WG-II-2015

Final minutes

12 June 2015

Minutes of WG-II-2015

23-27 March 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-II-2015 (23 March 2015)

1. Welcome and apologies

The Chair welcomed the participants indicating the presence of six 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 drafting of the minutes. The recording will not be released to anybody and any other recording is not allowed.

2. Administrative issues

A presentation on the 'Secure-CIRCABC' project was provided by ECHA for the information of the participants of the meeting.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. Two additional items were included:

- Analytical methods for substances of concern

- IUCLID access for e-CAs

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-I-2015

Two comments on Cyromazine and PHMB were brought forward. The minutes were modified accordingly. The modified minutes were agreed.

6. Criteria for Polymers

The document was welcomed by the working group members. But it requires more explanation on the scope which will be included in an updated version. The document and the criteria should be regarded as indicative. They might need revision or improvement when more experience with biocidal active polymers is gained.

Follow up for ECHA: update the document and make an e-consultation.

7. Reference specification-Reference Source

The working group members agreed on the re-phrasing and proposed changes to the document. That updated document will be distributed to the WG members and included in the Technical Agreement for Biocides (TAB).

Follow up for ECHA: editorial changes of the document and distribution to the WG members.

8. Commodity Chemicals as biocidal active substances

The definition of 'commodity chemicals' needs further elaboration. It was questioned whether these chemicals are actually manufactured always in the same way and hence have the same compositional profile. The reliability of recognised standards has also been discussed. The WG members agreed that a reference to the European Pharmacopeia is a trustworthy reference, whereas the Commission Regulation (EU) No 231/2012 (specifications for food additives) is considered more critical.

Follow up for ECHA: contact CEFIC to get an overview which substances in the review program are regarded as commodity chemicals. Update the document and initiate e-consultation with WG members.

9. Discussion of active substances

9.1 TMAC (ATMAC)

The set reference specification needs to be confirmed by submitting 5-batch analyses of substance per applicant / manufacturing location. The flammability of the substance needs to be confirmed by providing a test according to Test N.1: Test method for readily combustible solids (United Nation, part III, classification procedures, test methods and criteria).

9.2 Carbendazim

The WG members agreed on the reference specification which requires confirmation by new 5-batch analyses of the substance per applicant / manufacturing location.

10. Any other business

- Analytical methods for substances of concern

  A WG member provided a room document for 'Analytical methods for substances of concern'. Discussion took place whether these methods need to be provided for the biocidal product authorisation when substances of concern can originate as impurities from product ingredients or generated during storage. In case they originate from ingredients their content can be retrieved from the safety datasheet. Further discussion is necessary for the case when these substances are generated during storage.

  Follow up: WG member will update the document for an e-consultation.

Minutes of Human Health WG

WG-II-2015 (23-24 March 2015)

1. Welcome and apologies

The Chair welcomed the participants indicating that six core members, one alternate core member and 6 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. 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.

3. 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.

4. Agreement of the draft minutes from WG-I-2015

The minutes were agreed without further comments.

5. Administrative issues

SECR gave a brief presentation on housekeeping issues and the development of the secure CIRCABC (S-CIRCABC).

6. Discussion of active substances

6.1 Early WG discussion on silver containing active substances (eCA SE)

In general, a read-across approach was accepted as proposed by the eCA. The read-across is based on the silver content of the substances and the silver ion release rate, and takes into account the properties of the other constituents of the active substances.

The WG did not solve the problem that the eCA considers the information sufficient for risk assessment but not for classification; there are no data requirements for C&L and the WG has no mandate with respect to C&L.

6.2 DDAC (eCA IT) PT 8

Quaternary ammonium compounds (QUATs) are a group of active substances that share the quaternary ammonium (DDA) functional group, which is mostly responsible for the toxicity. An approach was agreed to be based on risk characterisation for local effects, as

it had been concluded earlier that there are no systemic effects but all the observed effects are secondary to irritation and corrosion.

Systemic reference values were considered not appropriate and these will be removed from the combined list of endpoints to clarify that there are no primary systemic effects. The results of the quantitative local risk characterisation will be removed from the CAR as the results were obtained using a draft guidance which is now outdated.

6.3 TMAC/ATMAC (eCA IT) PT 8

As for DDAC above (see agenda item 6.2), systemic reference values are not derived and the risk characterisation will be based on local effects. An ad hoc follow-up will agree on the remaining open issues concerning semi-quantitative assessment and secondary assessment.

6.4 Carbendazim (eCA DE) PT 7, 9, 10

The Working Group agreed on the evaluation of the evaluating Competent Authority with some changes and clarifications. The application will proceed to the BPC.

7. Technical and guidance related issues

7.1–7.3 Update on guidance development

This agenda item was skipped to save time. The SECR informed that there are no urgent issues that would require discussion at the WG.

7.4 Technical Agreements for Biocides (TAB)

The SECR explained that the first entries were sent to the TOX and ENV WGs and these entries would then be compiled together to form the first version of TAB. The intention of the TAB is to be purely scientific and not procedural, and in this respect it would be different from the predecessor MOTA. The SECR had first collected all issues that were still deemed relevant in the old MOTA and not covered in the biocides guidance, and additionally included new entries covering issues agreed at the WG meetings. Some text changes were included in the entries coming from the MOTA with the intention of clarifying the text and removing outdated information.

The members supported having a 6-week commenting period for each new version of TAB, after which the TAB would be considered endorsed except for entries where MS comments indicate that a discussion is necessary at the WG. The procedure of revising the TAB will be kept light; any member can at any time inform SECR of a need to revise the text.

The document is available for commenting in CIRCABC until **30 April 2015** after which SECR will combine the human health and environment documents into one file. Entries that are not commented will be considered as agreed.

8. Any other business

8.1 Feedback from the workshop "Reviewing the active substance assessment process"

Proposed time of applicability for new guidance and guidance related documents during evaluation and peer review

SECR clarified that the initial proposals made in the meeting document should be considered as a thought starter only. The following comments were made and will be considered when SECR will draft a proposal:

- The new scientific guidance documents should not be mandatory for CARs that are submitted (not finalised) up to one year after the endorsement of the new guidance.
- The moment when a document should be considered as endorsed/applicable should be clarified because there is not always a clear endorsement step, and there is also a time gap between the formal endorsement and publication. The publication date could be considered to be used as the reference time instead of the endorsement, although endorsement might be better for the guidance that is finalised/endorsed by the WG after which it is immediately applicable.
- Several members suggested for the HEAdhoc recommendations that eCAs should not be required to apply the recommendations indicating approaches and models for exposure assessment, if the CAR is submitted less than 6 months (not 3) after the endorsement of the recommendation. Where a HEAdhoc recommendation was developed for use in a specific CAR, it should be used immediately in that CAR, but for other CARs where this would be applicable, a note could be included indicating that recently endorsed guidance was not taken into account but should be taken into account at product authorisation. Such issues could also be mentioned in *Elements to be taken into account at product authorisation*.
- It needs to be made very clear whether the applicability refers to e.g. CARs under evaluation or CARs under peer review.
- There might be a need to include a time period for the TAB entries as well, instead of applicability from the meeting where they are agreed on. There may also be various kinds of agreements, some of which could be applied immediately, e.g. default values, and others would need a different time of applicability, e.g. new scenarios. A time period of 3 months was proposed.
- It would be desirable not to have strictly binding time limits for the applicability, but the document could also promote harmonisation within PTs and similar uses whenever possible.

The members supported the proposal to give the eCA the option to use endorsed guidance as soon as it is available, and not restrict the usability with the timelines.

SECR will take into account the input of this discussion and the ENV WG discussion and will provide a more elaborated proposal for discussion and commenting.

Can the exposure/risk assessment procedure be simplified

There was support to reduce the number of scenarios to be assessed by defining key scenarios for each PT. Such key scenarios might include a typical use as proposed by the applicant, as well as a best-case use which would be expected to be the one with least risk. It was pointed out that also the applicants have insisted on assessing all uses, which is also helpful at product authorisation. SECR proposed to try to reduce the uses and scenarios in cooperation with the applicants to avoid unnecessary work. It was pointed out that for some uses more scenarios are needed than for others and there should therefore be no strict limitations to what could be included in the CAR.

A 'light approach' was not supported to risk assessment of substances with low hazard profiles. It was clarified that the intention of this proposal was mainly to concentrate the efforts in substances where hazards are more severe.

The proposal of having new uses and scenarios discussed at the ad hoc WGs before applying them was in principle supported, but for HEAdhoc the workload is so high that in practice no more tasks can be taken up.

How to ensure that the important issues would be discussed at the WGs

There was an agreement to always discuss and agree the following values at the WG, regardless of whether these were commented:

- All reference values
- Oral absorption
- Dermal absorption
- Inhalation absorption

It was considered problematic that the WG agrees on how the risk assessment is performed but is not able to agree on the risk based on the final assessment because there is only one WG meeting. Therefore one additional step would be necessary between the WG and BP; this was also a proposal at the March workshop. Additionally, SECR briefly explained the suggestion made at the workshop to perform the MSCA commenting round before finalising the accordance check, thereby making the accordance check a collective effort and releasing this time within the 270 days peer review. This proposal would only be applicable to the CARs in the Review Programme.

It was requested that a cover note should always be sent together with the final CAR, explaining the changes made.

The response to comments tables (RCOMs) and the trilateral commenting were considered not to always function properly. All the agreements and any new or modified scenarios should be subject to peer review and this should be done in the context of the RCOM. The eCA has to be active in the trilateral discussions, contacting the commenting MSCAs, and then the results of these discussions need to be presented in the RCOM.

It was suggested that the following should always be discussed when relevant, i.e. whenever they take place:

- Agreements to add new scenarios or removing them
- Deviations from agreed default values for other reasons than available data
- Deviations from HEAdhoc recommendations
- NOAECs when local risk characterisation is triggered
- Changes agreed bilaterally that affect the outcome of the assessment

The eCA should thus mark as open any comments regarding these issues.

8.2 Lessons learned

Timing of different WGs

SECR informed that the intention is to always maintain the approximate order of the WGs, so that the APCP WG would be followed by TOX, EFF and ENV WGs in sequence and, when necessary, partly or fully in parallel. Exceptions to this order are also possible and for WG-IV-2015 the TOX WG will be organised as the last WG, to enable members to participate in the Eurotox meeting that is held 13-16 September. SECR regretted that the exact timing cannot be decided much in advance because the times depend on the

availability of meeting rooms, the possible need for parallel discussions, and the time needed due to the number of substances and guidance to be discussed.

SECR asked whether the members preferred the WG meetings in general to start in the morning or after lunch, and whether the ending would be better in the evening or by lunch time. Based on the input it became obvious that none of the arrangements would suit all members.

Provisional dates for each WG in 2015

SECR informed that the provisional dates for each WG are indicated in a document that is available in the non-confidential CIRCABC site. For the human health WG, the provisional dates for 2015 are 1-2 June, 16-18 September and 23-25 November. Three days have been reserved for the September and November meetings, but it is expected that at least the September meeting would be only two days.

Substances discussed earlier in TMs and WGs

When preparing for a substance discussion where an earlier discussion has been held in the TM or in the WG, SECR requested the eCAs to prepare a note to inform the WG on the background and what should and should not be discussed. SECR stressed that it should be made clear upfront to all members which issues have already been closed and should not be reopened, and also the specific reasons and past discussions concerning those issues that need to be discussed again.

Lack of transparency in Response to Comments tables

SECR reported of the discussion held at the workshop *Reviewing the active substance assessment process* held at ECHA on 5 March 2015, where a request was made for the eCAs to always include the proposed solutions to the comments instead of merely agreeing to e.g. including or modifying a scenario. The information should be sufficient to conclude whether the proposed approach is acceptable to both the commenting MSCA and other MSCAs. It was noted that currently, if the proposed solutions are not included, the technical level peer review can only be performed at the BPC stage which is not acceptable. All bilateral agreements should as well be transparently included in the RCOM.

Minutes of Efficacy WG

WG-II-2015 (25-26 March 2015)

1. Welcome and apologies

The Chair welcomed all participants to the sixth Efficacy WG meeting. All core members participated except for Ms Iuliana Radu. In addition, one alternate member and four flexible members and three stakeholder observers participated to 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 presentation on the administrative issues and the secure CIRCABC project.

3. Agreement of the agenda

The Chair introduced the agenda items and invited participants to discuss any additional items at AOB. 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-I-2015

SECR explained that there had been some comments on the minutes from the WG-I-2015 meeting. A revised version had been prepared.

Conclusions and action

The WG members agreed on the minutes with the proposed amendments.

6. Discussion of active substances[1]

6.1 Update of the ad hoc follow-up on Peracetic acid

SECR informed the WG members that one remaining open point from EFF WG-V-2014 had been closed after ad-hoc follow up discussion. The members agreed that the new efficacy data and the proposed dose were sufficient for approval of PAA in PT6 against

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

aerobic bacteria. The proposed dose should be adjusted to the intended use at product authorisation stage.

6.2 Carbendazim (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.

WG agreed on the evaluation of the eCA.

On request an initial discussion for monitoring of resistance took place. It was agreed that this issue needs to be further investigated and monitoring should not be requested without first considering if it is possible in practise. The current sentence *'periodic monitoring should be carried out'* should be reworded in the CAR by the eCA.

6.3 TMAC (ATMAC) (eCA IT)

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.

WG agreed on the evaluation of the eCA.

6.4 Update on the e-consultation on Triclosan

An e-consultation was initiated by the eCA (DK) as there was no safe use of Triclosan identified for ENV risk assessment and the applicant had for that reason submitted new efficacy data. During the e-consultation no agreement had been reached and it was necessary to discuss the issue further during the EFF WG meeting. Since agreement was also not reached during the discussion, the Chair asked all members to express their opinions. A majority (4 out of 6) of the EFF WG core members did not find that efficacy had been sufficiently demonstrated for the proposed concentration of Triclosan. Efficacy was demonstrated only for 'gram +' bacteria and not against 'gram –' bacteria, which was considered not enough for an active substance used as a disinfectant. In this case the efficacy should have been demonstrated for at least the representative bacteria in the EN Phase 1 test.

7. Guidance

7.1 Structure of the Efficacy 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. The idea would be to have one document with general principles for assessment and evaluation of efficacy followed by the PT-specific guidance and group-specific introductions.

There were some concerns among members regarding the possibilities for updating the document – would the whole text need to be revised every time one chapter was to be updated? ECHA confirmed that it would indeed be possible to revise individual chapters without reopening the whole volume.

Also the division of texts between the volumes in Part A, Information requirements, was raised, as texts on intended use (section 7 of Annex II to the BPR) are now in Volume I, Analytical Methods and physico-chemical properties. It was agreed NL would contact ECHA with a request to introduce these texts also in volume II, Efficacy, and possibly also in volumes II-IV.

The structure of the combined Part B/C of the Efficacy guidance was discussed based on a proposal by NL that had been circulated prior to the meeting. Comments received in writing were in general supportive. The main questions concerned Chapter 2, Claims,

which some participants felt should rather be part of Chapter 5, Product Authorisation. It was however decided to keep a general chapter on intended use and claims as Chapter 2 and in addition include sections on intended use and claims both in Chapter 4, Evaluation of Efficacy at active substance approval stage, and in Chapter 5, Product authorization.

UK volunteered to draft texts on intended use and claims. SE will work further with the sections on treated articles, and NL on the text on evaluation of efficacy of product families and possibly also on other parts of the general texts.

7.2 Next Efficacy guidance priorities

Drafting of the PT specific chapters where there is no updated guidance was discussed. DE confirmed that they will start working on PT 6 and 13 with the aim of having first drafts of these guidance ready by the end of the summer 2015. Workshops to discuss the drafts will be organized in Berlin.

SE offered to prepare 'mini guidance' for PT 7 and 9 based on tests for treated articles.

FR offered to draft guidance for PT 11 and 12 and AISE expressed their willingness to contribute to this work.

As regards guidance for non-arthropods for PT 19 UK offered to check if they could contribute as previously discussed. Some information is available from an e-consultation as well as in the CAR for nonanoic acid. It was also proposed that guidance could be prepared while working on the first product authorization for repellents for mammals by documenting the evaluation principles used.

It was concluded that most of the priorities would be covered by these initiatives. Some useful information might also be available in guidance from other organisations such as the US EPA. The stakeholder observers offered to check with their members where contributions to PT-specific guidance could be made, and members welcomed this proposal.

7.3 Efficacy Assessment in Biocidal Product Families (BPF)

Efficacy testing of BPF was discussed based on COM document: *'CA-Nov14-Doc.5.8 - Final - Implementing the new BPF concept'* and additional input from NL. A presentation concerning BPF and efficacy assessment including examples and case study was given by UK. It was agreed that efficacy should in principle only be tested for one product per BPF ('worst case' for the entire BPF - which shows the maximum risks and the minimum level of efficacy). In case when such assessment is not possible the 'worst case' should be identified at *'Meta SPC'* level.

However, depending on the composition of the BPF in terms of the number of active substances used in the products and the number of organisms addressed, several 'worst case' products could be identified.

Principles for testing of BPFs will be included as a section of the Efficacy guidance Part B/C in Chapter 5 and more specific issues described in respective PTs guidance.

NL will rewrite the draft document concerning BPF, including text proposed by COM as well as some issues for which legal interpretation is needed. It will be further discussed during next EFF WG meeting in June 2015.

7.4 Virus claim for teat disinfectants

As a consequence of HELPEX question posted by NL EFF WG discussed if it is sufficient to perform EN 14476 test only against Vaccinia virus and claim virucidal activity of the product for teat disinfection? EFF WG members indicated that full virucidal activity of the product required tests against enveloped and non-enveloped viruses. In case tests are

performed only against Vaccinia virus it should be possible to claim only virucidal activity of the product against enveloped viruses.

EFF WG agreed that test against Vaccinia virus for biocidal product used as teat disinfectant in PT3 is sufficient to claim virucidal activity only against enveloped viruses. To finalise this question NL will prepare a final answer and it will be included in the guidance.

7.5 Discussion on general guidance texts

The Chair proposed to have a general discussion on efficacy assessment at the active substance approval state as the circulated document had not been updated with the comments received.

The following issues were raised:

* The 'Role of efficacy' paper was drafted because the requirements for demonstrating efficacy at the active substance approval stage at that time were found to be too stringent. Now the requirements instead tend to be too lenient and we need to find a balance and be more specific about what 'innate efficacy has been demonstrated' actually means.

* The requirements on the biocidal product and its efficacy at the active substance approval stage tend to be very limited. Even if 'dummy products' are acceptable it should be clear from the guidance that for active substances already in use efficacy data from real products would be expected. Criteria for selection of example product should be given in the guidance.

* Situations where efficacy of a treated article needs to be demonstrated at the active substance approval stage should be explained in the guidance, keeping the legal basis in mind.

* Efficacy needs to be demonstrated for at least the active substance on its own or when it is incorporated in a product. Relevant controls should be used. Some members stressed the importance of demonstrating efficacy on the active itself at the a.s. approval stage.

* The importance of linking the dose at which efficacy is demonstrated with the dose used for risk assessment was stressed.

* Requirements for demonstrating efficacy in relation to the intended use and target organism(s) claimed should be further elaborated in the guidance.

* The 'Role of efficacy' document was originally drafted as a discussion paper. The text needs to be further revised to be more specific and 'guidance-like'.

The document, which forms Chapter 4 of the Efficacy guidance Part B/C will be revised by the drafting group to reflect comments received in writing and the outcome of this discussion.

8. Any other business

8.1 Feedback from the workshop "Reviewing the active substance approval process"

Two issues related to the workshop were discussed:

1. When the eCA and applicant agree on additional studies – how long is it reasonable to wait for the applicant to come back with more precise information about the time-table for the study?

Participants reminded about the possibility to propose non-inclusion of an active based on lack of information. If deadlines have been set for the response by the applicant and a reminder given, the eCA could proceed with the CAR based on non-inclusion. SECR will check the legal possibilities to propose non-inclusion based on non-responsiveness by the applicant.

2. When should new guidance become applicable?

This was one of the main issues discussed in the workshop. SECR offered to prepare a document that describes when guidance is to be applied based on discussions in the workshop and a previous paper presented to the CA meetings. The issue will be coordinated with the other WGs where similar documents are in preparation.

8.2 Lessons learned

Members asked for better information related to meeting time, timely uploading of meeting documents, notifications from CIRCABC when documents are uploaded, and more consistent naming of meeting documents, including indications of version. Also transparency in commenting was raised as comments are sometimes not circulated to all members. A possibility for improvement would be to use Newsgroups more consistently.

SECR agreed to pay better attention to these issues for the coming meetings.

Minutes of Environment WG

WG-II-2015 (25-27 March 2015)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 8 core members and 1 alternate member present in addition to 8 flexible members and 4 rapporteurs. Two accredited stakeholder organisations (ASO) were present at the meeting. Applicants were also 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. Agreement of the agenda

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

- Item 8.3 "AOB" to be added, with information from UBA on scheduled Workshop on monitoring in Berlin (June 2015).

  Note post-WG: The information was provided not during the WG meeting but was distributed by UBA via email on 30.03.2015.

3. 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 she had a conflict of interest with two active substances and the Vice-chair with one active substance. Therefore the Chair and the Vice-chair will take turns correspondingly to chair sessions on the respective active substances.

4. Agreement of the draft minutes from WG-I-2015

The Chair informed that comments were received for the ESD PT 19, PHMB, cyromazine and on the general minutes. During the meeting, FR suggested to modify the updated minutes for item 6.2 regarding e-consultation on scenarios to assess PT02 for private pool treatment with regard to market share. The minutes with this additional amendment were adopted.

5. Administrative issues

5.1 Housekeeping issues

The housekeeping roles were only provided as leaflet.

In addition, SECR informed of the migration to new SECURE-CIRCABC that will take place in summer 2015. It was noted that the only change for the CIRCABC users will be that of additional authentication when entering the library. Some of the old meeting documents may need to be removed.

6. Technical and guidance related issues

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

The Chair 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.

6.2 PT 19 - Final Emission Scenario Document for Repellents and Attractants

The Chair noted that CEFIF sent late comments shortly before the meeting. While due to the handover of the guidance it was not clear whether industry had been included in the first commenting on the Emission Scenario Document (ESD), SECR reviewed the comments and presented a proposal for dealing with them during the meeting for WG members' consideration.

The ESD was endorsed.

Action: SECR to include changes discussed at the WG meeting following comments from CEFIC and to send the ESD to WG members/ASOs for verification of changed text before uploading.

6.3 PT 13 - Gathering of information for the refinement of the Environmental Emission Scenario for metalworking fluids

The Chair reminded that the document on the refined ESD for PT 13 was intensively commented and discussed at WG-V-2014. Minor changes were subsequently made to the document.

The document was endorsed after correction of a dilution factor in Table 7 of the document (end user on-site treatment: factor of 150 for the first dilution step and factor 10 for the second dilution step).

Action: The document will be uploaded by SECR to the ESD specific ECHA webpage.

6.4 TAB (v.0): Technical Agreements on Biocides - replacing the MOTA under the BPR (ECHA)

The Chair presented the draft Technical Agreements on Biocides intended to replace BPD MOTA under the BPR.

On the request of the Chair, WG confirmed that the number of houses per hectare in groundwater scenario for PT 18 should be 16.

The Chair informed of the procedure foreseen for the amendment of the TAB in the future. The procedure does not involve any formal endorsement by WGs or BPC except for the first version. Instead it is considered to be a living document provided to WGs normally for written comments via CIRCABC and subsequently published on ECHA website.

Action: TAB will be distributed by SECR for comments after WG meeting (comments to be sent by 30. April). Based on the comments received it will be decided if another WG meeting discussion is needed.

6.5 Leaching to groundwater from paint, coatings and plaster (NL)

NL presented the document which was discussed earlier at TMII2015 as well as WG meetings. Some of the WG members were critical of non-transparent use of correction

factors which are needed to be able to use PEARL model for the calculations. This was said to lead to lack of clarity over the amount of the active substance that is leached. Several members judged it to be too complicated. NL stated that the new approach is more realistic compared to the current 10 time application approach presented in the ESD. NL also confirmed that with the new approach similar results are obtained as with the current approach that substantiates the current approach validity.

The WG agreed that the current approach should be continued to be used as Tier I (10 applications per year, which could be adjusted in newer PEARL versions to 12 applications). The new approach presented in the document by NL could be used as Tier II approach. The number of houses should be corrected however to 16 houses in line with the revised OECD ESD for PT 8, which was agreed to be applicable also to related PTs (PT 7, PT 9 and PT 10).

The document was not endorsed by the WG. NL agreed to make some clarifications in the document for better readability.

Action: SECR to distribute the document for commenting, and the document will be scheduled after revision following the commenting by NL for a discussed at a further WG meeting.

6.6 Fish net scenario in aquaculture (NO)

NO introduced the document. As the documents proposes a first tier scenario, whenever country specific values are available these may be used as a refinement.

The document was endorsed by the WG members. Some issues for further research (i.e. washing of nets/impact on sediment of a static structure) will be added to the document.

It was further agreed to clarify at WG-III-2015 meeting whether the new version of MAMPEC software is applicable for all calculations.

Action: SECR to initiate the discussion on the usefulness of the new version of MAMPEC (discussion table) and will invite the WG members for support.

6.7 PT 3 - Area of housing for application: conclusion on the outcome of the e-consultation of the Ad Hoc EE WG (ECHA)

- *When the application is done by fogging, should the area of housing consist of the following: floor, slatted area, wall and roof, and other areas?*

  Conclusion: Depending on the information provided on the product label, either the volume of the animal house (see default values in the ESD for PT 18) or the surface area should be considered. For the calculation of the surface area, all surfaces in the animal house should be taken into account.

- *When the application is done by foaming, should the area of housing consist of the following: floor, slatted area, wall, and other areas?*

  Conclusion: In a first tier assessment all the surfaces are to be considered. It is acceptable as second tier to take label information on reduced treatment areas in a stable into account.

- *What areas of the housing should be used in the case of application by spraying?*

  Conclusion: In a first tier assessment all the surfaces are to be considered. It is acceptable as second tier to take label information on reduced treatment areas in a stable into account.

- *Additional issues raised by eCAs during the e-consultation*

  UK raised the question whether the outcome of this e-consultation would apply to any relating final decision to be taken. SECR confirmed that the above approaches will be included in the TAB and are relevant for all substances in PT 3.

NL indicated that they reviewed some protocols for disinfection of stables and base on these, they conclude that manure storage systems may be emptied before disinfection. Therefore, they think that in addition to emission to soil via manure also discharge to the STP or direct discharge to soil should be considered. No conclusions was required (issue was outside the scope of the e-consultation).

Action: WG members to send information to ECHA on if an additional discharge to STP is relevant in their country (not only for poultry). In case yes, the ESD for PT 3 should be adapted accordingly.

6.8 Planned e-consultation on PT 21-related issues relevant e.g. for product authorisation (NL, UK)

NL informed that together with UK it will launch an e-consultation regarding antifoulings to settle questions around which parts of the freshwater ecosystems should be assessed and how it should be done and how to deal with combined exposure to different products. Members will be asked to provide information on their current national procedures relevant for assessment of antifoulings, scenarios applied, ongoing developments, needs for such assessment. Also the Dutch freshwater harbour scenario will be circulated.

6.9 Leaching from coatings: presentation of ongoing project (CEPE)

CEPE informed of its project regarding preservatives in coatings (PT 7) which addresses the need for semi-field leaching studies under PT7. Laboratory leaching tests performed within this project suggest that that leaching pattern of an active substance in a coating correlates with the binder content and pigment to binder concentration ratio. Before going to the next phase - semi-field studies CEPE expressed their interest to gain some feedback of the WG members on the project. Information on the leaching behaviour of the worst case coatings could be utilised to cover other coating types.

Action: SECR will distribute CEPE's presentation together with the laboratory test reports to be provided by CEPE after the WG meeting. WG members can submit comments until 10. April to ECHA (SECR will distribute the comments to CEPE).

6.10 Effect identification: conclusion on the outcome of the e-consultation of the ENV WG (ECHA)

- *Should any significant deviation (decrease or increase) from the control in a soil nitrification inhibition/carbon transformation tests be considered as a relevant effect for the derivation of PNEC for biocides in general?*

  It was agreed that any significant deviation (decrease or increase) from the control in a soil nitrification inhibition/carbon transformation test should be considered as a relevant effect for the derivation of PNEC for biocides in general.

- *If yes, is there any exemption to this conclusion?*

  It was agreed that there is no exemptions to the interpretation that any significant deviation (decrease or increase) from the control in a soil nitrification inhibition/carbon transformation tests is a relevant effect for the derivation of PNEC for biocides.

- *Would the WG members be interested in initiating a discussion and further guidance development on extending the conclusions reached for the soil nitrification inhibition/carbon transformation tests to other eco-toxicological studies? If yes, would you volunteer to initiate such discussions?*

  The WG agreed that there is no need at the moment to develop further guidance on this issue, nevertheless the topic would be further explored by 1) following the

discussions taking place at PPP level on soil risk assessment and soil nitrification test 2) including the issue in the upcoming workshop on soil risk assessment to be held in ECHA in October 2015.

Actions: - NL will report on the discussions being held at the PPP arena.
- SECR to propose to the soil risk assessment workshop organisers the issue as a topic for discussion.
- SECR to include the outcome of the consultation in the TAB.

7. Discussion of active substances[2]

7.1 DDAC (eCA IT) – Definition of a common list of endpoints PT8

The Working Group members agreed on the combined list of endpoints provided by the evaluating Competent Authority (eCA). Based on the outcome of the ad hoc follow up agreed for TMAC/ATMAC (see item 7.2), one endpoint may need to be revised.

Action: In general a discussion on the reliability rating on studies should take place.

7.2 TMAC (ATMAC) (eCA IT)

One point out of nine 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.

7.3 Carbendazim (eCA DE)

One point out of five 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.

7.4 Cybutryne (eCA NL)

Follow-up of BPC-8: One point out of four could not be agreed by the WG. The outcome of the discussions and the agreements of the WG will be forwarded to the BPC.

8. Any other business

8.1 Workshop feedback

The Workshop on "Reviewing the Biocidal Active Substance Assessment Process" took place on 5th March 2015. The aim of the Workshop was to analyse the process as a whole, evaluate how ECHA has been performing and identify issues to improve on efficiency. The Chair invited Simon Gutierrez to report on the Workshop and the Chair then gave an overview of action points identified during the workshop relevant for WGs.

WG members were particularly interested in the issues in relation to a light approach to risk assessment based on hazard raised during the workshop. In the same context members further brought up the clarity of the mandate of WGs vs BPC. They also asked SECR to look into the procedural handling of multiple dossiers.

Action: SECR to initiate an e-consultation to collect the feedback of the WG members on the issues identified by the workshop relevant for WGs.

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

8.2 Lessons learned and other information

The Chair informed of the timing and order of different WGs to be followed in the future, and provisional dates for WGs in 2015. It was suggested that the eCA should prepare a note for dossiers discussed earlier to describe the background and changes were proposed on the way how closed points are addressed by eCAs in RCOMs. CIRCABC newsgroups were recommended as a preferred channel for submission of comments to minutes. During the discussion members made requests to organise newsgroups better.

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List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MUEHLE Ulrike (DE)
GATOS Panagiotis (EL)
HUIZING Tjaartjan (NL)
WARBURTON Anthony (UK)
HUSZAL Sylwester (PL)
Alternate core members
WEBER Philippe (FR)
Flexible members
ILMARINEN Kaja (EE)
KARHI Kimmo (FI)
KORKOLAINEN Tapio (FI)
CATALDI Lucilla (IT)
CEBACEK Petra (SI)

ECHA Staff
KREBS Bernhard (Chair)
RODRIGUEZ UNAMUNO Virginia
SCHAKIR Yasmin
AIRAKSINEN Sanna
LISBOA MARTO Susana
Applicant(s)
Lonza
Akzo Nobel
Troy Chemical Company
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
NIKOLOPOULOU Dimitra (EL) (Rapporteur)
BRESCIA Susy (UK)
Alternate member
BOSMAN Saskia (NL)
Flexible members
CRESTI Raffaella (IT) - Rapporteur
BIRGANDER Pernilla (SE) - Rapporteur
HÄMÄLÄINEN Anna-Maija (FI)
PALOMÄKI Jaana (FI)
GAUSTAD Astrid (NO)
CEBASEK Petra (SI)

ECHA Staff
AIRAKSINEN Antero (Chair)
ESTEVAN MARTINEZ Carmen
JANOSSY Judit
PECORINI Chiara
RUGGERI Laura
MYÖHÄNEN Kirsi
Accredited Stakeholder Organisations
MIHAI Camelia (CEFIC)
LEROY Didier (CEPE) – only on 24.3
Applicants
EU BPR Silver Task Force
Dow
Lonza
Akzo Nobel
Troy

Efficacy WG

Core members
ATTIG Isabelle (FR)
GERRITSEN Lonne (NL)
GIATROPOULOS Athanasios (EL)
KECK Marianne (AT)
HAMEL Darka (HR)
LEPAGE Anne (BE)
SIKORSKI Martha (DE)
Alternate core members
MAXIMILIEN Yann (FR)
Flexible members
FRANK Ulrike (SE)
STRONG Colin (UK)
VOGEL Birte (DK)
Rapporteurs
CATALDI Lucilla (IT)
SIKORSKI Martha (DE)

ECHA Staff
THUVANDER Ann (Chair)
SZYMANKIEWICZ Katarzyna
SCHAKIR Yasmin
Applicants
Troy
Akzo Nobel
Lonza
BASF
Accredited Stakeholder Organisations
MIHAI Camelia (CEFIC)
CAZELLE Elodie (AISE)
POULIS Joan (AISE)-open session on 26.3
Apologies
RADU Iuliana (RO)

Environment WG

Core members
LEFÈBVRE Frederic (BE)
KOIVISTO Sanna (FI)
ALEXANDRE Stéphanie (FR)
CHION Béatrice (FR)
PETERSOHN Eleonora (DE)
KEHRER Anja (DE)
OKKERMAN Peter (NL)
KANDRIS Ioannis (EL)
Alternate member
MUIJS Barry (NL)
Flexible members
MUNCH CHRISTENSEN Anne (DK)
AHTING Maren (DE)
COSTA Lenia (PT)
SMIT Els (NL)
PASANEN Jaana (FI)
HARALDSEN Terje (NO)
NIEBRZYDOWSKA Agnieszka (PL)
GIBSON Richard (UK)

ECHA Staff
SCHIMMELPFENNIG Heike (Chair)
GUTIERREZ Simon (Vice Chair)
WIK Anna
LIPKOVA Adriana
Rapporteurs
ORRU Maria Antonietta (IT)
MARCHINI Silvia (IT)
Stakeholder observer
MIHAI Camelia (CEFIC)
LEROY Didier (CEPE)
Experts
MASON Paul (Expert for CEFIC on 25.3)
Applicants
Lonza
Akzo Nobel
Troy
BASF