WG-II-2016

Final minutes

1 June 2016

Minutes of WG-II-2016

14 – 17 March 2016

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-2016 (14-15 March 2016)

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. None accredited stakeholder organisation (ASO) was registered for this meeting.

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

2. Administrative issue

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

3. Agreement of the agenda

The Chair introduced the draft agenda and invited the working group members to include any additional items under any other business. No additional item was proposed.

Two additional agenda items were included under AoB:

- outcome of the e-consultation on residual solvents
- change of the composition of rodenticide formulation due to a change in classification and labelling and the need to perform a new storage stability test

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 2016

Comments on the storage stability were received. The minutes have been modified accordingly. After a brief discussion the modified minutes were agreed.

6. Follow up of previous working group meetings

6.1 Technical Agreements for Biocides (TAB)

The chair explained that the (general) conclusions on scientific and technical issues made at the working group meetings are summarise in the Technical Agreements for Biocides (TAB) which should be used as a reference for future similar cases. It was highlighted that the TAB is a living document that will be updated over time with new additions. Hence, the new text will be updated regularly by uploading a revised version in the Newsgroups of the BPC-WG CIRCABC site for a commenting period of 6 weeks for the WG members. After the commenting period, ECHA will revise the TAB if necessary, and publish it on the ECHA website. The procedure does not involve discussions at the WG. However, the TAB entry may be discussed at the relevant WG if necessary.

The first (APCP) document will be uploaded on CIRCABC after Easter with 6 weeks commenting period. If necessary issues might be discussed in the future WG meetings.

6.2 Open requests of previous working group meetings

The chair informed the WG members that open issues resulting of the decisions of previous WG meetings will be more closely monitored by ECHA. Therefore open issues of the discussion tables/minutes are listed. Hence, the eCA's are required to inform the others when e.g. data gaps have been closed.

7. Discussion on the active substances

7.1 Active bromine generated from bromine chloride

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

7.2 Sodium hypochlorite

All open issues were discussed and agreed by the working group members. The reference specification has been set. Additional information about analytical methods is requested.

7.3 Calcium hypochlorite

All open issues were discussed and agreed by the working group members. The reference specification has been set. Additional information about analytical methods is requested.

7.4 Chlorine

All open issues were discussed and agreed by the working group members. The reference specification has been set. Additional information about analytical methods is requested.

7.5 Piperonylbutoxide (PBO)

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

7.6 Momfluorothrin (S-1563)

All open issues were discussed and agreed by the working group members. The reference specification and reference source have been set. Additional information about analytical methods, physico-chemical and physical hazard properties are requested.

7.7 Acetamiprid

All open issues were discussed and agreed by the working group members. The reference specification has not been set yet. Additional information about analytical methods, physico-chemical and physical hazard properties are requested.

7.8 Peracetic acid

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

8. Technical and scientific issues

8.1 Redefinition of Citriodiol

The working group members, the evaluating competent authority and the applicants agreed to redefine the substance into '*Eucalyptus citriodora oil' hydrated, cyclized'.*

8.2 Reference specification and source of ATMAC/TMAC

The reference specification and source of ATMAC/TMAC was an open issue of the working group meeting II in 2015. The eCA received new 5-batch analyses of the applicants and derived reference specifications and reference sources for the substance. The working group members agreed on the conclusions of the eCA, hence the reference specifications and reference sources of ATMAC/TMAC are agreed by the working group members.

9. Any other Business (AoB)

9.1 Outcome of the e-consultation on residual solvents

ECHA described the outcome of the e-consultation on residual solvents in active substances. A summary of the e-consultation will be distributed.

9.2 Change of the composition of rodenticide formulation due to a change in classification and labelling and the need to perform a new storage stability test

One working group member explained that biocidal products containing anticoagulant rodenticides might need to be authorised with a lower content of these actives due to a change in the classification of these active substances. Hence, it was asked whether new storage stability tests need to be provided for product authorisation. It was agreed that a new storage stability test is needed to check that the decrease of the active substance is still acceptable after storage. In case of an a.s. decrease >10% upon storage, the need for additional palatability/efficacy data on aged baits should be envisaged.

9.3 Lessons learnt

The chair gave a presentation on the applicability time of new guidance, new information received during peer review and on general issues that attracted attention when preparing for the working group meeting. The presentation will be made available to the working group members.

Minutes of Human Health WG

WG-II-2016 (14-16 March 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that seven core members and 13 flexible members were present. No accredited stakeholder organisations were present. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

R4BP 3 is now in use for active substances for communication with applicants and eCAs. The relevant MSCA manual will be updated and sent to the MSCAs.

The members were reminded that confidential documents should be uploaded only in the 'Submissions' folder in S-CIRCABC.

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-I-2016

The minutes were agreed with one minor change.

6. Discussion of active substances

6.1 Active bromine generated from bromine chloride (eCA NL) PT 11

The WG mainly discussed the derivation of toxicological reference values. All discussion items were closed and the dossier will proceed to the Biocidal Products Committee.

6.2 Peracetic acid (eCA FI) PT 11, 12

This active substance has already been approved for other PTs. The discussion focused on human exposure assessment. All points were closed and the dossier will proceed to the Biocidal Products Committee.

6.3 Acetamiprid (eCA BE) PT 18

The main discussion item was the developmental neurotoxicity study, which was not available in the biocide dossier. The WG requested this study to be provided; the conclusions on e.g. the reference values will be made only once it is available. Other discussion points were closed. The evaluation of the developmental neurotoxicity study and its possible impact on reference values will first be discussed in an ad hoc follow-up and the dossier will then proceed to the Biocidal Products Committee.

6.4 Piperonylbutoxide (PBO) (eCA EL) PT 18

All discussion points related to effects assessment, reference values and absorption were closed. An ad hoc follow-up was launched to conclude whether the batches used in toxicological studies support the technical specification.

6.5 S-1563 (Momfluorothrin) (eCA UK) PT 18

The discussion points concerned toxicological reference values and human exposure assessment. All points were closed and the dossier will proceed to the Biocidal Products Committee.

6.6 Sodium hypochlorite (eCA IT) PT 1-5

This agenda item was discussed together with item 6.8 below.

6.7 Calcium hypochlorite (eCA IT) PT 2-5

This agenda item was discussed together with item 6.8 below.

6.8 Chlorine (eCA IT) PT 2, 5

There was insufficient time to discuss all the open points. Those agreements reached at the WG will be considered as finalised, but the remaining issues need to be finalised before the dossier can proceed to the Biocidal Products Committee. The process for finalising these dossiers will be clarified among the eCA, the applicant and ECHA.

6.9 Tetramethrin (eCA DE) PT 18

This agenda item was discussed together with item 6.10 below.

6.10 D-Tetramethrin (eCA DE) PT 18

This was an early WG discussion to agree on the effects assessment before submitting the CARs to ECHA. All points were agreed and the reference values established. The eCA will provide the full draft CARs for peer review.

7. Technical and guidance related issues

7.1 Update on guidance development

SECR informed that the Partner Expert Group (PEG) meeting for the first revision of guidance volume V on active micro-organisms is planned for 27 April 2016. This will be

followed by a CA consultation that is expected to be launched in May/June 2016. Publication of the guidance is expected to take place in July 2016.

The draft guidance on disinfectant by-products is being finalised by the dedicated ad hoc working group. The PEG consultation is expected to be launched in March/April 2016, followed by a virtual PEG meeting scheduled for 2 June 2016 for the human health part. The CA consultation would be launched in August/September 2016 with a publication target of November/December 2016.

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

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

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

The most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling: the main differences between PT 7 and PT 8 products are being clarified. The recommendation is being consolidated based on this information.

Product application amount for repellents – exposure assessment: the finalisation of this recommendation should take into account the outcome of the discussion on harmonized risk mitigation measures for repellents containing products within the Coordination Group. The outcome of the discussion has been forwarded to the Coordination Group for elaboration of regulatory and policy aspects.

7.2(a) Recommendation of the Ad hoc Working Group – Human Exposure

The recommendation "Hand disinfection in hospitals by professionals – Inhalation and dermal exposure during hand disinfection" was agreed by the WG.

7.3 Risk assessment of corrosive substances

SECR presented the meeting document WGII2016_TOX_7-3 as a thought starter for a discussion on the appropriate way forward with respect to dermal absorption of corrosive substances/products. SECR pointed out that dermal absorption had been discussed in length even for substances that are corrosive, considering this as an unnecessary effort because often the dermal absorption value for corrosive concentrations of a substance is not used in the risk assessment, thus questioning the relevance of setting dermal absorption values for corrosive concentrations of such substances.

One member pointed out that the assumption of 100 % dermal absorption should in any case only concern corrosive and not irritant concentrations.

Is systemic risk characterisation necessary for corrosive concentrations?

The use of appropriate personal protective equipment (PPE) and risk mitigation measures (RMM) will always be required for corrosive concentrations, resulting in no direct contact with the corrosive substances. Exposure to corrosive concentrations would thus be negligible. On this basis the members agreed that, provided that a safe use can be demonstrated with respect to local effects, exposure to corrosive concentrations can be excluded and systemic risk assessment would not be necessary for such concentrations. This has already been applied at least in some CARs. It has to be mentioned in the CAR that for corrosive concentrations the systemic risks are covered by the local risk characterisation.

Should the active substance penetrating the PPE still be considered as corrosive?

A member considered that the PPEs reduce the amount of substance reaching the skin, but not the concentration. Therefore, the active substance penetrating the PPE should still be considered as corrosive and exposure could also be relevant for e.g. splashes. Another member explained that corrosive substances had not been taken into account when the penetration factors for PPEs were established and the overall protection/risk mitigation should be higher for the handling of such substances to avoid penetration. Therefore it is not appropriate to use the PPE protection factors derived from non-corrosive substances.

To estimate the corrosivity of formulations that have not been tested, should only specific or generic concentration limits be applied?

For formulations that have not been tested, the members agreed that only specific or generic concentration limits should be applied in estimating corrosivity. The calculation method would then be applied where relevant. One member pointed out that this is the most usual case, as normally a study is not available.

Is it necessary to derive dermal absorption values for corrosive concentrations?

The WG agreed that deriving a dermal absorption value for corrosive concentrations is usually not necessary. It would still be mentioned that 100 % dermal absorption would be assumed but this would not need to be elaborated and the value would not be used in the systemic risk assessment unless this is required in a specific case.

8. Any other business

8.1 Other information & lessons learned

SECR informed of the ECHA activity on preparing advice for in situ generated active substances. The aim is to provide a practical guide on how to prepare a dossier for in situ generated active substance, specifically the precursors and their specifications, and how to deal with exclusion/substitution criteria.

A workshop will be organised on 19 May in Berlin on the assessment of dermal absorption for antifouling products and other matrices that form a dry film during testing.

SECR reminded the members of the importance of respecting deadlines, especially pointing out the step of providing the updated RCOM. This document is critical for the preparation for the WG meetings.

In order to reduce duplicate work, it is important to prevent redundant entries in the RCOM tables. Therefore, the commenting MSCAs should avoid repeating a point several times; instead it should only be indicated where it is relevant. In case other MSCAs have already made repeated comments, the eCA was encouraged to group them and indicate by colour coding or other means which is the leading comment to be discussed.

Even more important is to provide all product types in a single RCOM, instead of multiple files that often contain identical comments. Providing a single RCOM will have a major effect in the workload of all MSCAs involved, as well as SECR.

When there are late comments in the trilateral discussions, these can be left out from the updated RCOM and can instead be provided directly to SECR.

Minutes of Efficacy WG

WG-II-2016 (16-17 March 2016)

1. Welcome and apologies

The Chair welcomed all participants to the 11th Efficacy WG meeting. There were seven core members and one alternate member who participated in the meeting. In addition, ten flexible members and 2 ASO representatives participated to the EFF WG meeting. The Chair introduced also representatives of ECHA.

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

2. Administrative issues

The SECR gave a brief summary on the administrative issues.

3. Agreement of the agenda

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

Conclusions and actions

Members agreed on the proposed agenda.

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

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

5. Agreement of the draft minutes from WG-I-2016

The Chair informed that some comments were received from the COM, the most notable one refers to agenda item 6.1 and concerns the change from refillable to non-refillable tamper-resistant bait stations. COM comments were accepted by the EFF WG.

NL asked for clarification whether for agenda point 7.2 d it was agreed that "…such claims could be made on case by case basis". This will be checked and clarified by ECHA from the recordings.

6. Discussion of active substances[1]

6.1 Active bromine generated from bromine chloride (eCA NL)

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 Peracetic acid (eCA FI)

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.

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

6.3a Sodium hypochlorite (eCA IT)

Before the discussion the Chair alerted the EFF WG members that all open points for sodium hypochlorite are also relevant to calcium hypochlorite and the discussion table for calcium hypochlorite will be reopened.

There were three remaining open points in the RCOM table. The first one stated that it is not clearly shown in the CAR what has been demonstrated, tested and what is covered by the risk assessment. The EFF WG agreed that the CAR has to be restructured to be more clear and readable.

The second open point concerned efficacy against prions. The EFF WG agreed that efficacy against prions has not been demonstrated, but information that product is intended to be used against prions can be mentioned in the CAR, as long as it is clearly stated that it has not been tested. Additional information should be provided at product authorisation stage.

The third open point concerned efficacy against bacterial spores. The eCA pointed out that the CAR will be restructured and cross reference to part B will be made. It was accepted by the EFF WG.

An ad hoc follow up procedure was decided to be necessary.

6.3b Calcium hypochlorite (eCA IT)

The Chair reopened the discussion table as there were the same open points for discussion as for sodium hypochlorite. In addition to prions, a claim against mycobacteria had been made. The EFF WG concluded that efficacy against mycobacteria has not been demonstrated. The same actions as for sodium hypochlorite were agreed upon.

An ad hoc follow up procedure was decided to be necessary.

6.3c Chlorine (eCA IT)

There was one remaining open point in the RCOM table, stating that it should be clearly stated in the CAR that the efficiency tests done show a static and not a cidal activity. It was also noted that a concentration used in the risk assessment is not the same as presented in efficacy testing. The EFF WG agreed on that the applicant has to provide additional data to prove efficient concentrations used in the risk assessment for respective PTs.

An ad hoc follow up procedure was decided to be necessary.

6.4 Piperonylbutoxide (PBO) (eCA EL)

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.

6.5 Acetamiprid (eCA BE)

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.

6.6 S-1563 (Momfluorothrin) (eCA UK)

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

The WG agreed on the evaluation of the eCA.

6.7 Status of ongoing ad hoc follow-up of silver zinc zeolite (eCA SE)

SE presented the current status of the ongoing ad hoc follow-up of silver zinc zeolite. Before WGII2016 SE revised in Doc. IIB the chapter concerning efficacy of silver zinc

zeolite and prepared a background paper with certain questions addressed to the EFF WG. It was circulated as an e-consultation before the WG meeting but due to very few comments it was decided to discuss these questions during the EFF WG meeting. The EFF WG agreed that for PT7 and PT9 efficacy is not demonstrated. The Applicant was obliged to elaborate with the help of the eCA more detailed description of possible use categories for these PTs, and to carry out tests to demonstrate this. In relation to appropriate efficacy tests for PT 4, the EFF WG accepted the test carried out with granular activated carbon as sufficient, though another active substance was used (silver zeolite). This was accepted as a worst case, as silver zeolite releases less silver than silver zinc zeolite.

The EFF WG members were asked to provide comments to the revised Doc IIB.

An ad hoc follow up procedure was decided to be necessary.

7. Guidance

7.1 Continuous work on Efficacy Guidance Part B/C

Certain remaining issues related to Chapter 2, 4 and 5 were discussed. Finally the EFF WG agreed on chapters 2; 4.2 and 4.5. Chapters 5.2 and 5.3 were discussed and due to significant amendments needed they will be revised by NL and SE respectively. Because of time limitations it was decided that chapter 5.5 will be proceeded for PEG consultation without discussion at WG level.

7.1.a Appendices for PT1-5

Final discussion on Appendix 1 and 4 took place as there were some remaining comments from the PEG consultation.

Appendix 1 will be revised by ECHA based on the discussion, which took place during the meeting. It was decided to remove column 'Target site' as redundant from PT1. PT1 - claim related to preoperative treatment was removed as not appropriate. PT2 - sentence concerning malodour claim was rephrased and currently only malodour caused by microbial activity will be mentioned, odour panel test was added to appropriate methodology. Antistaining claim will be consulted with the COM level as related to the scope of the BPR. PT3 – disinfection of hard surfaces (veterinary health care) was moved to PT 2 according to current approach. In addition, tests with exotic organisms were deleted; they might be added as additional tests organisms when needed according the CEN standard. Some other minor comments were agreed as well.

Appendix 4 was revised by NL shortly before the meeting and only one remaining open point concerned the log reduction for handwash products in PT1. It was agreed to require log 3 for handwash products, but also to initiate the discussion in CEN WG concerning possible harmonisation of efficacy tests for handwash and handrub disinfectants.

7.1.b Efficacy testing of Treated Articles - (health) claim matrix

This agenda item was skipped because of time limitations.

7.1.c Guidance on Efficacy Assessment for PT14 – Rodenticides

ECHA presented certain recent comments raised by IND together with proposed answers from the EFF WG members and the revised PT14 draft guidance. The EFF WG agreed upon the answers to the comments. The guidance will be published on ECHA website end of March/beginning of April 2016.

7.2 SPC editor in relation to target organisms

This agenda item was skipped because of time limitations. It will be discussed during EFF WG meeting in May 2016.

8. AOB

8.1 Aircraft disinfection (BE)

This agenda item was skipped because of time limitations. E-consultation will be launched. SECR will circulate an email with deadlines for commenting.

8.2 Treatment against *S. lacrymans* (FR)

This agenda item was skipped because of time limitations. E-consultation will be launched. SECR will circulate an email with deadlines for commenting.

8.3 Tests against enveloped viruses (AT)

This agenda item was skipped because of time limitations. E-consultation will be launched. SECR will circulate an email with deadlines for commenting.

8.4 Workshop on the harmonisation of evaluation of repellents, PT 19 (AT)

This agenda item was skipped because of time limitations. AT prepared written information for the FF WG members.

8.5 Other information & lessons learned

This agenda item was skipped because of time limitations.

Minutes of Environment WG

WG-II-2016 (16-17 March 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were five core members, three alternate members and nine flexible members present in addition to one rapporteur. No representatives from accredited stakeholder organisations were present. 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

SECR gave a brief presentation on housekeeping and administrative issues.

R4BP 3 is now in use for active substances in communication with applicants and eCAs. The relevant MSCA manual will be updated and sent to the MSCAs.

The members were reminded that confidential documents should be uploaded only in the 'Submissions' folder in S-CIRCABC.

3. Agreement of the agenda

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

The Chair further indicated that due to the parallel EFF session, the agenda will be handled in a flexible way and informed on the following changes in the agenda:

Item 6.8 (Active bromine) will be discussed before items 6.5-6.7 (Chlorines)

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

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

The Chair explained that she has an interest with two active substances, which will be chaired by the Deputy-chair. However the Chair will act during the discussion of these substances as SECR-expert for general items which are related to guidance and not to the substance as such.

5. Agreement of the draft minutes from WG-I-2016

The Chair informed that comments were received for items 6.3a, 6.3b, 6.3c and the general minutes. The minutes with this amendment were adopted.

6. Discussion of active substances[2]

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

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

6.2 S-1563 (Momfluorothrin) (eCA UK) PT 18

All thirteen points for discussion were agreed by the WG (two points were provided only for information and no comments were made by the WG.). The eCA will prepare the updated CAR and it will proceed to the Biocidal Products Committee.

Action for AHEE:

- Development of RTU/small scale application scenario for PT 18 (household and professional use)
- Development of a proposal on how to use Fsim in an aggregated exposure assessment.

6.3 Acetamiprid (eCA BE) PT 18

Two out of eleven points could not be agreed by the WG. For one of the points an ***ad-hoc* follow-up** was concluded necessary. As the assessment of one of the PBT criteria is dependent on the results of the ad-hoc follow up, the respective discussion point was agreed to be finalised only once the ad-hoc follow up has been finalised.

Action SECR/WG:

- The following conclusions on simultaneity factor (Fsim) for calculating local release to STP will be added to the TAB:
    - Fsim should not be doubled for taking into account seasonality of a use
    - Fsim is considered also applicable for professional users.

  Both items will be considered in the future in the frame of a potential update of the ESD.

6.4 Piperonylbutoxide (PBO) (eCA EL) PT 18

Two out of nine points could not be agreed by the WG. For these points ***ad-hoc* follow-ups** were concluded necessary.

Action SECR:

- Check with FR/BE the discussion on the wet cleaning area for large building for previous substances and verify the area of 180 m² and add the value/conclusion in the TAB together with the volumes for house and large building defined by the WG during the meeting

Action SECR/DE:

- DE to provide a discussion paper on how to assess the formation of metabolites (Tier 1: assume a formation rate of 100%) for the AHEE meeting in April 2016 by 8th of April
- SECR to add the item on the agenda by for the AHEE meeting in April 2016.

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

6.5 Calcium Sodium hypochlorite (eCA IT) PT 2-5

One out of eleven points could not be agreed by the WG. For this point an ***ad-hoc* follow-up** was concluded necessary.

Action SECR:

- Conclusion to be added to the TAB that it is not necessary to include direct emission to soil from disinfection of vehicles used for animal transport in PT3 as the scenario is not included in the ESD and most of the treatments are done on hard standing.
- Conclusion to be added to the TAB that that the direct emission to soil from disinfection of pet case and litter trays does not need to be assessed since it is very unlikely as normally the disinfection of pet cases and litter trays is performed indoors.

6.6 Sodium hypochlorite (eCA IT) PT 1-5

This agenda item was discussed together with item 6.5 above.

6.7 Chlorine (eCA IT) PT 2, 5

This agenda item was discussed together with item 6.5 above.

6.8 Active bromine generated from bromine chloride (eCA NL) PT 11

Two out of five points could not be agreed by the WG. As these are related the two issues were agreed to be resolved jointly in one ***ad-hoc* follow-up**. The eCA will prepare the updated CAR and it will then proceed to the Biocidal Products Committee.

Action Applicant/AHEE:

- Applicant to provide their evaluation on PT 11 cooling systems to SECR. It will be evaluated in the frame of the AHEE consultation on refinement options for PT 11 to be initiated in the frame of the agenda item 6.9.

6.9 Peracetic acid (eCA FI) PT 11, 12

This active substance has already been approved for other PTs. The discussion focused on environmental exposure assessment. All points were closed, the eCA will prepare the updated CAR and it will then proceed to the Biocidal Products Committee.

Action SECR/AHEE:

- SECR to start a general discussion on refinement options for PT 11 (for once through and large recirculating systems).

7. AOB

7.1 Other information & lessons learned

SECR informed of the ECHA activity on preparing advice for in situ generated active substances. The aim is to provide a practical guide on how to prepare a dossier for in situ generated active substance, specifically the precursors and their specifications, and how to deal with exclusion/substitution criteria.

The physical AHEE meeting will take place in Amsterdam on 21/22 April. The timelines according to the working procedure for active substance approval will also apply for the AHEE meeting: Invitation and draft agenda four weeks before the meeting, i.e. shortly

after WG-II-2016. Document for discussion/agreement should be provided by 8 April 2016 and will be upload 10 days before the meeting (11 April 2016).

SECR reminded the members of the importance of respecting deadlines, especially pointing out the step of providing the updated RCOM. This document is critical for the preparation for the WG meetings.

In order to reduce duplicate work, it is important to prevent redundant entries in the RCOM table. Therefore, the commenting MSCAs should avoid repeating a point several times, instead it should only be indicated where it is relevant. In case other MSCAs have already made repeated comments, the eCA was encouraged to group them and indicate by colour coding or other means which is the leading comment to be discussed.

Even more important is to provide all product types in a single RCOM, instead of multiple files that often contain identical comments. Providing a single RCOM will have a major effect in the workload of all MSCAs involved, as well as SECR.

When there are late comments in the trilateral discussions, these can be left out from the updated RCOM and can instead be provided directly to SECR.

No additional items were raised by WG members.

List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MŰHLE Ulrike (DE)
WEBER Philippe (FR)
GATOS Panagiotis (GR)
HUIZING Tjaart-Jan (NL)
POUWELS Marianne (NL) alternate
HUSZAL Sylwester (PL)
WARBURTON Anthony (UK)
Flexible members
Van BERLO Boris (BE) Rapporteur
GROSSMANN Ven Stephanie (BE)
KARHI Kimmo (FI) Rapporteur
KORKOLAINEN Tapio (FI)
HYVARINEN Tuija (FI)
HELGERUD Trygve (NO)
CATALDI Lucilla (IT) Rapporteur

Applicants
Albemarle Europe
Endura S.p.A.
Sodium Hypochlorite Registration Group
Euro Chlor
Kwizda Agro
Peracetic acid registration group
Sumitomo
Citrefine International Ltd
Fulltec GmbH
ECHA Staff
KREBS Bernhard (Chair)
RODRIGUEZ UNAMUNO Virginia
AIRAKSINEN Sanna
LISBOA MARTO Susana
SCHAKIR Yasmin

Human Health WG

Core members
MAXIMILIEN Elisabeth (FR)
DE SAINT-JORES Jeremy (FR)
HOLTHENRICH Dagmar (DE)
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