WG-V-2015

Final minutes

29 January 2016

Minutes of WG-V-2015

23 – 27 November 2015

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

Minutes of Analytical methods and physico-chemical properties WG

WG-V-2015 (23 – 24 November 2015)

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. CEFIC was present as accredited stakeholder organisation (ASO). 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 endorsement 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. In particular ECHA explained that R4BP should be used for exchanging documents from February 2016 onwards.

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. The following additional items were included.

- Monitoring methods for relevant impurities
- Technical equivalence assessment of new sources
- Applicability of new guidance
- Renewal of anticoagulants
- Meeting arrangements

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

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

5. Agreement of the draft minutes from WG IV 2015

Comments on the active substances Tolylfluanid, Cuprous oxide, Copper granulated, Copper flakes coated and the general agenda items were received. The minutes have been modified accordingly. The modified minutes were agreed.

6. Follow-up's of previous working group meetings

6.1 WG IV 2015 – In-situ generated substances – data requirements for APCP

The WG members discussed the requirements for precursors used for in-situ generated biocidal active substances. The discussion focused solely on the analytical and compositional information requirements.

Document will be updated and incorporated in the Technical Agreements for Biocides (TAB) (drafting in progress).

6.2 WG IV 2015 – Requirements for certificates of analysis (CoA)

The WG members discussed the requirements for certificates of analysis.

The document will be updated and incorporated in the Technical Agreements for Biocides (TAB) (drafting in progress).

6.3 WG IV 2015 – Polymer identification for biocidal active substances

The chair informed the working group members that the received comments go beyond the competence of the working group and would require an official guidance procedure in coordination with REACH for which the resources are not available at ECHA. Hence, ECHA withdrew the document.

6.4 WG III 2014 – Technical equivalence assessment of Chrysanthemum cinerariaefolium extracts

Please refer to the minutes of the substance. The working group could not agree whether the compositions of the substance from different sources can be regarded as technical equivalent. Hence, the decision is forwarded to the human health and the environment working groups.

7. Discussions of active substances

7.1 Peracetic acid generated from tetraacetylethylenediamine (TAED) and sodium percarbonate (SPC)

The WG members discussed the relevance of the information submitted by the applicant on the two precursors sodium percarbonate (SPC) and Tetraacetylethylenediamine (TAED) of the active peracetic acid produced in situ to derive the specifications. Based on the proposal by the eCA, the WG agreed that the available information was not sufficient to derive the specifications. Therefore, following information needs to be submitted by the applicant.

TAED:

- TAED was not regarded as a commodity chemical. Therefore, 5 batch analysis need to be provided (closure 99%) on the crude TAED.
- In addition, exhaustive list of possible coatings should be provided.

SPC:

- SPC was regarded as a commodity chemical. Therefore, certificates of analysis (CoAs) need to be provided.
- Active oxygen and heavy metal content should be measured. Conversion from measured active oxygen to SPC should be provided.
- Similarly to TAED, exhaustive list of coatings should be provided.
- Level of hydration should also be included.

The applicant should provide the information by the 30th April 2016. E-consultation among the WG members will be launch before the relevant BPC meeting to agree on the specifications proposed.

7.2 Bacillus thuringiensis subsp. Kurstaki

Please refer to the minutes of the substance. Further information on analytical methods should be provided six months before the date of approval. All other points are closed.

7.3 p-Chloro-m-cresol (CMK)

Please refer to the minutes of the substance. Further clarification on the partition coefficient between n-octanol and water will be provided by the applicant six months before the approval date.

7.4 Calcium oxide / burnt lime

Please refer to the minutes of the substance. All points are closed.

7.5 Calcium dihydroxide / hydrated lime

Please refer to the minutes of the substance. All points are closed.

7.6 Calcium magnesium tetrahydroxide / hydrated dolomitic lime

Please refer to the minutes of the substance. All points are closed.

7.6 Calcium magnesium oxide / dolomitic lime

Please refer to the minutes of the substance. All points are closed.

8. Any other business

8.1 Active substance definition of Didecyl dimethyl ammonium carbonated mixed with unsweetened fruit juice

The WG discussed, upon request of one of the members, on active substance definition for two new biocidal products. Based on the information provided to the eCA by the applicant and following REACH naming convention, the WG members identified a least two active substances

1. reaction products of Didecyl dimethyl ammonium carbonated with extract (juice)
2. reaction mass of Didecyl dimethyl ammonium citrate and Didecyl dimethyl ammonium ascorbate

WG also agreed that the extract required a more precise characterisation.

8.2 Propiconazole – TE assessment contacted by Finland

The chair informed the working group members that the final assessment of technical equivalence for Propiconazole was provided by Finland. The document was uploaded on S-CIRCABC.

Additional agenda points

- **Monitoring methods for relevant impurities**

  The working group discussed the need of monitoring methods for relevant impurities generated during product storage. The WG members agreed:

  - In case relevant impurities are generated during storage a fully validated and specific analytical method needs to be provided and data on the storage stability
  - In case no relevant impurities are generated no analytical methods needs to be provided but a test on storage stability is (always) required.

- **Technical equivalence assessment of new sources**

  The working group members requested clarification where the assessments on Technical Equivalence (TE) are stored and accessible.

  - The assessment reports on TE conducted by the members states under the BPD are stored under the S-CIRCA BC at the folders – Biocides TM – CA reports (either review programme or new active) – active substance – Technical Equivalence
  - The assessment reports on TE conducted by ECHA under the BPR are stored in R4BP under the process (TE-APP), substance name and the case number.

- **Applicability of new guidance**

The applicability of new guidance is also discussed at the other working group. The BPC meeting in December 2015 will agree on the procedure.

- **Renewal of anticoagulants**

  Chair informed the WG members that discussions about the renewal of anticoagulants rodenticides have been started. In this context the most important issue is the setting of "missing" reference specifications which should be conducted in a parallel process to the actual approval and opinion making process.

- **Meeting arrangements**

The WG members ask for clarification on the meeting dates for 2016. The dates are already published on the ECHA website and are scheduled as follows:

- 25 January 2016 (virtual meeting)
- 14 and 15 March 2016
- 23 and 24 May 2016
- 19 and 20 September 2016
- 21 and 22 November 2016

8.3 Lessons learnt

The chair reminded to keep the deadlines for the providing documents for the meeting. In particular registration of the working group members and the applicants should be provided two weeks before the meeting at the latest.

Minutes of Human Health WG

WG-V-2015 (23-25 November 2015)

1. Welcome and apologies

The Chair welcomed the participants indicating that seven core members and 15 flexible members were present. One accredited stakeholder organisation (CEFIC) was present. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

The next meeting WG-I-2016 in January will be arranged as a virtual meeting. The provisional meeting dates for 2016 are available in S-CIRCABC.

R4BP 3 will be used for active substances in communication with applicants and eCAs starting 29 February 2016.

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-IV-2015

The minutes were agreed without comments.

6. Discussion of active substances

6.1 Limes (eCA UK) PT 2, 3

The WG discussed the use of assessment factors in the derivation of toxicological reference values, as well as open questions on human exposure assessment. All discussion items were closed and the dossier will proceed to the Biocidal Products Committee.

6.2 p-chlorocresol (CMK) (eCA FR) PT 1, 2, 3, 6, 9, 13

There were multiple discussion items on the derivation of toxicological reference values and human exposure. All points were closed and the dossier will proceed to the Biocidal Products Committee.

6.3 1,2-benzothiazole-3(2H)-one (BIT) (eCA ES)

Early WG discussion

The discussion concerned the effects assessment only. The main discussion concerned the derivation of toxicological reference values, as well as the waiving of some of the core data set. The WG concluded that based on the effects assessment, the risk characterisation should be performed for both systemic and local effects.

6.4 Bacillus thuringiensis subsp Kurstaki (eCA FR) PT 18

All discussion items were closed and the dossier will proceed to the Biocidal Products Committee.

6.5 Technical equivalence assessment of *Chrysanthemum cinerariaefolium* extract and pyrethrins (eCA ES)

The WG was not able to reach a conclusion but further clarifications were requested from the applicants.

7. Technical and guidance related issues

7.1 Update on guidance development

SECR informed that the first revision of guidance volume V on active micro-organisms is being planned due to the open issues identified during the development of the document. A Partner Expert Group will be nominated and consultations will be performed early 2016.

The revised guidance on human health risk assessment Volume IV Part B was published 13 October 2015 together with the *Biocides human health exposure methodology* document. These documents are available as follows:

- Volume IV Part B : http://echa.europa.eu/web/guest/guidance-documents/guidance-on-biocides-legislation
- Biocides human health exposure methodology: http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/human-exposure

A dedicated Working Group is expected to provide a draft Guidance on disinfectant by-products during 2015. When available, the draft will be provided to the Human Health WG members via S-CIRCABC and is expected to be discussed at WG-I-2016. The aim of this discussion will be to conclude whether there are any major reservations and whether the draft is seen as adequate as the starting point for the ECHA Guidance procedure including a Partner Expert Group (PEG).

7.2 Update on Ad hoc Working Group – Human Exposure (HEAdhoc)

SECR informed that the eight recommendations agreed so far by the Working group are publicly available on the ECHA website.

The recommendations currently under preparation or consolidation by the HEAdhoc concern the following:

- The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling: as a follow-up of the discussion at the WG-III-2105, the main differences between PT 7 and PT 8 products are being clarified. The recommendation will be consolidated based on this information and is planned to be presented at the WG-II-2016.

- Product application amount for repellents – exposure assessment: the finalisation of this recommendation should take into account the outcome of the discussion on harmonized risk mitigation measures for repellents containing products within the Coordination Group. Discussion is ongoing within the HEAdhoc regarding the two issues of technical relevance identified for further investigation. The outcome of the discussion will be forwarded to the Coordination Group for elaboration on regulatory and policy aspects.

- The scenario of hand disinfection: the recommendation is planned to be presented at the WG-I-2016.

7.3 Technical Agreements for Biocides (TAB)

The SECR presented a proposal for a new entry into the TAB concerning the interpretation of dermal absorption studies performed for antifouling products. The WG in general agreed with the proposal, but a commenting period until 16 December 2015 was launched to ensure the coherence of the text.

The first revision of TAB is expected to be provided for a 6-week commenting period in January 2016.

8. Any other business

8.1 Planning 2016

SECR introduced the document that presented a scheme for work sharing among MSCAs, as well as some general proposals, that are aimed to ensure efficient handling of substances to be discussed at WG meetings during 2016. The members in general agreed with the principles presented. The document was subjected to commenting by MSCAs by 16 December 2016, after which a revised document will be distributed.

8.2 Other information & lessons learned

Union authorisation

A presentation was given to highlight the current status and future perspectives of the Union authorisation. Awareness was raised on the critical aspects of the process, with particular emphasis on the short timelines, and some workable solutions were proposed to ensure efficiency.

A newsgroup was opened in S-CIRCABC for the WG members to provide input and proposals in view of the revision of the working procedure for Union authorisation. The deadline for providing comments in the newsgroup is 16 January 2016.

Renewal of anticoagulant rodenticides

SECR informed the members of a virtual meeting held with ECHA, COM and the eCAs for anticoagulant rodenticides on 5 November 2015. All eCAs indicated that evaluations will be "limited" and not "full".

Regarding the human health risk assessment, the most important agreements were that the lists of endpoints will be updated only if new studies are available, and that the exposure and risk assessments would not be revised. It was stressed that this approach is specific for the unique situation of the anticoagulant rodenticides and it should not be considered as setting a precedent for the renewal of active substances in general.

Backlog project

SECR informed that ECHA has launched a project to identify problematic substances among the backlog dossiers, in order to find appropriate solutions in advance. The aim would be to ensure that these dossiers are fit for BPC discussion, avoiding the need to send dossiers from BPC back to WG meetings, as this would result in delays and unnecessary additional work.

Harmonising CAR & CLH report templates

SECR reported of the action that is follow-up of the March 2015 workshop on reviewing the active substance assessment process.

A discussion group for the purpose of harmonisation of CAR and CLH report templates will be established during Q1 2016 with a goal to develop a template that is applicable for both CLH and biocides processes. An invitation will be sent to all MSCAs. During 2016 ECHA expects to organise virtual meetings and teleconferences, as well as possibly one workshop. The work will be performed in collaboration with EFSA which has a similar group working on the harmonisation of DAR and CLH report templates.

Minutes of Efficacy WG

WG-V-2015 (25-26 November 2015)

1. Welcome and apologies

The Chair welcomed all participants to the ninth Efficacy WG meeting. There were six core members and one alternate member who participated in the meeting. In addition, eight flexible members and 2 ASO representatives participated to the EFF WG meeting. The Chair introduced also representatives of ECHA.

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

The SECR gave a brief summary on the administrative issues and informed the WG members of the R4BP 3 status.

3. Agreement of the agenda

The Chair introduced the agenda items; no additional agenda items were added.

Conclusions and actions

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-IV-2015

The WG members agreed on the minutes of WG-IV-2015 meeting.

6. Discussion of active substances[1]

6.1 Status of the ad hoc follow-ups

SE informed that there is no new information concerning silver zinc zeolite. SE is in contact with the applicant.

6.2 Bacillus thuringiensis subsp. Kurstaki (eCA FR)

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 WG agreed on the evaluation of the eCA.

6.3 Limes (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.

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

The WG agreed on the evaluation of the eCA of all lime compounds, i.e.

- Burnt dolomitic lime (CAS 37247 – 91 - 9) – PT 2, 3;
- Burnt lime (CAS No. 1305-78-8) – PT 2, 3;
- Hydrated dolomitic lime (CAS No. 39445-23-3) – PT 2, 3;
- Hydrated lime (CAS No. 1305-62-0) – PT 2, 3.

6.4 CMK (eCA FR)

There were two remaining open points in the discussion table. The first concerned extrapolation of the efficacy tests performed in accordance with EN 1276 and EN 13697 for surface application in private areas into surface application in hospitals. EFF WG agreed to extrapolate these results into surface application in hospitals under clean conditions. Additional tests according to the claims should be provided at the product authorisation stage.

The second issue concerned questionable growth of the microorganisms in the unpreserved sample. The eCA provided a presentation and described in details the results presented in the CAR. The EFF WG members agreed to accept the presented results at the active substance approval stage as the test was performed before the PT6 guidance has been published. However it was indicated that applicants should be aware that unpreserved samples should not be inoculated by to high inoculation rate. Additional information should be provided at product authorisation stage.

7. Guidance

7.1 General update on guidance.

The Guidance Unit presented briefly an overview of the ongoing status of Volume II 'Assessment and Evaluation (Parts B+C)'. Three work packages (WP) were introduced:

- WP1: PTs1-5; PEG consultations are almost concluded, text for sections 1-5 is agreed, preliminary text for section 6 will be replaced by the text elaborated during ECHA Disinfectant Project. CA consultation will be launched by mid of December 2015 with the end of commenting period mid-January 2016.
  In relation to appendices 1 and 4, they will be published separately from the main guidance document in order to make them more accessible for changes. The direct links to the respective appendix will be provided in the guidance. This part is foreseen to be published March/April 2016.;
- WP2: Part B and Part C: drafting and consultation + WP3: Publication of Volume II: mainly editorial changes done by ECHA. For these WPs provisional timelines are foreseen: PEG consultation in January/February, PEG meeting in March and CA consultation in June/July. This part is foreseen to be published in September 2016.

Status of PT specific guidance documents was presented by the Chair. In the upcoming PEG procedure in 2016 it is proposed to include the following guidance documents: revised version of PT8 guidance, PT14, PT18/19, PT 21 and PT 22.

For the remaining part a separate PEG procedure will take place, possibly in autumn 2016.

7.2 Continuous work on Efficacy Guidance Part B/C.

A new version of the document 'Volume II Part B/C: Efficacy assessment and evaluation' had been circulated by the SECR prior to the meeting. The Chair informed the EFF WG members that there is no intention to discuss comments already introduced in the text, they may be discussed on request but the discussion will focus on comments in the bubbles, which will be discussed one by one.

Regarding general issues the glossary will be added to the document possibly before the next EFF WG meeting in January 2016.

Chapter 2: Label claim.

A new text of this chapter was prepared by UK and introduced shortly before the meeting. It was agreed that comments on that part will be sent by 18/12/2015 and it will be discussed again during next EFF WG meeting in January 2016.

Chapter 3: General considerations for the development and reporting of efficacy data.

At the beginning of this chapter clarification was added that it is related to active substances and biocidal products.

The text was slightly revised in relation to control tests, materials and methods, deviations concerning standard tests protocols and conclusions concerning field tests. This chapter is considered as agreed and for the time being will be 'frozen' for comments until the finalization of the remaining parts.

Chapter 4: Active substance approval.

ECHA will discuss internally if a statement concerning a full data package for a biocidal product in support of the label claims is needed in the BPC opinion and based on the outcome it may be reflected in the guidance. In the section 4.5: Treated articles a general remark will be added to emphasise that, if at the active substance approval stage the only representative product is a TA, at least one of its claim has to be proven as for biocidal product with an example use, as it was discussed and agreed with the COM.

Chapter 5: Product authorisation

In section 5.1 the sub-section 5.1.2 was deleted.

Section 5.2: Product families will be revised by NL taking into account received comments and WG discussion, mainly in relation to target organisms and different uses in the meta-SPC.

Section 5.3: Treated Articles will be revised by SE, taking into account taking into account received comments and WG discussion, some examples will be added to the text and distinction between requirements for active substance approval and product authorisation stage will be made. In addition the definition of material in accordance with OECD guidance will be provided. Some comments made by NL will be discussed bilaterally between SE and NL.

<u>7.2.a Appendix documents for PT 1-4</u>

Appendix 1. Some doubts arose in relation to references to anti-odour claims in this appendix. It is not clear if anti-odour claim should be assigned for PT2 or only for PT9. As it concerns also some sections in the main PT1-5 guidance ECHA will check with the COM the proper classification. It was also indicated that headings in different columns are incongruent with the fields in the SPC editor. It was proposed to add additional cell above first four cells with the heading 'claims'.

For information: COM confirmed that anti-odour claim is also relevant not only for PT9 but also for other PTs.

Appendix 4. At the beginning of the discussion on appendices NL clarified that a new version of Appendix 4 has been sent to ECHA Guidance Unit shortly before the EFF WG meeting. In comparison with the previous version it contains more uses placed in separate sections. As it is a standalone document some changes e.g. note to the reader has been added by ECHA.

Appendices 1 and 4 will be sent for comments and proposals for final conclusions by 18/12/2015.

Appendix 6 is currently put on hold and it will be reviewed (if necessary) when the Disinfectant Project is finalised.

7.2.b Efficacy testing of treated articles - (health) claim matrix

The working document has been prepared by SE. During the meeting SE made a brief introduction explaining that the purpose of this claim matrix is to set up some performance standards to show efficacy of the treated articles with the health claims. One of these claims should be then proven at active substance approval stage as for biocidal product with an example use. In the presented table claims were divided into three groups, i.e. 1) Materials with inbuilt disinfection properties (like bed-site table), 2) Biocidal products with the purpose of treating materials, surfaces or articles and adding disinfective properties to that material, surface or article after drying (like coatings) and 3) Biocidal products applied onto a carrier material and placed on the market together with the carrier (like disinfecting wipes, clothes impregnated with insecticide).

WG members made few comments indicating that the third part should be written in different way not to address impregnated wipes with biocidal claim, in relation to different claims i.e. hypoallergenic and hygienic claims as not relevant for biocides, and antimicrobial as to broad (general) claim. Log 3 reductions were accepted as to be feasible, however it was indicated that log reduction has to be specified for different types of organisms. It would be also pragmatic to mention that the claim should be substantiated for certain amount of time, e.g. in case of clothes, how many times they can be washed still having biocidal activity.

As this document was discussed the first time it was agreed that SE will revise it taking into account the EFF WG discussion and send the updated version before next EFF WG meeting in January 2016.

7.2.c Guidance on Efficacy Assessment for PT8 (Wood Preservatives) – FR proposal for revision

FR introduced the proposed changes in PT8 guidance. The first proposed amendment concerned alignment of the guidance requirements to the EN 599-1:2014. One general remark was made in relation to applicability of new/revised guidance document. During the discussion the WG members proposed to clarify that mentioned in the text all relevant specific beetle species refer to *H. bajulus*, *L. brunneus* and *A. punctatum* and add this information in parenthesis. Also the phrase 'most resistant' would be better to replace by "less tolerant" or "less susceptible". ECHA informed that a written comment was sent by IND shortly before the meeting and it should be taken into account by FR when revising the guidance.

It was also clarified by FR that until now, for a claim against wood boring beetles, the available data (mainly French certification) considered with the current active substances on the market that *Hylotrupes bajulus* was the less sensitive target. It appears this position is not always verified anymore in the submitted dossiers, reason why this revision is proposed to be in accordance with EN 599.

The second amendment concerned curative treatment against dry rot (*S. lacrymans*). FR proposed to delete from section 2.3 a part of the sentence related to ENV 12404 (as well as form Table 11) and as it is a preventive and not curative treatment. Instead of this new short section 2.2.5 concerning treatment against *S. lacrymans* will be adedd.

WG members agreed with FR proposal. The revised version of PT8 guidance will be sent by FR before WG meeting in January 2016 for agreement. Then it will pass the PEG procedure and will be incorporated into Volume II (part B+C). AT will check DIN 68 800-4 standard if it is used for *S. lacrymans*, and if yes it may be sent to FR in a way to add it to the list of norms for wood preservatives.

7.2.d Future work on PT5 guidance

This agenda item was skipped because the contract between ECHA and Contractor has not been signed yet.

7.3 Conversion of a frame formulation into a Biocidal Product Family - problems regarding efficacy of PT8 products

DE presented an example case study related to efficacy of PT8 products in case a conversion from FF into BPF takes place. Regarding efficacy, in the presented case study the conversion allowed authorizing a biocidal product without efficacy assessment with much higher pigment content than the representative product for which efficacy has been proven. It was agreed that DE will prepare an information and it will be communicated DE to the CG.

7.4 Practical tests for teat disinfectants in PT 3 - preliminary results (closed session)

This discussion concerned ring trials performed for phase 2, step 2 tests for teat disinfectants. Based on submitted information the EFF WG agreed that:

- for post-milking disinfection log 4 reduction is required;
- for pre-milking disinfection contact time 30 sec. and log 3 may be accepted, if justified;

Soiling conditions should be reflected in the test in accordance with the efficacy PT 1-5 guidance document.

FR highlighted also that the results of the different controls expected in the protocol should be added to ensure the validity of the results.

In addition during this closed session SPC editor issue in relation to target organisms was signaled by NL. As this point was not in the agenda items it was agreed to discuss it during next EFF WG meeting in January 2016.

7.5 Efficacy evaluation of repellents (closed session)

A test describing some conditions and criteria for efficacy evaluation of repellents against cats had been submitted by AT. EFF WG pointed out that some information is missing in that test, however in general agreed that it is a good base for future revision of PT19 guidance.

AT offered to organise a PT19 workshop in Vienna in spring 2016, what was supported by the EFF WG members.

7.6 Evaluation of applications for Union authorisations

A presentation was given to highlight the current status and future perspectives of the Union authorisation. Awareness was raised on the critical aspects of the process, with particular emphasis on the short timelines, and some workable solutions were proposed to ensure efficiency.

A newsgroup was opened in S-CIRCABC for the WG members to provide input and proposals in view of the revision of the working procedure for Union authorisation. The deadline for providing comments in the newsgroup is 16 January 2016. The WG members have been informed accordingly via e-mail.

7.7 Renewal of anticoagulant rodenticides

ECHA informed that virtual meeting concerning renewals of anticoagulant rodenticides was organised in November between ECHA, COM and the eCAs. During this meeting all eCAs indicated that the evaluations will be "limited" and not "full" in accordance with Article (2)(2) of the BPR. Targeting discussion will take place during EFF WG meeting in January 2016 in relation to efficacy and resistance of these substances.

ECHA will send in advance to the EFF WG members a report on RMM.

8. AOB

8.1 Other information, questions & lessons learned

This agenda item was skipped because of time limitations.

Minutes of Environment WG

WG-V-2015 (25-27 November 2015)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were six core members, one alternate member and thirteen flexible members present. Three WG members were participating for AP. 7 via WebEx. In addition four rapporteurs and three experts where present in the meeting. Four representatives from three accredited stakeholder organisations (CEFIC, CEPE and AISE) were present as well for AP. 7. Applicants were present 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.

2. Administrative issues

The housekeeping rules were provided to the participants.

The following administrative issues were communicated:

- DSA related to meeting participation will be paid from January 2016
- WG-I-2016 meeting in January will take place via WebEx
- The meeting participants were reminded to provide for the future meetings via Webropol registration page all required data and that signed declarations are needed from all new advisors/rapporteurs
- R4BP3 will be introduced for communication with applicants and eCAs from 29 February 2016
- The MSCA manual will be updated and sent to eCAs in mid-January 2016
- S-CIRCABC migration was successful and the platform is running smoothly; submissions folder to be used for CARs

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the WG members to provide any additional items. No additional items were proposed.

The Chair further informed that the Item 8.3 (information on Soil RA workshop) was removed from the agenda and will be presented in WG-I-2015 in the frame of the discussion on revision of Vol IV Part B. Instead SECR will provide some information on Union authorisation under a new item 8.3. In addition, the items for discussion will be considered first and the items for information at the end if time allows (i.e. items 7.1, 6.1 will follow at the end between items 8.2 and item 8.3) due to many open points for discussion.

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.

The Chair explained that the Deputy-Chair has a conflict of interest with one active substance and the Chair has a conflict of interest with two active substances. Therefore

the Deputy-Chair and additional person will chair the sessions of the respective active substances.

5. Agreement of the draft minutes from WG-IV-2015

The Chair informed that comments were received for item 6.3. and the general minutes. The minutes with this amendment were adopted.

6. Discussion of active substances[2]

6.1 Status of ongoing Ad hoc follow-ups (ECHA)

The Chair provided an overview on the status of ongoing (ad-hoc) follow ups for five active substances.

6.2 1,2-benzothiazole-3(2H)-one (BIT) (eCA ES) - early WG discussion

Two points out of seven could not be agreed by the WG. For this point, a **follow-up** was concluded necessary. The results of this follow-up will be included in the CAR before the start of the commenting period.

Action eCA: to prepare the follow-up in collaboration with SECR. eCA to update the CAR based on the outcome of the follow-up accordingly.

6.3 Technical equivalence assessment of Chrysanthemum cinerariaefolium extract and Pyrethrins (eCA ES) - early WG discussion

Three points out of six could not be agreed by the WG. For this point, a **follow-up** was concluded necessary. The results of this follow-up will be included in the CAR before the start of the commenting period.

Action eCA: to prepare the follow-up in collaboration with SECR. eCA to update the CAR based on the outcome of the follow-up accordingly.

6.4 (p-chlorocresol (CMK) (eCA FR) - PT 1, 2, 3, 6, 9, 13

One point out of thirteen could not be agreed by the WG. For this point, an ***ad-hoc* follow-up** was concluded necessary. eCA to initiate the ***ad-hoc* follow-up** in collaboration with PL and SECR. The results of this *ad-hoc* follow-up will be included in the updated CAR before proceeding to the Biocidal Products Committee.

Action SECR:

- Comparison of PEC and PNEC (initial/TWA) to be taken up as high priority point in the first revision of Vol IV Part B (to be started at the beginning of 2016).
- Prepare a TAB entry on the default value of the Freundlich isotherm taking into account the new PPP guidance.

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

6.5 Limes (eCA UK) - PT 2,3

- **Calcium oxide/lime/burnt lime/quicklime**
- **Calcium dihydroxide/calcium hydroxide/caustic lime/ hydrated lime/slaked lime**
- **Calcium magnesium tetrahydroxide/calcium magnesium hydroxide/hydrated dolomitic lime**
- **Calcium magnesium oxide / dolomitic lime**

The Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee.

Action SECR/WG: The text for the PNEC derivation for soil should be review in the frame of the first revision of Vol. IV Part B.

6.6 Bacillus thuringiensis subsp Kurstaki (eCA FR) - PT 18

The Working Group members agreed on the evaluation of the eCA. The eCA can prepare the updated CAR and proceed to the Biocidal Products Committee.

Action SECR: An entry will be included in the TAB further clarifying the most relevant unit to be used for the assessment for microorganisms producing toxins (taking into account already available guidance).

7. Technical and guidance related issues

7.1 Update on guidance development, issues identified for the AHEE and e-consultations (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.

SECR will initiate a third request for volunteers for issues identified for the AHEE. Remaining open items will then be distributed by SECR between the AHEE members.

It was further highlighted that it was important to develop the scenarios for RTU products (PTs 2-4) at least one year after approval of relevant actives and not only when product authorisation starts. ASOs expressed that IND is willing to provide support in the development of these scenarios.

Actions:

- Environment Substances of Concern (SoC): **DE** to provide the document to SECR, **SECR** to create a dedicated newsgroup in S-CIRCABC for the commenting
- PT 21 - How to use data on background concentrations in the env. risk assessment: **SECR** to further clarify with UK (who raised the point) the background of the item.

7.2 AHEE consultations/recommendations:

7.2a PT 6.1: Amount of disinfectant for laundry + PT 6: Harmonisation of the daily emission from fabric washing (FR+NL)

Follow-up WG-IV-2015

Conclusion: The WG members agreed that the values proposed by NL should be used and that the method used to derive the default value for N_{wash} was acceptable.

The following equation to derive the detergent consumption per household and per day was agreed: $[N_{wash} * F_{liquid} * DOSE_{liquid}] + [N_{wash} * DOSE_{fabricsoftener}]$, with:

N_{wash} = the number of laundry washes per household per day (proposed 0.61)

F_{liquid} = the fraction of washes performed with liquid laundry detergents (proposed 0.60)

$DOSE_{liquid}$ = the dosage of liquid laundry detergents (75 mL)

$DOSE_{fabricsoftener}$ = the dosage of fabric softeners (40 mL)

In addition, the proposal for a total quantity of preserved detergent for dishwashing is 7.2 mL per household per day = 2.9 mL per inhabitant per day was agreed. This new value considers the fact that only liquids are preserved and the higher consumption of solid detergent for machine wash.

Action NL/DE: NL will finalise the recommendation taking into account the conclusion of the WG and one proposal from IND for re-phrasing (i.e. "AISE figures are lower than the average values"); DE will update the ESD for PT 6 accordingly.

7.2b PT 18: Draft recommendation PT18 manure (NL)

The first consultation of the Ad hoc Environmental Exposure WG (AHEE) was launched at September 29, 2014 and discussed during WG-V-2014. Following the WG discussion, DE and NL met bilaterally on April 23, 2015, as proposed by ECHA, to discuss the consultation and propose answers to the consultation. Based on the results and agreements of the bilateral meeting, the two questions from the consultation are answered and for each question, a proposal for an amendment of the existing OECD ESD PT18 No. 14 (2006) is presented in the recommendation.

The draft recommendation was commented by AHEE members, the following remaining open items were summarised in a discussion table (DT) and concluded by the WG:

- *DT No. 1: Section 1.2.4 Calculation of Napp-bio$_{manure}$ in the ESD*

  Conclusion: A new arable land scenario was proposed. The WG members agreed to the proposed methodology.

- *DT No. 2 + 3: Section 2.3.2 Rounding (covering also Section 2.3.3 Implications for Napp-manure$_{gr}$)*

  NL further responded to a UK comment (saying that the disadvantage of rounding off at one decimal place is that it would lead to an unrealistic number of applications): the advantage is that degradation in manure can be more easily factored in for grassland since an average time for manure storage is calculated. In addition NL stated that rounding up can result in over-dosing. FR stated that since for arable land there is only one storage period, the approach may be less appropriate and zero decimal place should be used. IND supported the rounding to one decimal place for both, grassland and arable land. DE preferred not having different calculation routines for grassland and arable land and was of the opinion that rounding off to one decimal place is the most realistic approach.

  Conclusion: The WG agreed to use for arable land as well as for grassland the following procedure: rounding off at 1 decimal place in the calculations.

- *DT No. 4: Section 3.1 Equation to calculate PIECs*

  Conclusion: This point was provided only for information and initial discussion, not for agreement, since it is already a priority item to be taken up in the first revision of Vol. IV Part B (scheduled for 2016).

  Action: SECR/WG

- *DT No. 5: Section 3.2 PIEC calculation – mixing depth*

  Following a question of IND, SECR further explained that the soil depths for sewage sludge and manure depositions have been reconfirmed by the WG members at WG-V-2015 and referred to the respective TAB entry (ENV 73). IND further pointed out different new application methods which are not reflected in the OECD ESD.

  Conclusion: The WG agreed to include soil depths in ESDs differing from those provided in Vol. IV Part B in an overview table in the revised Vol. IV Part B together with explanations (in the frame of the first revision).

  Action: SECR

  In addition, the WG members did not see a need to revise the differing depth provided in the ESD for PT 18 compared to Vol. IV Part B.

- *DT No. 6: Section 3.2 PIEC calculation – degradation in manure*

  UK stated that taking into account degradation may become important in the future as further refinement, which was confirmed by other WG members.

  Conclusion: The WG agreed to open a new item for the AHEE to develop equations taking into account degradation in manure.

  Action: SECR/AHEE

  SECR further noted that in light of the work programme for the next year with a focus on substances in PT 18, the conclusions drawn for this recommendation should nevertheless remain valid.

- *DT No. 7: Section 3.6 Use of PIECs in (groundwater) risk assessment*

  Proposal of NL to use initial PEC as Tier 1 and was supported by WG members. FR asked on how secondary poisoning can be further refined in a second tier since no simulation tool exists as for the groundwater assessment.

  Conclusion: For groundwater exposure assessment the initial PEC in soil should be used as basis for calculations (Tier 1). If needed, PEARL/PELMO can be used as higher tier to refine the assessment.

  In the frame of the first revision of Vol. IV Part B also secondary poisoning should be considered (possibility of refinement of the risk assessment in case initial values are used as basis for the assessment)

  Action: SECR

Action NL/SECR/eCAs: NL will finalise the recommendation and provide it to SECR. SECR to include the recommendation in the TAB. SECR to finalise the Excel Sheet for PT 18 including the above agreed changes and distribute first to NL and then subsequently to WG members for confirmation in order to provide a harmonised calculation tool. SECR to check with OECD TFB the possibility to clarify/revise the OECD ESD for PT 18 in the future.
Proposed way forward in case the eCA has already prepared the CAR for PT 18: Add the revised calculations taking into account the final recommendation as appendix to the RCOM/Discussion table (see example provided by FR for WG-V-2015).

7.3 Draft ESD for PT 6 (DE)

At the Technical Meeting IV/2011, the UBA (German Federal Environment Agency) informed the other Member States and the participating representatives from the industry that the UBA had initiated a R&D-project to further develop the evaluation method for the environmental emission estimation of in-can preservatives (PT 6) and that the consulting company SCC GmbH has been contracted by the UBA for this project.

In March 2012 a questionnaire was sent out to get input from MSCAs and industry experts.

In July 2015, the draft version of the revised ESD PT 6 (contractor SCC GmbH) was sent for commenting. Several comments were received which were compiled in a RCOM table. Comments which did not need any discussion are marked as closed and were integrated in the new draft as far as possible.

The following remaining open items were summarised in a discussion table (DT) and concluded by the WG:

- *DT No. 1: Table 1 (Sub-categories in PT 6 according to MOTA v.6) & Table 2 (Sub-categories in PT 6 covered in this ESD)*

  Conclusion: NL will provide a text proposal to DE for further clarification of uses which are not covered in the tables (tables focus on main categories).

  Action: NL

- *DT No. 2: Section 1.5, Table 3 (Overview on main scenarios for each sub-category and for the relevant life cycle stage)*

  Conclusion: The WG considered the scenario mentioned by NL (i.e. preservation of unrefined fuels) as relevant, it should be prepared in the future. For the time being it will be only listed as subject for further research in the draft ESD.

  The scenario will be added to the open issue list of the AHEE.

  Action: SECR/AHEE

- *DT No. 3: Section 2.3 (Disposal of the active substance and the biocidal product) / 3.5.4.1 (PT6.5 Fuels, emission scenario for formulation)*

  FR indicated that it is difficult the find the relevant value in the spERC tables and that the tables can be interpreted differently. NL further noted that in spERC values, RMM are already implicitly accounted for. Therefore a case by case discussion is needed if a spERC value is applicable also to biocides. IND explained that for spERCs also fact sheets with operational conditions are available which provide further information. UK asked for keeping records if it is deviated from default values provided in the A&B tables.

  Conclusion: For the assessment of biocides the A&B tables in Vol IV Part B should be used. On a case-by-case basis, default values in the A&B table can be replaced by values that are more specific provided in spERCs but such a replacement needs the agreement of the WG. Replaced default values agreed by the WG will be recorded in the TAB.

  Action: SECR

- *DT No. 4: Section 3.2 (PT6.2 Preservation of paints and coatings)*

  IND questioned the relevance of the scenarios for direct release. DE noted that there need to be a defined time by which further information (i.e. outcome of AHEE consultations) can be taken into account in order to finalise the ESD. CEFIC provided feedback on the internal commenting procedure, indicating that they need a certain time to combine comments from CEFIC members.

  Conclusion: Scenarios covering direct release to environmental compartments should be added. For soil, the house scenario should be added. For surface water, reference is made to the AHEE consultation on adding the city scenario to PT 8.

  The worst case scenario to be defined for surface water (bridge over pond or city scenario) should be added to the ESD for PT 6.

  In order to be able to proceed with the ESD for PT 6 for the time being only a reference to the AHEE consultation related to this issue will be included. The

outcome of the AHEE consultation will be added to the TAB and included at a later stage in the ESD for PT 6.

- *DT No. 5+8: Section 3.3. / PT 6.3 - Calculation of emissions from wet-end or other operations (taken over from WGIV2014_ENV_7.2c / Recommendation – Fbroke in PT 6.3) Section 3.3.1.4.2 Table 17 (Emission scenario for paper making (according to OECD ESD no. 23 (2009))*

  NL stated that it is not realist to set *Fpaper_making* to a value of 1. On the other hand using substance specific values from the OECD ESDs is also not applicable since they refer to additives used in paper processing as such. IND further explained that the fluids are usually collected and reused; assuming a value of 1 is unrealistic.

  Conclusion: The scenario provided in the ESD will be adjusted according to the scenarios/default values previously discussed and agreed for two active substances in PT 6.

  Action: DE

- *DT No. 6: Section 3.3.1.4 (PT 6.3.1 Paper production, Emission scenario)*

  IND explained that in the introduction of the BREF documents a summary on current techniques in industry is provided, which can provide further information for refinements. DK reflected on their experience using BREF documents in PT 8.

  Conclusion: The WG agreed to take into account additional information provided in BREF documents on BAT for the refinement of the risk assessment on a case by case basis. If such a refinement is not substance specific but in general relevant for a scenario, it should be added to the TAB.

- *DT No. 7: Section 3.3.1.4.2 (PT 6.3.1 Paper production, Emission scenario - Application phase)*

  Conclusion: It was agreed that a reasonable harmonised notation of the fraction of preservative should be $F_{in\text{-}can}$.

- *DT No. 9: 3.3.3. General (PT6.3.3 Leather production)*

  Conclusion: The scenario mentioned by NL (for leather additives based on data on additive consumption for different papers taken from OECD-scenarios) should be added to the list of subjects for further research, there is no need to include a new scenario in the ESD now.

  The currently available scenario should be checked if the proposed default values are in line with agreed default values and approach agreed for previous substance discussed in PT 6.

  Action: DE

- *DT No. 10: Section 3.3.3.1 (PT6.3.3 Leather production, Description of use area)*

  Conclusion: The WG agreed that the scenario for in-can preservation for tanning is relevant; the scenario should therefore remain in the ESD for PT 6.

- *DT No. 11: Section 3.3.3.4 Leather (PT6.3.3 Leather production, Emission scenario)*

  Conclusion: The scenario should be streamlined and adjusted with the conclusions taken for another substance in PT 6 with regard to the default values to be used for *Qactive* and *Fchemical*.

- *DT No. 12: Section 3.4 (PT6.4 Metalworking fluids)*

  Since there is no difference in the evaluation of a substance in PT 6 compared to PT 13, FR stated that using the ESD for PT 13 also for PT 6 is an acceptable approach.

Conclusion: The WG agreed to add only a reference to the new ESD for PT 13 in the ESD for PT 6 (reference to the latest version on the ECHA ESD webpage).

- *DT No. 13: Section 3.6 (PT6.6 Glues and adhesives)*

  Several WG members stated that the use is covered by paints and coatings, further refinement options were discussed (e.g. reducing the treated surface) as well as a tiered approach. Since the level of release is very small, the need for a scenario as such was questioned.

  Conclusion: The WG agreed not to have a separate scenario for glues and adhesives in the ESD for PT 6 since the area from which exposure could occur and the level of release is very small.

Actions:
- **Commenting MS** and **ASOs** to provide feedback on points DE has closed in the RCOM table by 16 December 2015.
- **SECR** to clarify (with COM) if human hygienic products are within the scope of the BPR or not.
- **DE** to update the ESD based on the conclusions of the WG meeting.

8. AOB

8.1 Planning 2016

SECR introduced the document that presented a scheme for work sharing among MSCAs, as well as some general proposals, that are aimed to ensure efficient handling of substances to be discussed at WG meetings during 2016. The members in general agreed with the principles presented. The document was subjected to commenting by MSCAs by 16 December 2016, after which a revised document will be distributed.

Action SECR/WG: SECR to include PTs in the overview table on work distribution between MS (if possible also distinguish between household/stable uses). SECR to upload the document in a dedicated Newsgroup in S-CIRCABC, WG members to provide comments by **16 December 2015**.

8.2 Other information & lessons learned

Concerning **"Other information",** the main items are provided in the following, all other items are provided in Appendix 2 below:

- *General information*

  The following actions are still planned to take place in 2015: An update of ENV entries in the TAB and the preparation of summary minutes covering WGs in 2014-2015.

  Concerning the AHEE, two separate meetings are planned for 2016: A physical meeting in April (⇒ 21-22 April - alternative meeting location in central Europe?) and a physical or virtual meeting in October.

  In the future e-consultations related to environmental issues will take place via a S-CIRCABC Newsgroups (⇒ new Interest Group "AHEE").

- *Renewal of anticoagulant rodenticides*

  SECR informed the members of a virtual meeting held with ECHA, COM and the eCAs for anticoagulant rodenticides on 5 November 2015. All eCAs indicated that evaluations will be "limited" and not "full".

  A targeted discussion on PBT assessment for actives where new data was provided will take place at ENV WG-I-2016 (⇒ difenacoum, coumatetralyl, flocoumafen).

Regarding the environmental risk assessment, the most important agreements were that the lists of endpoints will be updated only if new studies are available, and that the exposure and risk assessments would not be revised. It was stressed that this approach is specific for the unique situation of the anticoagulant rodenticides and it should not be considered as setting a precedent for the renewal of active substances in general.

- *Disinfectants project (PTs 3, 4, 5)*

  WG members/eCAs to provide feedback by 8 December on problematic issues you have identified with disinfectants (message to CAs to be sent by SECR).

  Action: WG/eCAs

- *Backlog project*

  SECR informed that ECHA has launched a project to identify problematic substances among the backlog dossiers, in order to find appropriate solutions in advance. The aim would be to ensure that these dossiers are fit for BPC discussion, avoiding the need to send dossiers from BPC back to WG meetings, as this would result in delays and unnecessary additional work.

- *Harmonising CAR & CLH report templates*

  SECR reported of the action that is follow-up of the March 2015 workshop on reviewing the active substance assessment process.

  A discussion group for the purpose of harmonisation of CAR and CLH report templates will be established during Q1 2016 with a goal to develop a template that is applicable for both CLH and biocides processes. An invitation will be sent to all MSCAs. During 2016 ECHA expects to organise virtual meetings and teleconferences, as well as possibly one workshop. The work will be performed in collaboration with EFSA which has a similar group working on the harmonisation of DAR and CLH report templates.

The following **"Lessons learned"** has been presented:

- Items for discussion at WG meetings to be provided to ECHA at the latest ten days before the start of the WG meeting week
  - This is also relevant for items related to study protocols or guidance documents
  - Items provided later will be only for information, not for discussion
  - Points for discussion also related to guidance documents/study protocols should be clearly indicated (e.g. in a discussion table)

Additional items raised by WG members
At WG-I-2016 the discussion of renewal of anticoagulant rodenticides in EFF and ENV WG should not take place in parallel.

8.3 Presentation on Union authorisation

A presentation was given to highlight the current status and future perspectives of the Union authorisation. Awareness was raised on the critical aspects of the process, with particular emphasis on the short timelines, and some workable solutions were proposed to ensure efficiency.

In addition, a newsgroup was open in S-CIRCABC for the WG members to provide input and proposals in view of the revision of the working procedure for Union authorisation. The deadline for providing comments in the newsgroup is 16 January 2016.

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List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MUEHLE Ulrike (DE)
SIX Therese (FR)
GATOS Panagiotis (EL)
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Rapporteurs
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Environment WG

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