WG-I-2016

Final minutes

26 May 2016

Minutes of WG-I-2016

25 – 28 January 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-I-2016 (25 January 2016)

1. Welcome and apologies

The Chair welcomed the participants of the working group meeting. No 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.

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 V 2015

Comments on the active substances 'Bacillus thuringiensis subsp. Kurstaki, Serotype 3a3b, Strain ABTS-351 (BTK)' and the general agenda items were received. The minutes have been modified accordingly. The modified minutes were agreed.

6. Discussion on the active substances

6.1 Cyanamide

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

7. Follow up of previous working group meetings

7.1 Storage stability

Discussion table – Storage Stability		
a) **No.**	**b) Issue and background** **Ref. in RCOM**	**c) WG discussion** **Ad hoc follow-up where relevant**
1.	**Which approach and/or limits are MS following when the active substance content decreases >10%?** **Background from guidance:** The active substance content should be determined using a validated method of analysis. It is generally recognised that a decrease in the active content of ≤10 % should not adversely affect the efficacy and risk assessment of the product. Where the degradation of the active content is >10%, or in cases where a decrease of <10% may affect the efficacy and/or the risk assessment, then a justification for the acceptability of the decrease should be provided. This may require an assessment of the degradation on the efficacy and risk assessment. The fate (degradation products) of the active substance may have to be assessed. Alternatively, a more appropriate shelf life, in which the degradation of the active content is considered acceptable, should be proposed. For this reason, particularly when the active is known to degrade, it is advantageous to perform ambient storage studies in which the active content is assessed at interim times. **Questions**: 1. Should a maximum limit of allowed AS decrease be set? 2. If so, this maximum limit should be set/defined. 3. If not, how should cases with very high decrease of active substance (e.g. 80%) best be treated? This in connection to the issues of overdosing and of consumer deception.	The working group members concluded that a degradation of content of the active substance by more than 10% should be assessed on a case-by-case basis as the request of further information depends on the active substance and the product. Hence, the working group members regarded the setting of maximum degradation limits as not appropriate. In general, a decrease of the active substance content by more than 10% requires further efficacy data, information on the degradation products and information on the toxicity and eco-toxicity of these degradation products. In general, overdosing is not acceptable for the working group members. Nevertheless, there are no criteria on overdosing available.

Discussion table – Storage Stability		
a) No.	**b) Issue and background Ref. in RCOM**	**c) WG discussion Ad hoc follow-up where relevant**
2.	**Shelf life – analytical methods** How to address the requirements of storage stability studies if the active substance is analysed with an accepted analytical method through a species that is present/detectable in the active form but also in its degradation products?	The choice of the analytical method(s) should be done case-by-case and depends on the chemical species to be analysed. An appropriate method should be required by the applicant.
3.	**Shelf life – UVCB substance** What information is required if the active substance is an UVCB substance and no single active ingredient is specified?	Due to the complexity of the different groups of UVCB substances, the assessment should be done to be case by case. It was highlighted that for UVCB substance not only the analytical data should be considered but also other parameters such as the analytical finger-print, physico-chemical properties, toxicity and eco-toxicity data may be used along with efficacy data after storage.

8. Any other business

8.1 How to deal at product authorisation with reference sources with a higher purity than the minimum purity in the implementing regulation

(WGI 2016_APCP_8-1_Reference sources with higher purity)

The working group members agreed with the proposal made in the document.

- Purity should not be lower than the minimum purity used for the inclusion regulation:
  87< X <97.9%
- Impurity profile remains the same (i.e. no new relevant or significant impurities are present)
- The limits of all significant but not relevant impurities as certified on the basis of a five batch analysis for the reference source are not exceeded by more than the following limits:

Limits of significant but not relevant impurities in the technical specifications of the reference source	Acceptable maximum increase in the alternative source
≤6 g/kg	3 g/kg
>6 g/kg	50% of the certified limit

If one of these conditions is not met, the applicant has to submit an application for technical equivalence assessment.

Minutes of Human Health WG

WG-I-2016 (26 January 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that six core members and 20 flexible members were present. One accredited stakeholder organisation (CEFIC) was present. Applicants were registered for their specific substance discussions.

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

2. Administrative issues

SECR gave a brief presentation on housekeeping and administrative issues.

The remaining meetings in 2016 will be physical meetings. The provisional meeting dates are available in S-CIRCABC.

The S-CIRCABC interest group "Biocides TM" will be renamed as "Biocides Active Substances" and restructuring will also take place.

Some members have had problems receiving the e-mail invitations as they have been automatically moved to the junk mail folder. The invitations will from now on be also uploaded to S-CIRCABC.

3. Agreement of the agenda

The Chair introduced the draft agenda and invited any additional items. 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-V-2015

The minutes were agreed without further comments.

6. Discussion of active substances

6.1 DBDCB (eCA CZ) PT 6

The WG discussion only concerned the assessment factor used in deriving the long-term AEL (acceptable exposure level) and the ADI (acceptable daily intake). The default assessment factor of 2 was agreed for duration extrapolation.

6.2 Cyanamide (eCA DE) PT 3, 18

The discussion mainly concerned dermal absorption and the derivation of human health reference values. The working group also agreed that the substance should not be

considered as genotoxic and the margin of safety was considered sufficient for possible non-genotoxic carcinogenic effects. All discussion items were closed and the dossier will proceed to the Biocidal Products Committee.

6.3 Empenthrin (eCA BE) PT 18

Early WG discussion

The early working group discussion concerned the acceptability of waiving of a study, where the working group agreed that the waiving was not acceptable.

7. Technical and guidance related issues

7.1 Update on guidance development

SECR informed on the timing of the first revision of guidance volume V on active micro-organisms. The Partner Expert Group consultation will be launched in February and the guidance is expected to be finalised and published in July 2016.

The first revision of the Technical Agreements for Biocides (TAB) will be provided after the working group meeting for a six-week commenting period by the Competent Authorities.

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 were clarified. The recommendation will be consolidated based on this information and is planned to be presented at the WG-II-2016.

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

- **The scenario of hand disinfection**: during the preparation of this recommendation, it was pointed out that the choice of the parameters for the room size and the ventilation rate lacked clear references. Considering the relevance of those two factors in the exposure assessment, further discussion will be needed within the HEAdhoc.

SECR informed that a physical meeting of the HEAdhoc would take place on 21 and 22 April 2016 and that the Federal Institute for Risk Assessment (BfR) in Germany will host the event. The HEAdhoc members will receive the invitations and the draft agenda one month before the meeting.

7.3 Technical Agreements for Biocides (TAB) – dermal absorption of antifouling paints

The SECR proposal for a new TAB entry was not agreed on, as it was considered that further clarifications would still be necessary on several aspects.

The working group agreed that, as a temporary measure until the availability of results from the workshop that will be organised on PT 21 dermal absorption, the stratum corneum should not be considered as absorbed material, provided that the 24-hour results are used to calculate the dermal absorption value. Where this agreement would be applied, the applicants should be aware that further information may be requested later.

7.4 Guidance on disinfectant by-products

The draft guidance document on disinfection by-products for human health and the environment have been prepared by a dedicated ad hoc Working Group. This guidance will be included as a part of the ECHA guidance documents using the official ECHA Guidance procedure, and before starting the procedure, the agreement of the Human Health working group was requested to ensure that the members find the guidance in general appropriate and have no major reservations.

The members welcomed the document and no reservations were expressed. The WG agreed that the guidance document is in general appropriate and the ECHA guidance procedure can be initiated.

The draft guidance will be uploaded to S-CIRCABC for commenting until 29 February with the aim of thereafter providing a final document for the PEG consultation.

8. Any other business

8.1 Other information & lessons learned

Documents relevant for working groups

Three documents were agreed at BPC-13 in December 2015 having implications for the working groups. These documents were introduced with special focus on the aspects relevant for the working groups. The principles of these documents will be applied starting from WG-II-2016:

- *Applicability time of new guidance and guidance-related documents in active substance approval*. http://echa.europa.eu/documents/10162/4221979/applicability_guidance_jan_16_en.pdf
- *Introducing new information during the peer review process of active substance approval*. http://echa.europa.eu/documents/10162/4221979/peer_review_info_jan2016_en.pdf
- *Clarification of some elements regarding the role of the BPC Secretariat in the active substance approval process*.

  Available in S-CIRCABC:

- Path: /CircaBC/echa/Biocidal Products Committee (BPC)/Library/Non Confidential Folder/01. Procedural Documents/02. Active substance approval/13. Role of BPC Secretariat in active substance approval process.pdf
- https://webgate.ec.europa.eu/echa-scircabc/w/browse/c4f13a65-9b4e-45b8-99e4-723584ab107a

Disinfectants project

The purpose of this project is to develop and implement harmonised and coordinated approach for risk assessment of biocidal active substances used as disinfectants. The kick-off meeting with the contractor took place on 17 December 2015.

Harmonising CAR & CLH report templates

A Task Force has been formed consisting of 20 representatives from 12 MSCAs. The members will be asked to indicate challenges in transferring the information from CAR to CLH dossier with the aim of harmonising the templates so that it would not be necessary to repeat the information in two documents, or that this work would be facilitated as much as possible.

Workshop on PT 21 dermal absorption

A workshop will be organised in cooperation with MSCAs and ASOs. The organising committee has members from ECHA, DE, UK, NL, CEFIC and CEPE. The WG members will be informed as soon as the time and venue have been established.

R4BP 3 in active substance approval

Starting 29 February 2016, R4BP 3 will be used in official communications such as legal steps, providing meeting documents to applicants and requests for further information. Starting from WG-II-2016, SECR will send discussion tables and minutes to applicants via R4BP.

Work programme in 2016

The work programme includes a high number of substances for the remaining working group meetings in 2016. Reference was made to the final document WGI2016_TOX_8-1a_Planning 2016 "Tackling the workload in WG meetings in 2016".

The measures to be implemented from WG-II-2016 onwards include the following:

- Time limits for agenda items and discussion table points
- ECHA-eCA teleconferences will be targeted to cases where an outstanding issue is identified

The following requests were made to MSCAs:

- Increase efforts made in commenting
- Focus on major issues when commenting
- Reinforce cooperation/discussions to minimise the numbers of open points
- eCAs to request e-consultations (instead of early working group discussions) for unclear major items that might be solved before the main WG discussion

Registration for WG meetings

All participants were urged to respect the deadline for registration to the WG meeting and to clearly indicate the role of each participant (rapporteur, adviser, ASO expert etc.). Any new attendees need to provide the following declarations:

- MSCAs: confidentiality & commitment
- ASOs: confidentiality & acceptance notice (Code of Conduct)

Templates for declarations (for MSCAs and ASOS) are available in S-CIRCABC:

- Path: /CircaBC/echa/BPC-WG/Library/Non-confidential/09. General information and procedural documents
- https://webgate.ec.europa.eu/echa-scircabc/w/browse/66370341-4fa3-44b1-bf47-adb0d3f57187

Starting from WG-II-2016, a stricter policy will be applied and late registrations will generally be rejected.

Minutes of Efficacy WG

WG-I-2016 (27 January 2016)

1. Welcome and apologies

The Chair welcomed all participants to the tenth Efficacy WG meeting. Seven core members and one alternate member participated in the EFF WG meeting, in addition, 15 flexible members and 2 ASO representatives. The Chair introduced also the representatives of ECHA.

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

2. Administrative issues

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

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-V-2015

The Chair informed that comments were received from FR concerning agenda point *7.2.c - Guidance on Efficacy Assessment for PT8 (Wood Preservatives) and* 7.4 Practical tests for teat disinfectants in PT 3 - preliminary results. With reference to point *7.2.c DE was asked for the proper DIN standard and it was agreed that it will be sent after the meeting and included in the minutes.* The minutes with these additional amendments were agreed by the EFF WG.

6. Discussion of active substances[1]

6.1 Renewal of anticoagulant rodenticides, PT 14

The Chair presented an introduction to the discussion table on renewal of anticoagulant rodenticides, i.e. chlorophacinone, coumatetralyl, warfarin, brodifacoum, bromadiolone, difenacoum, difethialone and flocoumafen. As all applications for renewals are processed in parallel, exceptionally all substances were discussed together. All applicants agreed to have a joint discussion on risk mitigation measures in relation to efficacy. The main issues for discussion were indicated in the discussion table with four points:

1) FGARs vs SGARs in relation to efficacy and resistance management

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

Discussion was focused on the use of first and second generation anticoagulants in the view of a first choice for use to control rodents taking into account efficacy and resistance management aspects. There were different views based on the situation in each Member State. In general, the resistance situation is not clear and it is difficult to recommend the use of FGARs or SGARs as a first choice against mice due to the lack of supportive data. WG members were of the opinion that the statement proposed in section 2.3.3, point 4 of the AR: *Product information of products [containing a FGAR substance; delete for SGAR substances] authorised for the general public against mice shall recommend that in case of suspected lack of efficacy by the end of the treatment, the user should switch to another rodenticide or call a pest control service'* should be more general as non-professionals are not aware about the differences between FGARs and SGARs. Consequently, the EFF WG agreed to remove the phrase *'switch to another rodenticide or'* and section *[containing a FGAR substance; delete for SGAR substances]* from that statement. COM indicated that they would have some reservations regarding deletion of the phrase *'switch to another rodenticide or'* due to the policy implications in some MSs.

2) Monitoring of resistance in relation to testing proposals and target organisms

Several questions were raised during the discussion on monitoring resistance about need of resources, costs, need for a harmonised protocol, networking, data collection procedures as well as use of alternative non-chemical methods and availability of data.

Taking into account all these uncertainties the EFF WG concluded that appropriate data for resistance monitoring should be provided by the applicants during the next renewal process depending on the feasibility of the implementation of resistance monitoring programme at EU level. A relevant sentence will be included into section 2.3.4 in the current AR template.

3) Baiting strategies in relation to pulsed baiting, permanent baiting, duration of baiting, pre-baiting survey and use of non-conventional bait stations as well as frequency of visits

- Pulsed baiting and permanent baiting:

The EFF WG agreed with the statement in section 2.3.2/B.2/2.b of the AR: for professional users (other than PCOs): *'Products shall not be authorised for use in permanent or pulse baiting treatments'.*

With regards to permanent baiting some MSs indicated that the key point for permanent baiting is the determination of frequency of visits. As it depends on national policies and practices the number of required visits is not included in the statement in the AR. DE will circulate a Code of Best Practice to the EFF WG which is used by PCOs in this country.

As the discussion on baiting strategy took place only at the EFF WG, some contradictions may occur in the ARs in relation to ENV. Harmonisation of statements will take place during physical meeting in Helsinki in mid-February 2016.

- Duration of baiting:

The EFF WG agreed with the statement proposed in section 2.3.3, point 1: *Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.*

- Pre-baiting survey:

COM clarified the meaning of the pre-baiting survey (as visual survey conducted before the baiting programme) and informed that the intention of this statement in the AR was to make the pre-baiting survey mandatory. Based on the discussion and in order to avoid misunderstanding of that statement, the EFF WG proposed to amend 'pre-baiting survey' (which suggest un-poisoned bait) to 'pre-treatment survey'. The EFF WG agreed on the following statement: *Products authorised either for professional or trained professional users shall require a pre-treatment survey of the infested area in order to determine the extent of the infestation.*

With reference to integrated pest management control strategies COM informed that it is a part of an ongoing discussion at CG concerning harmonisation of information in the SPC, especially in relation to instruction for use.

- Non-conventional bait stations:

The EFF WG agreed with the statement in section 2.3.2/B.1/1.a: *Products shall only be authorised as ready-to-use refillable tamper-resistant bait stations.*

With reference to the statement in section 2.3.2/B.1/1.b the EFF WG agreed that the determination of maximum bait content should be defined at product authorisation stage. A respective phrase was added to the presented statement: *Products shall only be supplied to the general public in ready-to-use non-refillable tamper-resistant bait boxes with a maximum bait content of [to be defined at product authorisation stage by rodent species, type of bait formulation and active substance group – FGAR vs. SGAR]*.

The statement in section 2.3.2/B.3/3.b was amended as well: *Products may be authorised for use in covered bait points other than refillable tamper-resistant bait stations* by adding [*as long as these bait points provide the same level of protection for non-target species and humans*]*'.*

As this point is also related to ENV DK requested to indicate in the minutes that no other RMM in relation to environment was discussed at WG level.

- Frequency of visits:

Some MSs indicated that it would be worth to specify the number of visits; but based on the previous discussion on permanent baiting it was agreed to leave the statement like it is in section 2.3.3, point 7 of the AR: *Products authorised for trained professional users shall establish recommendations regarding the frequency of revisiting the treated area.*

4) Updated PT14 efficacy guidance

The EFF WG agreed that in section 2.3.3 of the AR the recommendation to applicants to take into account the requirements, standards and criteria of the revised PT14 guidance should be made. For the time being it is on voluntary basis – as the revised PT14 efficacy guidance will be mandatory after 2 years of publication.

COM suggested to discuss it at BPC if such general recommendations should be included in the AR in the future.

6.2 Cyanamide (eCA DE)

There was one remaining open point in the discussion table concerning in-use concentration of the product in PT3. In principle, it was doubtful if the intended use of such a biocidal product could be addressed against one specific micro-organism. Taking into account clarification given by the eCA and the applicant concerning in the first instance the area of use, the EFF WG concluded that the presented concentration of cyanamide in PT3 is sufficient for the intended use.

7. Technical and guidance related issues

7.1 General update on guidance

ECHA informed about the current status of the guidance documents.

1) PT 1-5: Two comments were received during CA consultation. The Guidance is foreseen to be ready for publication at the end of February/beginning of March.
2) PT14: see point 7.2.d

7.2 Continuous work on Efficacy Guidance Part B/C

The discussion on specific chapters of Volume II: Efficacy Guidance Part B/C was postponed for the EFF WG meeting in March. EFF WG members were invited to send comments on Chapter 5, section 5.2 - Product families and section 5.3 - Treated Articles by the end of February 2016.

7.2 a Appendix documents for PT 1-4

Appendix_1_PT1/2/3_claims_matrix – ECHA will implement the comments received in the PEG consultation and liaise/check with NL on final text. The final version will be circulated for the next WG meeting.

Appendix 4 was commented by CEFIC/AISE and FR; due to lack of time during the EFF WG meeting it was agreed that it will be discussed internally between commented parties and finalised by NL by the end of February. The final version will be circulated for the next WG meeting.

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

The Chair proposed to postpone this agenda item to the next meeting. EFF WG members were asked to send comments on the document by the end of February 2016.

7.2 c Guidance on Efficacy Assessment for PT8 - Wood Preservatives

The EFF WG agreed with the proposed changes. One minor modification was suggested, i.e. to add a short clarification concerning certification data. In addition, EFF WG agreed that appendices 2 and 3 will be taken out and published separately on ECHA website.

7.2 d Guidance on Efficacy Assessment for PT14 - Rodenticides

ECHA informed that about 120 comments were received on the draft efficacy guidance during the consultation phase with CAs. The consolidated list of comments will be sent to the EFF WG, editorial comments will be introduced into the text and comments which require EFF WG input will be highlighted. The EFF WG members were invited to send comments by the end of February 2016; and based on the input ECHA will decide about the best way forward and possible discussion during the next WG meeting in March.

Once again the issue concerning resistance and label claim was brought up by IND. COM indicated that flexibility is needed and at least a minimum of information for applicants how to address resistance statement should be given in the guidance document. The same should be done for pulse baiting strategy as it is an important issue for product authorisation and should be supported in the guidance. EFF WG members supported COM and agreed that some parts of the guidance should be amended.

7.2 e Future work on PT5 guidance

The Chair informed about the current status of the ongoing disinfectant project. With reference to preparation of assessment and evaluation guidelines for efficacy of drinking water disinfectants (PT 5) the Contractor received all necessary and available information. The draft PT5 guidance should be ready by July 2016. Two commenting rounds, one virtual/WebEx meeting and one physical workshop are foreseen.

7.3 SPC editor in relation to target organisms

The Chair gave a presentation containing a proposal for improvement of the SPC editor. ECHA will circulate to the EFF WG a list of target organisms (TO) currently included in the SPC editor. EFF WG members were invited to send comments by the end of February 2016.

8. AOB

8.1 Other information & lessons learned

The Chair informed about three new documents agreed at BPC-13 meeting in December. 2015:

- Applicability time of new guidance and guidance-related documents in active substance approval
- The role of the BPC Secretariat in the active substance approval process
- Introducing new information during the peer review process of active substance approval

They will be published on ECHA's website.

From 1st March 2016 onwards, R4BP3 will be used in official communication.

Starting from WG-II-2016 ECHA will send discussion tables and minutes to applicants via R4BP3.The next EFF WG meeting is foreseen to be held in Helsinki 15-16 March 2016.

Minutes of Environment WG

WG-I-2016 (27-28 January 2016)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were six core members and twenty-three flexible members present. In addition three rapporteurs and two experts where present in the meeting. Three representatives from three accredited stakeholder organisations were present (partly only for item 7). Applicants were present for their specific substance discussions.

Participants were informed that the meeting would be recorded solely for the purposes of writing the minutes and that this recording would be destroyed after the agreement of the minutes.

2. Administrative issues

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

The following administrative issues were communicated:

- Daily allowances are re-introduced as of WG-II-2016 (new rules)
- WG-II-2016 will be a physical meeting
- The meeting participants were reminded to provide for the future meetings via Webropol registration page all required data and that signed declarations are needed from all new advisors/rapporteurs
- R4BP3 will be introduced for communication with applicants and eCAs from 29 February 2016
- The MSCA manual will be updated and sent to eCAs in mid-January 2016
- Nomination of new members: procedure to be updated.

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 very flexible way informed on the following changes in the agenda:

- Item 6.3: Change of order of rodenticides, first flocoumafen (6.3c) and difenacoum (6.3a) since same applicant, then coumatetralyl (6.3b)
- Item 7.2 (FOCUS groundwater scenarios: proposals for standard scenarios and parameter setting): item was removed from the agenda.
- Item 7.5 (Guidance on DBP) will be discussed as first item under item 7.
- Item 7.7 (COMLEAM) will be presented on Thursday between 11:00 – 12:30.

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 a conflict of interest with one active substance. Therefore the Deputy-Chair will chair the sessions of the respective active substances.

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

The Chair informed that comments were received for items 6.2, 6.4, 6.5, 6.6 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 Diflubenzuron – New PNEC values (eCA DK)

The Working Group members agreed on all points. The revised endpoints should be reflected in the list of endpoints.

6.3 Renewal of anticoagulant rodenticides – PBT assessment

6.3a Difenacoum (eCA FI)

6.3b Coumatetralyl (eCA DK)

6.3c Flocoumafen (eCA NL)

Two out of two points for Difenacoum 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 included in the updated CAR before proceeding to the Biocidal Products Committee. Concerning the other substances, the Working Group members agreed on the evaluation of the eCAs. The eCAs can prepare the updated CAR and proceed to the Biocidal Products Committee. In addition the WG concluded that the substance should be send to the PBT expert group.

Action: eCA to prepare the *ad hoc* follow up in collaboration with SECR. eCA to update the CAR based on the outcome of the *ad hoc* follow up accordingly.
Action for **AHEE**: it needs to be clarified which DT50 values according to the FOCUS guidance should be in general used for modelling purpose and which for the PBT assessment.

6.4 Cyanamide (eCA DE) - PT 3, 18

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

7. Technical and guidance related issues

7.1 Update on guidance development, issues identified for the AHEE (ECHA)

SECR presented the status on guidance development, issues identified for the AHEE and e-consultations. Updates from WG members during the meeting have been included after the WG meeting.

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

7.2 FOCUS groundwater scenarios: proposals for standard scenarios and parameter setting (DE) (DE)

The item was removed from the agenda; the discussion was postponed to the physical AHEE meeting in April 2016.

7.3 Evaluation of the model SimpleTreat (DE)

Item was presented only for information: DE provided an overview on differences between SimpleTreat versions 3.1 and 4.0.

Actions:

- DE to initiate in collaboration with SECR a written procedure.
- Question to be commented: Does the ENV WG agree to use SimpleTreat version 4.0 for the exposure assessment of biocides instead of version 3.1?
- If WG agrees in the written procedure to use version 4.0 in the future, SECR to include link to the new Simple Treat version on the ECHA webpage.

7.4 Priority list for the first revision of Vol. IV Part B (ECHA)

The aim of the discussion was to agree on which of the items provided in the commenting list should be assigned as high priority items and be taken up in the first revision. In addition the distribution of priority items between WG members for the preparation of a draft text was discussed.

It was concluded that the following items will be taken up in the first revision of Vol. IV Part B (in addition to the preparation of the product part of Part B as well as the preparation of Part C to be prepared by ECHA):

WG meeting	Item	Issue	Conclusions WG-I-2016
WG-I-2014	5.1	Harmonisation of conversion factor dry to wet sediment (Infobox 8)/ consideration of organic matter content	No revision of Infobox 8 in Vol. IV Part B is considered relevant at the moment. Consideration of organic matter content: UK volunteered to take over this item and cross-check recent EFSA opinion. ASOs to send comments to UK.
WG-IV-2014	6.1	Should it be a general requirement for all biocides to add the phyla of organisms in the list of endpoints?	Item postponed for a future revision.
WG-IV-2015	6.3	When can an AF of 1 be used for the derivation of $PNEC_{freshwater}$?	FR and SE volunteered to take over this item bilaterally. DE to be consulted.
WG-V-2015	6.4 + 7.2 b point 4	PEC_{intial}/PEC_{TWA} comparison to $PNEC_{initial}/PNEC_{TWA}$ + calculation of initial PEC in soil after sewage sludge application (=> streamlining with PT 18 manure application to soil)	NL volunteered to take over this item.
	6.5	Derivation of $PNEC_{soil}$: Clarification of the text in the guidance (Infobox 10)	Item postponed for a future revision.

WG meeting	Item	Issue	Conclusions WG-I-2016
	7.2 b point 5	PIEC calculation – mixing depth	SECR will prepare an overview table.
	7.2 b point 7	Secondary poisoning - possibility of refinement of the risk assessment in case initial (PEC) values are used as basis for the assessment	NL volunteered to take over this item.
Items prioritised from the commenting list	RCOM 214	It seems that EUSES applies a different approach in order to derive K_{volat}. $kasl_{air}$ is 120 m/d in the TGD, but 90.5 in EUSES. $kasl_{solair}$ is a fixed value in the TGD, but calculated in EUSES, etc. Therefore, the TGD and EUSES result in different values for K_{volat}. Please harmonise the TGD with EUSES or v.v.	NL volunteered to provide a solution.
	RCOM 353	Assessment of secondary poisoning: It should be considered to add guidance on the assessment of primary and secondary poisoning for rodenticides/insecticides.	SE volunteered to take over this item.
Additional items		Considerations related to sediment testing (available in the TGD but not taken over to Vol. IV Part B).	SE proposed to include this point and prepare a draft (*SECR to check history why point was deleted*). SE to cross check also with EFSA guidance (see point assigned to UK).

Actions:

- SECR to upload priority/commenting list in a Newsgroup with a short deadline for WG members to further prioritise and take over items from the commenting list
- Draft texts to be ready by June 2016 at the latest.

7.5 Guidance on disinfectant by-products

The focus on the discussion was on if the WG consider the guidance document for the environment in general appropriate with no major reservations.

The possible outcomes of the WG discussions were:

1. *The WGs might consider the guidance in general appropriate and have no major reservations. The draft guidance would be taken as the starting point for the ECHA Guidance procedure where a Partner Expert Group (PEG) is nominated soon after the WG discussion.*
2. *The WGs might have major reservations. The draft guidance would need to be modified before starting the ECHA Guidance procedure.*

Conclusions:

The WG agreed that the guidance document for the environment is in general appropriate and the ECHA guidance procedure can be initiated.

Actions:

- **WG members** to send in any comments by end of February which can then be included in the guidance before initiating the procedure (**SECR** to indicate platform).
- **SECR** to initiate ECHA guidance procedure.
- Nomination of PEG members.

7.6 Outcome of the e-consultation on product authorisation PT 21 (NL)

It was discussed if the survey can be shared with IND (=> question to CAs filling out the survey), how the survey should be followed up and if a workshop should be organised.

Conclusions/Actions:

- It was agreed that the document can be shared with IND. However, **FR** will check if their comments can be shared and will provide feedback to NL. DE disagreed to share their comments; **NL** will take the comments of DE out before sharing the document (**DE** to indicate points to NL).
- SECR will await outcome of ongoing discussions at CG on the possibility of organising a workshop
- As fall-back position, the item will be taken up in the physical AHEE meeting in April. **SECR** will inform WG/AHEE members on if the item will be taken up in the AHEE meeting by the end of February. Any items for discussion should then be provided in a dedicated Newsgroup during March (e.g. NL to get in contact with UK for preparing a meeting document with main discussion items).

7.7 Presentation of COMLEAM model (M. Burkhardt, HSR Rapperswil)

Item was presented only for information. Mr. Burkhardt presented the COMLEAM model and the potential application of it for biocides.

8. AOB

8.1 Other information & lessons learned

In the following the main information and lessons learned presented at the meeting are summarises.

Three documents with implications also for the WGs have been agreed at BPC-13 in December 2015. Two of them have been uploaded to the ECHA webpage; these documents were briefly presented and will be applied from the next WG meeting on:

- **Applicability time of new guidance and guidance-related documents in active substance approval**. Link: http://echa.europa.eu/documents/10162/4221979/applicability_guidance_jan_16_en.pdf
- **Introducing new information during the peer review process of active substance approval**. Link: http://echa.europa.eu/documents/10162/4221979/peer_review_info_jan2016_en.pdf
- **Clarification of some elements regarding the role of the BPC Secretariat in the active substance approval process.** Published on S-CIRCABC since only relevant for SECR/MSCAs. The document clarifies the tasks and role of SECR:
  - Early eCA-ECHA teleconferences for new applications
  - Clarifications on the need for RAC opinion or PBT Expert Group for CMR/PBT/vPvB substances
  - Peer review of the CARs by MSCAs remains crucial as SECR does not have sufficient resources for systematic/extensive commenting

The following **ongoing projects** were presented:

- **Disinfectant project**: purpose is to develop and implement harmonised and coordinated approach for risk assessment of biocidal active substances used as disinfectants. Kick off meeting with contractor took place on 17 December 2015.
- **Harmonising CAR & CLH report templates**: Invitations for the Task Force have been sent to MSCAs and 15 representatives from 10 MSCAs have been nominated. Task Force members will be asked to indicate challenges in transferring the information from CAR to CLH dossier.
- **PBT guidance update**: scientific approach developments will be prioritised, e.g. choice of first degr. simulation test compartment, terrestrial bioaccumulation, use of field-B data. PEG consultation planned for 05-10 2016, publication is estimated for May 2017.
- **ESD spreadsheet status overview**. The following WG members have volunteered to check and validate the second batch of calculation sheets prepared so far:
  DE: spreadsheets for PTs 7, 8, 9, 10, 11, 6,7&9 and 18
  DK: spreadsheets for PT 7, 8, 9, 10 and 6,7&9
  NL: spreadsheets for PT 7, 8, 9, 10, 11, 6,7&9 and 18.
  NO: spreadsheets for PT 8 and PT 21 in future.

SECR further informed that there will be a **physical AHEE meeting** on 21/22 April 2016. A preliminary draft agenda will be provided shortly after WG-I-2016, in light of the workload preparing WG-III-2015 no meeting minutes will be prepared, only action points and conclusions. ASOs can participate for non-confidential items; there will be no additional WebEx access.

R4BP 3 for AS approval process will be used in communications starting 29 February 2016. Starting from WG-II-2016, SECR will send discussion tables and minutes to applicants via R4BP.

With regard to **full agendas in 2016** reference was made to the final document WGI2016_ENV_8-1a_Planning 2016 "*Tackling the workload in WG meetings in 2016*". Measures to be implemented from WG-II-2016 onwards:

- Time limits for agenda items & discussion table points
- ECHA-eCA teleconferences should be targeted to cases where an outstanding issue is identified

Requests to MSCAs:

- Increase efforts made in commenting
- Focus on major issues when commenting
- Reinforce cooperation/discussions in order to minimise the numbers of open points
- eCAs to request e-consultations for unclear major items that might be solved before the main WG discussion

Concerning **registrations for WG meetings** all participants should respect the deadline for registration to the WG meeting. In addition roles should be clearly indicated (rapporteur, adviser, ASO expert etc.). Any new attendees need to provide the following declarations:

- MSCAs: confidentiality & commitment
- ASOs: confidentiality & acceptance notice (Code of Conduct)

Templates for declarations (for MSCAs and ASOS) are available in S-CIRCABC:

- Path: /CircaBC/echa/BPC-WG/Library/Non-confidential/09. General information and procedural documents
- https://webgate.ec.europa.eu/echa-scircabc/w/browse/66370341-4fa3-44b1-bf47-adb0d3f57187

Starting from WG-II-2016, stricter policy will be applied and late registrations will generally be rejected (high workload).

No additional items were raised by WG members.

8.2 Feedback from the soil risk assessment workshop

A short summary was provided on the outcomes of the soil risk assessment workshop. It is not summarised in this minutes since a separate workshop report is in preparation by the organisers of the workshop, which will be uploaded to the ECHA webpage.

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List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MUEHLE Ulrike (DE)
HUSZAL Sylwester (PL)
HUIZING Tjaart-Jan (NL)
WARBURTON Anthony (UK)
Alternate core members
WEBER Philippe (FR)
Flexible members
THANNER Gerhard (AT)
VAN BERLO Boris (BE)
SCHMIDT Marianne (DK)
ILMARINEN Kaja (EE)
KORKOLAINEN Tapio (FI)
KAHRI Kimmo (FI)
HELGERUD Trygve (NO)
CATALDI Lucilla (IT)
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GONZALES Lorena (ES)
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HOLTHENRICH Dagmar (DE)
KNEUER Carsten (DE) – Rapporteur
BOS Carina (NL)
BRESCIA Susy (UK)
Rapporteurs
MIKOLAS Jan (CZ)
POTTIE Lode (BE)
Flexible members
POTTIE Lode (BE)
VIDICK Nicolas (BE)
MIKOLAS Jan (CZ)
MARTINEK Michal (CZ)
SCHMIDT Marianne (DK)
PETERSEN Annika Boye (DK)
HÄMÄLÄINEN Anna-Maija (FI)
HYVÄRINEN Tuija (FI)
REY Marion (FR)
POPPEK Ulrich (DE)
PEISER Matthias (DE)
HECKER Dorothee (DE)
LINDBERG Vibeke (NO)
HAUGSTAD Kjetil (NO)
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