WG-III-2015

Final minutes

30 September 2015

Minutes of WG-III-2015

1-3 June 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-III-2015 (1 June 2015)

1. Welcome and apologies

The Chair welcomed the participants indicating the presence of five core members. One accredited stakeholder organisation (ASO) 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 endorsement of the minutes. The recording is not released to anybody outside ECHA and any further recording is not allowed.

2. Administrative issues

Presentations on the virtual meeting tool, the 'Secure-CIRCABC' Project and concluding procedure at working group level were provided by ECHA for the information.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. One additional item was included:

- Evaluation of storage stability studies introduced for product authorisations

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 2015

Three comments on Carbendazim and TMAC were brought forward. The minutes have been modified accordingly. The modified minutes were agreed.

6. Discussion of active substances

6.1 Silver zinc zeolite

Please refer to the minutes of the substance.

6.2 Bacillus amyloliquefaciens

Please refer to the minutes of the substance.

6.3 Formaldehyde

Please refer to the minutes of the substance.

7. Iodate stabiliser or active substance

The working group discussed the issue whether iodate and iodide present in a biocidal product shall be regarded as stabiliser for iodine present in the biocidal product as active substance.
It was concluded that four cases need to be distinguished:

1. IO_3^- + I^- without I_2
   The biocidal product does not contain iodine itself (in the beginning) but iodine is generated from iodate and iodide. In this case iodate and iodide are not stabilisers. Hence, iodate and iodide are regarded as a new active substance either as iodine-releaser or as an in-situ system generating iodine.
2. IO_3^- + I_2 without I^-
   The biocidal product does not contain iodide. But iodide is generated as a degradation product, e.g. during storage. Iodate is reacting with iodide to re-generate iodine and keep the concentration of iodine stable in the biocidal product. Hence, iodate is acting as a stabiliser.
3. IO_3^- + I^- + I_2
   The biocidal product contains iodate, iodide and iodine. Iodate and iodide are generating iodine. Hence, the concentration of iodine is increasing steadily in the biocidal product or at the place of use. Iodate and iodide are not stabilisers. Hence, iodate and iodide are regarded as new an active substance either as iodine-releaser or as an in-situ system generating iodine. The biocidal product contains actually two active substances iodine and 'iodate / iodide' as iodine-releaser or as in-situ system generating iodine.
4. IO_3^- + I^- + I_2
   The biocidal product contains iodate, iodide and iodine. Iodate and iodide are not generating iodine. Hence, the concentration of iodine is stable in the biocidal product. Iodate and iodide are regarded as additives which might have stabilising properties.

The cases number 3. and 4. can only be distinguished if the iodine concentration is monitored. Therefore it was agreed by the working group members that a shelf-life study under normal storage conditions of a batch of the biocidal products needs to be provided for product authorisation. This shelf-life test shall include the monitoring of the iodine content after one day, one week, four weeks and 26 weeks after the production of the biocidal product. Iodate and iodide are only regarded as stabilisers if the concentration of iodine is not increasing during the storage.

Follow up: ECHA to inform the Coordination Group and the Commission on the conclusion of the APCP working group. ECHA to include this decision in the Technical Agreements for Biocides (TAB).

8. Reference specification-Reference Source

The working group members were informed on the updated document which will be forwarded to the Biocidal Products Committee (BPC). The chair informed that ECHA intends to include the presence of the reference specification(s) and reference source(s) in the draft CAR as a part of the accordance check. An Annex was developed to include the necessary data on the reference specification(s) and reference source(s).

9. Any other business

- Evaluation of storage stability studies introduced for product authorisations
  BE asked the WG members which level of degradation is acceptable during storage. A short discussion on this topic took place and it was agreed that further discussions might be necessary at another WG meeting.

  Follow up: BE will provide a document for an e-consultation. The WG members should provide their comments within four weeks. BE will present the outcome of the e-consultation at the next WG meeting.

- Lessons learnt

  The chair gave a brief presentation on the expected structure of the RCOM table, informing MSCAs which do not have members at the WGs and the migration of existing active substances into R4BP3.

  The ASO (CEFIC) commented that virtual meetings should be reconsidered and not only the number of agenda items but also their complexity need to be taken into account.

Minutes of Human Health WG

WG-III-2015 (2 June 2015)

1. Welcome and apologies

The Chair welcomed the participants indicating that six core members, one alternate core member and 13 flexible members were present. Two accredited stakeholder organisations (ASO) were present. Applicants were registered for their specific substance discussions.

Participants were informed that the virtual 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

2.1-2.2 Virtual meeting tool and Secure CIRCABC platform

SECR gave a brief presentation on the WebEx virtual meeting tool and an update of the secure CIRCABC (S-CIRCABC) project. Instructions on changing to S-CIRCABC will be sent by email to all WG members. Training manuals and user support will be available.

2.3 Follow-up BPC-10: Concluding procedure at WG

As a follow-up from discussions at BPC-10, SECR clarified that formal voting does not take place in the WG, but for concluding and consensus finding, the view of the WG members can be asked in a "tour de table". The views would be asked from all WG members and this would not be limited to core members – however only one opinion per member state will be taken into account.

If there is no WG agreement and no clear majority, the issue is brought to BPC as an open point. The distribution of opinions of the WG members will in this case be reflected in the WG minutes.

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-2015

The minutes were agreed without further comments.

6. Discussion of active substances

6.1 Bacillus amyloliquefaciens (eCA DE) PT 03

The Working Group agreed on the evaluation of the evaluating Competent Authority. The application will proceed to the BPC.

6.2 Formaldehyde (eCA DE) PT 02, PT 03

The Working Group agreed on the evaluation of the evaluating Competent Authority with some changes and clarifications. Risk characterisation for local effects will be finalised in an ad hoc follow-up. The application will proceed to the BPC.

7. Technical and guidance related issues

7.1 Update on guidance development (ECHA)

The DE member gave a presentation on recent activities of OECD Biopesticide Steering Group and DG SANTE on biopesticides, concentrating on the development of guidance and methodologies.

a) Technical agreements for biocides (TAB)

Several entries were deleted as they were either considered to be covered by other guidance (entries 1, 6 and 7), they were considered too specific (entry 15), or were not considered appropriate anymore (entry 34). Minor modifications and clarifications were made on several other entries according to written comments and further comments made during the meeting.

It was agreed that the exact wording of entry 24 would be agreed trilaterally between FI, NL and SECR; the agreement was to change the wording from 'transfer coefficient' to 'transfer efficiency'.

b) ECHA guidance Vol III Part B

SECR informed that the reformatted Vol III Part B, including the document on substances of concern, was published on ECHA Biocides Guidance webpage on 29 April 2015.

Concerning the update to Vol III Part B/Chapter 3 Exposure Assessment, a CA consultation was launched on 29 May 2015 and the publication is foreseen in July/August 2015 to be in parallel with publication of the technical document from Ad hoc Working Group - Human Exposure (HEAdhoc).

c) ECHA guidance Vol V on micro-organisms

SECR informed that two commenting rounds have now been finalised for this guidance, involving the MSCAs and ASOs. The second commenting round was finalised on 29 May 2015.

After the two commenting rounds, further open issues have still been identified that need discussion. It has nevertheless been decided that the guidance shall be finalised and a revision would be started following the ECHA consultation procedure which would include the nomination of a PEG (Partner Expert Group) and a PEG meeting.

Publication of the guidance is foreseen in July/August 2015, and the PEG consultation of the subsequent revision is foreseen in Q1 2016.

7.2 Update on Ad hoc Working Group - Human Exposure

The recommendations agreed so far are publicly available on the ECHA website.

The recommendations currently under preparation include the recommendation on "Product application amount for repellents – exposure assessment" and on the scenario of hand disinfection in hospitals.

a) Recommendation of the Ad hoc Working Group – Human Exposure: Consumer use of biocidal product and protection from typical clothing

The recommendation was discussed at the WG to obtain input in relation to the applicability of specific clothing (long-sleeved shirt and trousers) as risk mitigation measures for non-professional users.

The different guidance documents analysed in the recommendation indicate that it is not ensured that non-professionals will comply with the instructions for use of a product. One member observed that not following the product label should be considered as misuse of the product.

It was concluded that the recommendation should be consolidated for the WG-IV-2015 to present the rationale for the selection of the protection factor of 50% for one layer of clothing against dry contamination or light liquid contamination. In addition, the recommendation should mention the possibility of including long-sleeved shirt and trousers as risk mitigation measures on a case-by-case basis, also taking into account the product-type.

A wider consultation may be considered to discuss further the applicability of specific clothing as Risk Mitigation Measures for non-professional-users.

b) Recommendation of the Ad hoc Working Group – Human Exposure: The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling

One member pointed out that the Austrian/BfR study of human exposure to wood preservative, proposed as the model for dermal exposure evaluation during brush or roller painting, would need post-processing of the collected data. In the meanwhile, the model can be used as such in the exposure assessment.

Another member observed that the Austrian/BfR study is based on wood preservatives, whereas the recommendation covers all kind of paints, with the exception of antifoulings. The same member supported the use of the US-EPA Wall Paints Exposure Assessment Model (WPEM), which is applicable to classic paints. In addition, for wood preservatives assessment, a model is already available in the TNsG 2002 User Guidance - Version 1.

A member commented that WPEM only estimates the potential inhalation exposure of professionals and non-professionals during indoors application and it is limited to the active substances which can be evaluated with this model, depending on the molecular weight and vapour pressure. It was proposed not to disregard the WPEM, but to further examine its applicability in a separate recommendation.

An agreement could not be reached on the recommendation and it was proposed that further reflection was needed within the Ad hoc Working Group – Human Exposure, based on the discussion at the WG.

c) Recommendation of the Ad hoc Working Group – Human Exposure: Professional exposure assessment to biocidal products used in metalworking fluids (PT 13)

The recommendation was agreed by the WG.

7.3 Update on Ad hoc Working Group - Assessment of Residue Transfer to Food

The 'Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses' will be published in June 2015 as a pilot project on ARTFood webpage (http://echa.europa.eu/about-us/who-we-are/biocidal-products-committee/working-groups/assessment-of-residue-transfer-to-food). The guidance will be open for comments for one year and after that the ECHA guidance procedure will follow.

SECR informed that there is a policy discussion ongoing on MRLs for biocides among COM, MSCAs and ASOs that might affect the timelines for the agreement of the two guidance documents under development:

- Guidance on estimating livestock exposure to active substance used in biocidal product
- Guidance on estimating transfer of biocidal active substance into foods – professional exposure

8. Any other business

8.1 Lessons learned

SECR brought up the issue raised in the March workshop on the active substance approval process, namely the lack of transparency in some of the RCOMs. Especially the following points were raised:

- During the commenting of CARs, it is important to not repeat points but only provide them once
- The trilateral discussions are initiated by eCA and SECR should be kept in copy
- The commenting MSCA was also asked to indicate when a point can be closed
- When providing the RCOM, it needs to be clearly indicated for each point whether they are open or closed

An example of a generic RCOM was also presented, available in CIRCABC as follows:

- Path: /CircaBC/echa/BPC-WG/Library/Non-confidential/WG - Human Health/Meetings 2015/WG-III-2015 (2 June)/RCOM example.pptx
- https://circabc.europa.eu/w/browse/30bf40a0-aba5-4d3f-8b59-36b74d04d91f

SECR urged the eCAs to contact SECR as early as possible if there is the need to assess a new scenario or a use during the evaluation of an active substance. The most appropriate way forward can then be discussed, including the possibilities to involve HEAdhoc or to launch an e-consultation.

CEFIC commented that the applicants are in general happy to have virtual WG meetings, but only when there are only a few open points. A physical WG meeting would be more appropriate when discussions are wider and concern lots of open points. CEFIC asked SECR to take this into account in the planning of the meetings.

SECR remarked that the decisions on having either a virtual or a physical meeting need to be made much before it is possible to know the number and nature of the open issues to be discussed. Therefore the decision is in practice made on the basis of the number of discussions concerning active substances and guidance. CEFIC input would be taken into account, although in practice it may be difficult to decide on having either a virtual or a physical meeting on this basis.

One member asked for a workshop to be organised to discuss the human exposure related issues, as this would greatly facilitate the development of the recommendations.

It was considered difficult to discuss complex scientific issues in a WG meeting. SECR would take this into consideration and inform on any developments.

SECR reminded that the next Human Health WG meeting would exceptionally be the last of the WGs to take place during the week 14-18 September because of the EuroTox meeting ending on 16 September.

Minutes of Efficacy WG

WG-III-2015 (3 June 2015)

1. Welcome and apologies

The Chair welcomed all participants to the seventh Efficacy WG meeting. All core members participated. In addition, eight flexible members and four stakeholder observers participated in the 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 procedures for concluding on issues in the WGs. Following the discussions on a couple of active substances where the Chair had asked WG members to express their opinions as no consensus could be reached the issue was discussed at the BPC meeting in April 2015. It was concluded in the BPC that if consensus could not be reached the WGs should ask the opinion of all WG members, both core or flexi members, minute the outcome and leave the final decision for the BPC.

The SECR also updated on the development of the secure CIRCABC project.

3. Agreement of the agenda

The Chair introduced the agenda items and announced two extra items for AOB. Apart from this 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-II-2015

SECR explained that there were no comments on the minutes from the WG-II-2015 meeting.

Conclusions and action

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

6. Discussion of active substances[1]

6.1 Formaldehyde (eCA DE)

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.

6.2 Bacillus amyloliquefaciens (eCA DE)

There was one open point concerning which data requirements and criteria that could be acceptable for biocidal products containing microorganism as an active substance. The WG agreed that criteria could be different from those for chemical products. In general in addition to laboratory tests suitable field tests should be submitted at product authorisation stage showing the benefits of the use of the biocidal product. It should also be made clear that the mechanism of action, and thus exposure times etc., are different from products containing chemicals as active substances.

6.3 Silver zinc zeolite (eCA SE)

The eCA made a presentation concerning different aspects of the evaluation that were seen as problematic. It covered allocation of the various uses to its proper PT, efficacy testing of Treated Articles and bacterial resistance.

Regarding the discussion table there was one open point concerning the fungicidal activity.

The EFF WG also agreed that additional efficacy tests should be requested from the applicant. These tests will be specified by SE and agreed by the WG in ad-hoc follow up procedure.

7. Guidance

7.1 Continuous work on Efficacy Guidance Part B/C

Some outstanding issues related to Chapter 4 were discussed and participants were encouraged to send comments in writing. SECR will circulate an email with deadlines for commenting and re-drafting.

Participants expressed their satisfaction with the texts that had been drafted and noticed they were clear, concise and reflected well the discussions in the EFF-WG-II-2015 meeting.

7.2 Efficacy evaluation of repellents

A question concerning repellents against dogs and cats had been posted on HelpEx by IE. As there are neither existing standard test methods to perform efficacy tests for cats and dogs repellents nor efficacy guidelines to be followed that include specific, well defined criteria the company proposed to submit end-user trial data in the form of a questionnaire. The IE question was discussed by the EFF WG and it was concluded that there were not enough details to provide a specific response. Some general guidance could however be given regarding testing of repellents. It was concluded that ECHA will

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

prepare a general answer to this question and which can also be used to address this issue in the efficacy guidance. The draft response will be circulated to the EFF WG members for comments and then posted on HelpEX.

7.3 Practical tests for teat disinfectants in PT 3 (closed session)

This discussion concerned two test protocols for phase 2, step 2 tests for teat disinfectants. The protocols are based on European standards and may be used by applicants for preparation of efficacy data for PT3 teat disinfectants.

The EFF WG agreed that these protocols are suitable and should be accepted by MSCAs during the evaluation of PT 3 applications for teat disinfectants.

7.4 PT14 - efficacy tests for a Biocidal Product Family

IE had posted on HELPEX a question concerning efficacy tests for biocidal products in PT 14 belonging to a Biocidal Product Family. The products are divided into four different meta - SPCs, and differ in the type of formulation (grain, paste, block and gel). The eCA proposed to carry out efficacy testing on one (block) formulation and extrapolate the results to other formulations.

EFF WG members were of the view that each of the formulations should be tested, as different formulations may have different palatability and hence efficacy. It is difficult to predict which form is the least palatable and thus difficult to select one candidate for testing.

ECHA will draft a proposal for a response, which will be circulated to the EFF WG for comments. In addition this issue will be addressed in the PT14 guidance under revision.

7.5 Insecticidal activity of co-formulants in PT18 products (closed session)

Questions related to the efficacy evaluation of co-formulants, which may have biocidal activity on their own, had been submitted by FR. FR had proposed to demonstrate by additional testing that these ingredients did not have sufficient insecticidal activity to be characterized as active substances, i.e. in lab tests performed with the ingredient X or Y alone, and with the in use concentration of the product, according to the recommendations and criteria of the TNsG PT18 for all the target species for which efficacy of the product will be validated.

The EFF WG members found it difficult to determine thresholds for showing presence or absence, respectively, for the biocidal activity of co-formulants. The EFF WG nevertheless agreed that the co-formulants have to be tested alone to demonstrate that they have no significant influence on efficacy of the product following the methodology proposed by FR.

FR proposed two possible ways forward. The first was based on a two-steps approach; first to perform the methodology proposed by FR and then circulate the results to other MS for comments.

The second proposal was to change the methodology and perform topic applications with the in-use concentration of the co-formulants in order to determine the threshold (lethal concentration) of their biocidal effect on insects.

EFF WG accepted both proposals and left it to FR to decide on how to proceed. The results will be circulated to other MS for comments.

7.6 General update on guidance

The Guidance Unit in ECHA gave a brief overview of the ongoing work with Part B and C of the Efficacy guidance – Assessment and Evaluation. They also informed about the work with guidance for micro-organisms used as active substances.

DE informed briefly about the ongoing work with PT 6 and 13. A workshop will be held in Berlin in early autumn 2016.

NL informed about the work with guidance for PT 14. The work is foreseen to be finalized at the EFF WGIV 2015 in September.

7.7 Cat and dog shampoos

Questions concerning classification of a product had been submitted by NL. NL asked if a product in the form of shampoo with the claim 'contributes to fight against bacteria and fungal proliferations' should be acceptable as a biocide and covered by PT3. Alternatively they could be regarded as veterinary medicinal products.

Following some exchange of experiences between the members of this type of products NL was advised to submit the questions to COM as these kinds of issues are policy issues that are not within the EFF WG's remit.

It was agreed that NL will prepare a general question to COM concerning the proper allocation of this type of products. ECHA will ask COM to discuss the issue at the CA level.

8. AOB

8.1 Lessons learned

ECHA gave a brief presentation concerning the cooperation between ECHA, the eCA and the applicant during the trilateral discussion, focusing on the preparation and submission of RCOM tables, clear indication of open points (by using color codes) and the necessity to indicate the date of any agreement. The second part of the presentation covered the migration of active substances from R4BP2 to R4BP3. Further instructions on the use of R4BP for work on active substances will be prepared.

8.2 Technical agreements for biocides (TAB)

ECHA introduced the new technical document 'Technical agreements for biocides (TAB)', which will replace the Manual of Technical Agreement (MOTA) developed during the Technical Meetings. The TAB will contain scientific/technical agreements of the WGs which have not yet been included in any other BPR related guidance documents. The TAB will be publicly available on ECHA's website.

ECHA explained the relationship between the TAB and other information exchange tools (e-consultations, Helpex) that will still exist and explained in which cases each of the tools should be used.

Participants were invited to send comments on the document in writing, in particular on the relevance of the questions proposed to be transferred from MOTA to TAB.

8.3 Feedback on some issues raised at the workshop 'Reviewing the active substance assessment process'

A document containing proposals for when different types of guidance or other agreements should be implemented was briefly presented. Participants were invited to send comments on the document in writing.

Minutes of Environment WG

WG-III-2015 (2-3 June 2015)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were seven core members and two alternate members present in addition to 23 flexible members, one advisor and four rapporteurs. Two accredited stakeholder organisations (ASO) were present at the meeting. 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

2.1/2.2 Administrative issues

A short presentation on WebEx and an update on SECURE CIRCABC were provided.

2.3. Concluding procedure at Working Group level

The Chair provided the following explanations and instructions on the concluding procedure at WG level, as follow-up of WG-II-2015 and BPC-10:

- Formal voting does NOT take place in the WG (voting procedure described in the Rules of Procedure for the BPC)
- For concluding and consensus finding, the view/opinion of the WG members can be asked in a "Tour de Table"

  Procedure (Tour de Table):

  All WG members can provide their view (not limited to core members), one opinion per member state will be taken into account.

  If there is no WG agreement and no clear majority, the issue is brought to BPC as an open point. For an open point, the distribution of opinions will be reflected in the WG minutes.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. The following changes to the agenda were proposed:

- Item 7.3 will be discussed before item 6.6 since they are interlinked.

The Chair further indicated that the agenda will be applied in a flexible manor for this meeting since there are several parallel sessions ongoing and in case applicants are not yet available for the discussion of their substance, later agenda items will be taken in-between active substances.

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-2015

The Chair informed that comments were received from DE and the applicant on item 7.3, which have been included in the updated minutes. The minutes with this additional amendment were adopted.

6. Active substances

6.1 Silver Zinc Zeolite (eCA: SE)

One point out of four could not be agreed by the WG. For this point, an ***ad hoc* follow-up** was concluded necessary. The results of this *ad hoc* follow-up will be forwarded to the BPC together with the updated CAR.

Action: eCA to prepare the *ad hoc* follow-up in collaboration with SECR.

6.2 DBDCB (eCA: CZ)

The Working Group members agreed on the evaluation of the evaluating Competent Authority (eCA). The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

6.3 Bacillus amyloliquefaciens (eCA: DE)

The Working Group members agreed on the evaluation of the evaluating Competent Authority (eCA). The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

6.4 Cyfluthrin (eCA: DE)

Two points out of seven could not be agreed by the WG. For this point, an ***ad hoc* follow-up** was concluded necessary. The results of this *ad hoc* follow-up will be forwarded to the BPC together with the updated CAR.

Action: eCA to prepare the *ad hoc* follow-up in collaboration with SECR. In addition, a general discussion on how to derive values for the cleaning efficiency (F_{CE}) should be initiated in the Ad hoc EE WG.

6.5 Formaldehyde (eCA: DE)

The Working Group members agreed on the evaluation of the evaluating Competent Authority (eCA). The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

Action: SECR to check the pick list in the ESD for PT 3, if the default values for formaldehyde and para-formaldehyde are inverted.

6.6 Ampholyt 20 (eCA: IE) – consultation of the WG on the exposure assessment

The Working Group members agreed on a way forward related to the exposure assessment. The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

7. – Technical/guidance related issues

7.1 Update on guidance development, e-consultations and issues to be sent to the Ad hoc EE WG (ECHA)

SECR presented the status on guidance development, e-consultations and consultations of the Ad hoc EE WG. Updates from WG members during the meeting were agreed to be included after the WG meeting.

The following questions were raised:

- *Evaluation of the model SimpleTreat (point 1.4)*

  CEFIC asked by when it is intended to follow up with this issue. They further state that the RIVM report is available (RIVM report 601353005/2014) describing the revised model Simple Treat 4.0 and the announced manual (Feb. 2015) explaining how it can be used.

- *Vol. IV Part B for the active substance / 1st revision (point 1.11)*

  NL questioned by when Vol. IV Part B will be effective. SECR referred to document WGIII2015_ENV_8-2 (to be followed-up by the BPC meeting).

7.2 Technical agreements for biocides (TAB)

SECR presented the updated TAB (Environment section). Some comments received after WG-II-2015 triggered changes that needed re-confirmation by the WG:

- *Chapter 1, item 4: $PNEC_{microorganism}$ derivation: how should the PNEC be derived when both the EC50 and the NOEC from a respiration inhibition test are available?*

  DE asked for specification of the prerequisites and that statistics are sufficient to substantiate the reliability of the NOEC.

  Conclusion: NL and FR in principle agreed to the current text in the TAB, DE will provide an updated text by 12 June 2015, which will be included in the TAB.

- *Chapter 2.4.2, PT 1 - item 1: Professional hand disinfection: how to derive a value for $Q_{substpres\_bed}$ (and $Q_{substoccup\_bed}$) for substances for which no default values is provided in the pick list of the ESD?*

  DE stated that for clarity reasons, two separate equations should be provided for nursing staff and surgical. In addition, if a substance is used for both, the results have to be sum up.

  Conclusion: The proposed changes by DE were agreed by the WG.

  SECR presented further proposals for changes for default values in the scenario for surgical staff (for commenting after WG-III-2015) in order to harmonise with the Human Health exposure assessment:

  Q_{formS}: The current default value of 3g/event (based on ConsExpo) only takes the skin area of the hands into account. In order to include also the forearms in the assessment, which are usually also treated by surgical staff, the product amount should be extrapolated to 7g/event based on the default skin surface (based on ConsExpo) to offer a more realistic determination of the amount used (1980 cm^2/ 860 cm^2 ~ 2.3 à 2.3 x 3 g ~ 7g/use).

  N_{applS}: The Ad hoc Human Exposure WG *(*HEadhoc) is currently discussing the number of applications for surgical staff: a default value of 4 events/day should be used instead 10. The value of 4 events/day is already indicated in the HEadhoc recommendation No. 1 as an option, it will be discussed (at WG-IV-2015) if it should

be added also to the conclusions section. If the value of 4 events/day is confirmed by the HEAdhoc, it should be used as default value for N_{applS}.

- *Chapter 2.4.7, PT 8 - item 8: When is the assessment of risks to groundwater from on-site storage necessary?*

  UK asked if the consideration of groundwater risk is necessary when the site is stated as being bunded to comply with other "storage of major hazards" legislation (or when risk assessment for losses to ground indicates unacceptable risks).

  Conclusion: It was agreed to change the text in the TAB accordingly, however the correct RMM wording should be used instead of "bunding".

Action: Following the procedures described in the TAB, SECR will upload the revised TAB (Environment entries) to a dedicated Newsgroup in CIRCABC for a six week commenting period before publication on the ECHA webpage.

7.3 Acceptability of reducing the default treatment area in the emission estimation in order to identify a safe use (ECHA)

The Chair presented the item and took comments from the WG members.

Conclusion: The issue should be send to the Ad hoc EE WG in order to prepare specific scenarios for (RTU) small scale applications for PT 2, PT 3 and PT 4.

As in interim solution, it was agreed to use 10% of the surface area provided in the ESDs for PT 2 and PT 4 as an interim default value, until respective scenarios are developed. The interim solution will be included in the TAB. It was specifically highlighted that this interim solution is only valid for RTU products which are exclusively meant for small scale applications.

DE expressed their disagreement with the conclusion.

Action: SECR to send request for the development of specific scenarios for RTU – small scale applications to the Ad hoc EE WG, SECR to add interim solution to the TAB.

7.4 Harmonised approach of PIECsoil calculation for active substances in PT 18 – feedback on the meeting in April 2015 (DE/NL)

NL provided feedback on the meeting between DE/NL that took place on 22 April 2015 in Bilthoven, the Netherlands:

- An agreement was found on the questions originally raised in an e-consultation of the AD hoc EE WG (related to one active substance in PT 3). NL is currently drafting the answers which will be distributed first to the meeting participants for commenting and then to SECR to be shared with the WG members.
- In addition, the integrity of equations in the OECD ESD for PT 8 (taking into account degradation) was discussed: the background of this equation will be explained in a document, which will be provided to the WG members.
- Leaching to groundwater - wall scenario (PT 7-10), document discussed at WG-II-2015, will be updated by NL to clarify points which were unclear between NL and DE. This document will be provided to the WG for endorsement.

The Chair thanked NL and DE for their work and informed that the items raised in the bilateral meeting will be discussed in one of the next WG meeting.

Action: NL/DE to provide the respective documents, SECR to distribute and schedule discussion at WG meeting.

7.5 Acceptability of the current methods to assess the exposure/risk of wood preservatives (PT 8)(ECHA)

The Chair presented document WGIII2015_ENV_7-5: based on previous WG discussions and comments received from MS and industry SECR prepared three different options for discussion. The following feedback was received:

- DE: Until a political decision is done to change the current protection goal, the assessment should be performed on a local scale as currently done.
- NL: Due to low number of responses from MS the proposed three options are not well founded. NL understood that ECHA would draft a proposal for protection goals. First protection goals should be defined and then the acceptability assessment should be discussed. There are different opinions among experts in the definition what protections goals are (e.g. terrestrial ecosystem, special functions within the ecosystem which should be protected). Overall, NL was in favour of option 1 at this moment in time.

  SECR clarified that it is not in ECHA's remits to define protection goals (this should be done on political level).

  NL responded that however an agreement would be needed on what are the protection goals under the BPR and it may need to be feed back to the CA/BPC meeting.

  SECR responded that the aim of the e-consultation was to first identify if there is a need at all to revise the current procedure before taking further actions or if the current status is considered acceptable (e.g. the general protection goals defined in the TGD).
- FR, UK and FI expressed their agreement with DE and NL for option 1.
- DK supported options 1 and 3.
- CEFIC supported the evaluation and potential revision of current protection goals.
- EWPM expressed concerns if the option 1 would be continued to pursue, refinements to the methodologies would be needed, particularly in aquatic scenarios.
- UK further requested harmonisation between different legislations and referred to the Soil Risk Assessment Workshop in October, where protection goals are one topic.

Following one question, SECR clarified that the approach using a third time point for the assessment of service life (PT 8) was only agreed at WG level. It was sent to the CA meeting since it represents a change in the risk assessment procedure. At CA meeting level, an impact assessment was requested. This impact assessment, since linked to the discussion on protection goals, was not yet performed. SECR has reported back the CA meeting to the WG members in one of the last meetings in 2014.

Conclusions: The majority of WG members supported option 1 (⇒ The current methods to assess the exposure/risk of wood preservatives (PT 8) are realistic enough to derive a realistic worst case PEC value for the soil compartment. Therefore, the exposure assessment should remain as it is currently performed and no further refinement is needed).

The point was closed with a comment that it can be discussed again depending on reactions from BPC/CA meeting.

Action: SECR to share the document prepared and the comments received with the BPC/CA meeting.

8. Any other business

8.1 Lessons learned

The Chair introduced the item:

1. Commenting & RCOM

   Commenting: Points should be provided only once in the RCOM and they should be referred to elsewhere if necessary. Focus for commenting should be on major issues.

   Trilateral discussions: They are initiated by eCA, SECR should be kept in copy. It is good practice that a commenting MSCA indicates when a point can be closed.

   RCOM: Clearly indicate for all points whether they are open or closed. Examples on how the RCOM and updated RCOM should ideally be filled in were provided (see Appendix II, below)

2. General issues
   New scenarios: contact SECR as early as possible (preferably during evaluation) if new scenarios/default values are used in the exposure assessment so that an Ad hoc EE WG consultation or an e-consultation can be initiated in time to confirm the scenario/default value.

   How to keep those CAs informed who do not regularly attend WG meetings? They should be encouraged to regularly check the TAB/Lessons learned.

The following additional points were raised during the WG meeting:

- DK asked for clarification on trilateral discussions.

  Action: SECR to provide links on ECHA webpage to the Work Program (updated on each BPC meeting) and the workflow calendar to WG members.

- CEFIC provided feedback from industry on the WebEx meetings for the WG: the applicants were very satisfied with WebEx meeting when the discussion concerned only few open points. For extended discussion applicants would appreciate face to face meeting rather than WebEx. CEFIC asked if it would be possible to schedule WebEx and face to face meetings on active substances based on the number of open points/length of discussion.

  SECR explained that the length of discussion/number of open points can only be predicted very late before the meeting while the decision on virtual/face to face meetings takes place much earlier. SECR stated that in addition applicants raised the issue of unfair treatment if their substance is discussed in a virtual meeting. SECR referred to the Code of conduct for applicants participating in the Biocidal Products Committee and its WGs (Point 4.1) where it is stated that applicants shall not interfere with members, their advisers, invited experts, other observers or the Secretariat, in any way which, in the view of the Chair, constitutes inappropriate behaviour and/or may hinder the work of the BPC.' This applies to both physical and virtual meetings and means, in practice, that the applicant is not supposed to talk to the WG members outside the meeting and thus clearly puts the applicants of all WG meetings (virtual/physical) in an equal position.

- NL suggested to categorise issues for discussion by their importance, since there are long discussions of parameters which are not relevant for the outcome of the risk assessment (e.g. because RMM are applied anyway).

  SECR responded that this item is currently also part of the follow-up of the March workshop. Currently according to the working procedures, each point indicated in the updated RCOM table as being open also needs to be discussed at the WG meeting. SECR therefore re-encouraged commenting MS to comment only on major issues.

8.2 Feedback on the workshop "Reviewing the active substance assessment process"

The document WGII2015_ENV_8-1 was distributed for comments after WG-II-2015. The comments received from DE NL NO and DK were included in the document. The Chair explained that the document is only for information; it is aimed to be discussed/agreed at a BPC meetings.

The Chair invited the members to provide additional comments. FI pointed out that their comments have not been included.

Action: SECR to update the document based on the written comments received and forward it to the BPC meeting for discussion and agreement.

8.3 Information on the PBT Expert Group

SECR introduced document WGIII2015_ENV_8-3 which was prepared to raise the awareness of BPC Expert Group (EG) when dealing with the active substances in the approval process in relation with the exclusion criteria set out in Article 5(1) and in relation with the candidate for substitution criteria set out in Article 10(1) of the BPR.

The document clarifies the role of the PBT EG and provides information on when the eCA can make a request for consultation to the PBT EG and explains how to submit a consultation to the PBT EG. The document provides also the updated contact details.

DK asked for clarification on starting from which percentage metabolites should be assessed: >0.1% or >10%?

SECR replied that ECHA had prepared a document for the CA meeting to clarify this point. For the time being it is recommended to consider only metabolites occurring >10%, until further clarification takes place.

Action: ECHA to circulate the presented document WGIII2015_ENV_8-3.

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List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MUEHLE Ulrike (DE) - Rapporteur
HUIZING Tjaartjan (NL)
WARBURTON Anthony (UK)
HUSZAL Sylwester (PL)
Alternate core members
WEBER Philippe (FR)
Rapporteurs
DIETERICH Frank (DE) - Rapporteur
FRANK Ulrike (SE) - Rapporteur
Flexible members
ILMARINEN Kaja (EE)
THANNER Gerhard (AT)
KARHI Kimmo (FI)
KORKOLAINEN Tapio (FI)
CATALDI Lucilla (IT)
VAN BERLO Boris (BE)
SCHMIDT Marianne (DK)
CEBACEK Petra (SI)
HELGERUD Tryve (NO)
GONZALEZ Lorena (ES)
ÖSTERWALL Christoffer (SE)

ECHA Staff
KREBS Bernhard (Chair)
RODRIGUEZ UNAMUNO Virginia
SCHAKIR Yasmin
AIRAKSINEN Sanna
LISBOA MARTO Susana
Applicant(s)
Cobiotex
EWABO
Interhygiene GmbH
TSGE
Accredited Stakeholder Organisations
MIHAI Camelia (CEFIC)

Human Health WG

Core members
DE LENTDECKER Chloe (FR)
DE SAINT-JORES Jeremy (FR)
HOLTHENRICH Dagmar (DE)
RITZ Vera (DE) - Rapporteur
GHITULESCU Rita-Elena (RO)
BRESCIA Susy (UK)
Alternate member
BOSMAN Saskia (NL)
Flexible members
HÄMÄLÄINEN Anna-Maija (FI)
HYVÄRINEN Tuija (FI)
GAUSTAD Astrid (NO)
BOYE PETERSEN Annika (DK)
CEBASEK Petra (SI)
PAPARELLA Martin (AT)
HECKER Dorothee (DE)
UJMA-CZWAKIEL Monika (PL)
MARTINEZ Marta (ES)
GONZALEZ Lorena (ES)

ECHA Staff
AIRAKSINEN Antero (Chair)
ANTAL Diana
JANOSSY Judit
PECORINI Chiara
RUGGERI Laura
Accredited Stakeholder Organisations
MIHAI Camelia (CEFIC)
WAGNER Kristina (Animal welfare organisations)
Applicants
Cobiotex
EWABO
Fraunhofer
Interhygiene GmbH
Experts
POPPEK Ulrich (DE)
TOBOLDT Anne (DE)
KNEUER Carsten (DE)

Efficacy WG

Core members
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GIATROPOULOS Athanasios (EL)
KECK Marianne (AT)
HAMEL Darka (HR)
LEPAGE Anne (BE)
SIKORSKI Martha (DE) - Rapporteur
RADU Iuliana (RO)
Flexible members
VOGEL Birte (DK)
DUH Darja (SI)
HUSZAL Sylwester (PL)
HAHLBECK Edda (SE)
FRANK Ulrike (SE) – rapporteur
GONZALES Lorena (ES)
STRONG Colin (UK)
SCHMOLZ Erik (DE)

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SZYMANKIEWICZ Katarzyna
SCHAKIR Yasmin
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Interhygiene GmbH
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TSGE
Accredited Stakeholder Organisations
MIHAI Camelia (CEFIC)
BUCKLE Alan (CEFIC)- open session only
CAZELLE Elodie (AISE)
POULIS Joan (AISE)-open session only

Environment WG

Core members
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ALEXANDRE Stéphanie (FR)
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MUNCH CHRISTENSEN Anne (DK)
AHTING Maren (DE)
ROOP Evelin (EE)
PASANEN Jaana (FI)
GROSSMANN-VEN Stephanie (FR)
STRACZEK Anne (FR)
CONROY Kenneth (IE)
CASEY Clare (IE)
SMIT Els (NL)
VAN VLAARDINGEN Peter (NL)
HARALDSEN Terje (NO)
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WALTON Christopher (UK)
Advisors/Experts
SCHMIDT Jana (DE)
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HARRISON John (IE)
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