A Maria (CH)
AESCHBACHER Michael (CH)
CORDUA Brigitte (DK)
PASANEN Jaana (FI)
AAMODT Solveig (NO) - Rapporteur
HADAM Anna (PL)
VIANNA Bruno (PT)
SAFHOLM Moa (SE)
Advisors / Experts
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PAREVA
Sumitomo
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ASOs
COGNAT Flore (CEFIC)
MASON Paul (CEFIC expert)
ECHA Staff
SCHIMMELPFENNIG Heike (Chair)
GUTIERREZ Simon (Vice-Chair)
LIPKOVA Adriana
NOGUEIRO Eugenia
LAITINEN Jaana
WEBER Jan
RODRIGUEZ UNAMUNO Virginia
SCHAKIR Yasmin