WG-V-2014

Final minutes

09 February 2015

Minutes of WG-V-2014

18-21 November 2014

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

Minutes of Analytical methods and physico-chemical properties WG

WG-V-2014 (18 November 2014)

1. Welcome and apologies

The list of attendees is given in Annex 1.

2. Administrative issues

Administrative issues information was given in leaflet.

3. Agreement of the agenda

The Chair introduced the draft agenda, which was distributed in advance together with invitation along with link to ECHA website. NL had requested earlier to include following in AOB. Could the extrapolation of packaging materials for shelf life studies as stated in the Guidance on information requirements under 3.4.2, table 6 acceptable extrapolations for different packaging types for storage stability studies to be clarified.

The agenda was then agreed by the WG.

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.

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 was declared.

5. Agreement of the draft minutes from WG-IV-2014

The WG-IV meeting minutes were agreed.

6. Discussion of active substances

6.1 Triclosan PT 1 (eCA DK)

The Working Group members agreed on the evaluation of the eCA. The CAR will be updated based on the agreements. The application proceeds to the BPC.

6.2 Hydrogen peroxide PT 1, 2, 3, 4, 5, 6 (eCA FI)

The Working Group members agreed on the evaluation of the eCA. The CAR will be updated based on the agreements. The application proceeds to the BPC.

6.3 Peracetic acid PT 1, 2, 3, 4, 5, 6 (eCA FI)

The Working Group members agreed on the evaluation of the eCA. The CAR will be updated based on the agreements. The application proceeds to the BPC.

6.4 Biphenyl-2-ol PT 1, 2, 3, 4, 5, 6 (eCA ES)

The Working Group members agreed on the evaluation of the eCA. The CAR will be updated based on the agreements. The application proceeds to the BPC.

7. AOB

NL: Could the extrapolation of packaging materials for shelf life studies as stated in the Guidance on information requirements under 3.4.2, table 6 acceptable extrapolations for different packaging types for storage stability studies be clarified.

Minutes of Human Health WG

WG-V-2014 (18-19 November 2014)

1. Welcome and apologies

The Chair welcomed the participants indicating that five core members and 15 flexible members were present; apologies were received from three 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 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-IV-2014

The minutes were agreed without further comments.

5. Administrative issues

The Chair informed that a presentation on the housekeeping rules would not be made anymore, and instead instructions were available as a leaflet.

6. Discussion of active substances[1]

6.1 C(M)IT/MIT PT 2, 4, 6, (eCA FR)

The Working Group members agreed on the evaluation of the eCA. The application proceeds to the BPC.

6.2 Triclosan PT 1(eCA DK)

The Working Group members agreed on the evaluation of the eCA except for the NOAEL (no observable adverse effect level) that will be used in deriving reference values for risk characterisation. The NOAEL will be decided in an ad hoc follow-up by 5 December.

The CAR will be updated based on the agreements of the Working Group and the ad hoc follow-up. The application then proceeds to the Biocidal Products Committee (BPC).

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

6.3 Biphenyl-2-ol PT 1, 2, 3, 4, 5 (eCA ES)

The Working Group members agreed on the evaluation of the eCA except for the assessment factor used to derive reference values for risk characterisation. This assessment factor will be decided in an ad hoc follow-up by 5 December.

The CAR will be updated based on the agreements of the Working Group and the ad hoc follow-up. The application then proceeds to the Biocidal Products Committee (BPC).

6.4 Hydrogen peroxide PT 1, 2, 3, 4, 5, 6 (eCA FI)

The Working Group members agreed on the evaluation of the eCA. The CAR will be updated based on the agreements. The application proceeds to the BPC.

6.5 Technical equivalence Tier II: copper oxide and basic copper carbonate

The Working Group was not able to conclude on the assessment. Further discussions are necessary to decide the way forward.

7. Technical and guidance related issues

7.1 Update on guidance development

Update of guidance Vol III Part B/Chapter 3

SECR informed on the progress and on the planning for the guidance. The members of the HEAdhoc (Ad hoc Working Group – Human Exposure) have been informed of the proposed new structure with a possibility of commenting until 30 November. Based on the input received, ECHA will make a first draft of the guidance document. Requests for nominations for the Partner Expert Group will be sent to biocide CAs in December 2014 and a PEG (Partner Expert Group) consultation is foreseen to be launched by the end of January 2015.

Guidance on substances of concern

SECR informed that the guidance document on substances of concern was endorsed at the CA meeting the previous week. It is expected that this document will be annexed to the existing human health guidance.

Vol V Micro-organisms guidance

SECR informed that the CA/ASO consultation closed on 26 September and a total of 297 comments were received. There was however a problem in processing the comments because the majority of them were included within the document and not in the Excel table, thus resulting in a significant additional workload for SECR in reformatting these comments. SECR urged all members to use the appropriate format to avoid unnecessary delays in the process.

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

The four recommendations agreed so far by the Working group are publicly available on the ECHA website.

Two recommendations are currently under preparation by the HEAdhoc:

- the recommendation on "Product application amount for repellents – exposure assessment";
- the "NL Opinion on the use of models for the assessment of exposure to different biocidal products used in different product types".

The recommendations intended to be drafted cover the following topics:

- the hand-to-mouth transfer scenario;
- the most appropriate model to be used for the scenario of non-professional application of paints by brushing and rolling;
- the revision of the HEEG Opinion 5 on "Human exposure assessment to biocidal products used in metalworking fluids (PT13)";
- the discussion on the 50% penetration factor for non-professional (amateur) clothing;
- the scenario of hands disinfection in hospitals.

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

SECR informed on the progress on the three guidance documents that are in an advanced status of preparation but still in a drafting phase:

- Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional: the guidance should be finalised in Q1 2015 and published afterwards on the ARTFood webpage as a pilot project.
- Uses Guidance on Estimating Transfer of Biocidal Active Substances into Foods – Professional Uses: due to the complexity of the issue, the document is still under discussion among the ARTFood members.
- Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products: the document is still under discussion among the ARTFood members; the final draft document should be finalised by ARTFood in Q2 2015.

8. Any other business

8.1 Lessons learned

Revised working procedure

SECR noted that a revised working procedure for active substance approval will be discussed at BPC-8 in December. This document contains significant changes that are very relevant for the work of the WG members, and all members were encouraged to check the document and to inform their BPC member on potential issues to ensure that their possible input is taken into account at the BPC meeting. The members were asked to note especially the 'peer review' in closing points in RCOMs, presenting a mechanism by which MSs can ensure that the points are discussed when necessary. SECR stressed the importance of clearly indicating points as open or closed, as this is the key to successful 'peer review' in closing points.

RCOM (response to comments table)

SECR again stressed that comments should be included only once in the RCOM. If the same comment is relevant to several documents (e.g. Doc I, Doc IIA, Doc IIIA), which is usually the case, then the comment should be given once and if necessary this comment can refer to where else it is relevant.

Discussion table

SECR pointed out that no written comments are expected to the issues in the discussion tables. The only exception might be where an agreement is found only after the discussion table is available, in which case the agreement could be briefly explained in the discussion table.

Early WG discussions

SECR encouraged the MSs to make use of the possibility for an early WG discussion. Such a possibility could be used before finalising the CAR in order to have a common agreement to an issue that is known to be problematic or controversial, or might have a large impact in the assessment.

Embedded documents

It was mentioned that there had been problems in opening some of the embedded documents and therefore the use of these should be avoided where possible.

Modifying CARs between WG and BPC

One member brought up the principles on modifying a CAR following the WG discussion. Normally a CAR indicates safe uses before commenting but, following the comments and the WG discussion, some aspects of the evaluation may be changed to be more conservative. Sometimes this may lead to unacceptable uses unless further modifications are made. Such modifications may be well justifiable as e.g. a Tier I exposure assessment may have been safe and no refinements were thus attempted. Nevertheless, any changes following the WG discussion are not covered by any form of peer review except for that of the BPC – which should not be covering such issues at all.

Several possibilities were discussed for establishing procedures for peer review. The proposals included:

- Ad hoc follow-up
- E-consultations immediately following the WG discussion to verify whether the other MSCAs agree to the further modifications proposed by the eCA.
- Virtual WG meetings (or other discussions) following soon after the WG meeting

None of the solutions were considered optimal for the purpose and maybe several alternatives would need to be available.

SECR agreed to open a newsgroup in CIRCABC for the MSs to send in any proposals. Information of the newsgroup will be sent to all WG members.

Minutes of Efficacy WG

WG-V-2014 (20 November 2014)

1. Welcome and apologies

The Chair welcomed all participants to the fourth Efficacy WG meeting. All core members participated except for Ms Iuliana Radu. In addition one alternate member, three flexible members (of which two were rapporteurs), two rapporteurs and one stakeholder observer participated to the WG-V 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 overview of some of the functions of the virtual meeting tool (AdobeConnect).

3. Agreement of the agenda

The Chair introduced the agenda items and invited participants to discuss any additional items at AOB. Only active substances were scheduled for discussion as guidance will be addressed in a separate virtual meeting on 18 December 2014.

Conclusions and actions

It was proposed to ask the eCA for citric acid about an update of the developments of the dossier following WG-IV-2014.

With that modification the participants agreed on the proposed agenda.

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

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

5. Agreement of the draft minutes from WG-IV-2014

SECR introduced some changes to the minutes for citric acid to better reflect the possibilities to request data depending on the definition of the tissue as a Biocidal product or a treated article. A corresponding change was agreed for the discussion table.

For PBO it was agreed to add two additional sentences related to the evaluation of studies submitted by the applicant before the WG-III-2014.

For agenda item 7.2, draft guidance document on PT 14, it was agreed to add to the minutes that a sentence in the draft guidance stating that 'field trials are not considered animal experiments' should be removed.

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

6. Discussion of active substances[2]

6.1 Triclosan (eCA DK)

There was one remaining open point concerning the composition of the products tested for efficacy.

The issue was raised whether treated articles could be included under PT 1. No example could be given, but if that should be the case resistance could be an issue. To be in line with the evaluation for Diclosan it was agreed to add to the CAR a sentence saying that Triclosan should not be used in treated articles unless the efficacy and benefits of the treated article was clearly demonstrated.

With these additions to the CAR the WG agreed on the evaluation of the eCA.

6.2 Peracetic acid (eCA FI)

There were two remaining open points in the Discussion Table. The first concerned demonstration of efficacy for PT 6. The applicant had submitted additional information. This point could not be agreed by the WG due to the very late incoming data. An ad hoc follow-up was concluded necessary. The timeline for the public consultation will be circulated shortly.

The second issue concerned demonstration of efficacy for peracetic acid in general. The discussion concerned the contribution by H2O2 (and to some extent acetic acid) to the efficacy of peracetic acid. It was concluded that the efficacy of the acid was higher than that demonstrated for H2O2 alone based on the new data. Thus, members felt the inherent efficacy was adequately addressed. It was agreed to add a sentence on the possibility of synergistic effects to the CAR.

With the proposed addition to the CAR the WG agreed on the evaluation of the eCA, except for the pending issue with point 1 in the Discussion Table that will be subject to written consultation.

6.3 Hydrogen peroxide (eCA FI)

There was only one remaining open issue for the substance which concerned the demonstration of efficacy at the concentrations used for the risk assessment. The eCA introduced the issue by explaining that the risk assessments were to be revised taking the levels demonstrating efficacy into account.

Members expressed the importance to justify the levels used in the risk assessments by making reference to use levels demonstrated to be efficacious.

It was also agreed that more detailed information concerning efficacy testing for PT2 and PT 6 should be included in the CAR.

With these additions the WG agreed on the evaluation of the eCA.

6.4 Biphenyl-2-ol (eCA ES)

There were only three open points in the discussion table (No 1, 3 and 4) as points number 2 and 5 had been closed after the distribution of the table.

Before starting the discussion the applicant explained that only the acid (OPP) was to be

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

supported as an active substance. The sodium and potassium salts will be withdrawn. This closed discussion points number 1 that concerned whether the data in the CAR could be regarded to cover both the efficacy of OPP and its salts.

Point number 2 was closed before the EFF WG-V. New information according to the correct European norm had been submitted and accepted as sufficient to prove efficacy as hand and skin disinfectant. For product authorisation additional efficacy testing may be needed. This statement should be added to the CAR.

Point number 3 on contact time could not be agreed by the WG due to very late incoming data. For this point an ad hoc follow-up was concluded necessary. The results of the ad hoc follow-up are expected by 3 December 2014 and will be forwarded to the BPC together with the updated CAR.

Point number 4 concerned the demonstration of efficacy to yeast and bacteria. It was concluded that the available data demonstrated efficacy against bacteria, but not against yeast and fungi. Efficacy testing against yeast and fungi had not been done in accordance with the guidelines and could for that reason not be accepted. Methodology would need to be revised for the product authorisation step.

Point number 5 had been closed prior to the EFF WG-V. Additional information had been submitted, that sufficiently demonstrates the efficacy against yeast.

However, members found the methodology used insufficient and stressed it would need to be improved for the authorisation stage. Also efficacy against bacteria remains to be demonstrated.

With these additions the EFF WG agreed on the evaluation of the eCA, except for point 3 in the Discussion Table that will be subject to a written procedure.

7. AOB

7.1 Lessons learned

The Chair opened the floor for views regarding the way the Efficacy Working Group meetings are organised.

Members called for more discussion and information on procedural issues, for example a presentation of the updated procedures for active substance approval. SECR proposed to include such a presentation in the next WG meeting. They also proposed to make better use of the chat function during virtual meetings to facilitate exchange of views.

7.2 Update on citric acid

Upon request Anne Lepage briefly updated the WG about the state of play with citric acid. To conclude whether the tissue should be classified as a Biocidal product or a treated article a request to COM in accordance with Article 3(3) of the BPR is under preparation.

Minutes of Environment WG

WG-V-2014 (20-21 November 2014)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 7 core members present, in addition to 4 flexible members and 3 rapporteurs. One accredited stakeholder organisation (ASO) was 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 7.3 was moved after item 7.5
- Item 8.2 deleted since relevant issues were included in the "lessons learned" (item 8.1).

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 has an interest with the applicant for one active substance due to a former work relationship. Following internal consultation at ECHA this was however not seen as a conflict of interest, also because the issue to be discussed was of a general nature related to emission estimation principles.

4. Agreement of the draft minutes from WG-IV-2014

The Chair informed that no comments were received. Since no comments have been received on the minutes these have been considered as being agreed.

5. Administrative issues

5.1. Housekeeping issues

The Chair informed that the housekeeping rules are available as a leaflet at the meeting room entrance.

6. Discussion of active substances[3]

6.1 Hydrogen peroxide (eCA FI)

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

6.2 Bisphenyl-2-ol (eCA ES)

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

6.3 Triclosan (eCA DK)

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

7. Technical and guidance related issues (Ad hoc EE WG partly by Adobe Connect)

The Chair welcomed the Ad hoc EE WG members.

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

The Chair presented and updated the status on guidance development, e-consultations and consultations of the Ad hoc EE WG.

7.2 Guidance documents for discussion/agreement (ECHA)

7.2a Gathering of information for the refinement of the Environmental Emission Scenario for metalworking fluids (PT 13) under BPD/R (Consortium)

The following was discussed and concluded:

- Degradation of biocide between last dosing and actual start of PC treatment (storage, transport etc.): It was concluded that the degradation rate in surface water should be taken out as a default. In addition, the suggestion to mention storage times longer than 7 days should be taken out.
- Dilution factors (for end-users): It was concluded that the second dilution step should be left at 10. A new proposal for first dilution step based on available data will be provided based on available data.
- Fraction of mwf in treated waste (fmwf): Fmwf was questioned as there is one company in the datasets which only treats emulsions. Further data points were collected and it was explained that it is not aimed to cover the very worst case for each separate input parameter, as this would result in an unrealistic end-scenario. It was concluded that the suggestions are acceptable (Fmwf = 0.5 is considered as a reasonable worst-case).
- Evaporation as a technique for emulsion splitting: Report to be rephrased: Tier 1 (active substances) both splitting techniques have to be safe. Tier 2: If only one technique shows a safe use, it has to be ensured with relevant data during

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

product authorisation, that the respective technique is applied as necessary RMM. A summary table including Tier 1 and Tier 2 approaches and the differences between the approaches will be included into the report.

- Communication of measures: Covered by the previous point.
- General approach or the new exposure algorithm(s): The new suggestions are based on two scenarios (end-user with on-site treatment of waste + external waste treatment company). Emulsifiable and water soluble mwf are not calculated separately but discussed together as "water based mwf". No differentiation between intermittent and daily release is made. This general approach was accepted by the WG.

Actions: Fraunhofer will update the report before Christmas and distribute it to the WG members (via ECHA) for commenting. Comments should be provided by 20 January 2015 to Fraunhofer (ECHA functional mailbox in copy). Final approval is scheduled for WG-II-2015.

7.2b Follow-up BPC-7 - Confirmation of risk assessment procedure for PT 13 (ECHA)

The Environment WG was requested by the BPC to re-confirmed the following: taking into account the fact that the ESD for PT 13 seems to overestimate the risk especially for emulsifiable MWF, it is acceptable to base the exposure assessment for the time being on the default values provided in the (not agreed) 1st version of the Fraunhofer report. It should however be stated in the assessment report (and in the opinion) that at the product evaluation stage the new ESD should be used.

The WG reconfirmed the proposal. However, as soon as the new ESD (i.e. the revised status report of Fraunhofer) is endorsed, the approach and the default values presented in this new ESD should be used. As NL has pointed out during several discussions of active substances in previous WG meetings, they object to the re-confirmed approach.

7.2c Leaching to groundwater from paint, coatings and plaster (NL)

The document was not discussed. The discussion was postponed to one of the first WG meetings in 2015.

7.3 Priority list of points for first revision of Vol. IV Part B (ECHA)

The document was not discussed. The discussion was postponed to the next WG meeting since additional comments have been received during the ASO/CA consultation, which need to be taken into account in the prioritisation.

7.4 Outcome of e-consultations (ECHA)

7.4a Conversion factor wet-dry sediment

The following proposed conclusion was discussed during the meeting: When test are available on the sediment compartment, the endpoint should be reported in dry weight (as recommended by the OECD 218) and consequently the $PNEC_{sediment}$ will be expressed in dry weight. This means no correction procedure would be needed on the effects endpoint. Then the PEC should be converted to dry weight by:

a. Replacing the RHOss (wet) of 1150 kg wwt/m³ with RHOss (dry) 250 kg dwt/m³ in the TGD (or ECHA Guidance for Environmental Risk Assessment Vol IV part B) formula for the PECsediment.
b. Keeping RHOss (wet) to calculate a PEC wet weight and then convert it to dry weight by multiplying the PEC wet weight by the default conversion factor of 4.6 kgwwt/kgdwt

The WG agreed on the proposed conclusion and the change will be described in the MOTA.

Action: The CAR template needs to be adapted accordingly. ECHA will clarify by when the procedure applies.

7.4b $PNEC_{microorganisms}$ derivation: how should the PNEC be derived when both the EC50 and the NOEC from a respiration inhibition test are available?

The following proposed conclusion was discussed during the meeting: When a NOEC/EC10 and an EC50 from study compliant with OECD 209 are available and both values are derived from the same study, the $PNEC_{microorganisms}$ should be derived by dividing the NOEC/EC10 by an AF of 10. The use of the EC50 with an assessment factor of 100 should still remain as an option when the NOEC/EC10 derived from OECD 209 test is not reliable.

Special attention should be paid to the reliability of the statistical analysis performed to derive the NOEC. Substantial variance within the response of the replicates or a poor statistical fit may result in a less reliable NOEC due to a lack of statistical power. In that case a study can only deliver an EC50/EC10 which should then be used with an AF of 100/10.

The WG agreed on the proposed conclusion and the change will be described in the MOTA. DE expressed their concern on the conclusion.

Action: ECHA will clarify by when the procedure applies.

7.5 Ad hoc EE WG related issues (ECHA)

7.5.1 Working procedures of the Ad hoc EE WG

The working procedures for the Ad hoc EE WG are proposed to be in line with the working procedures of the Ad hoc WG on Human Exposure:

- ECHA to provide an overview on open issues with a proposed prioritisation/ timelines – to be agreed by the Ad hoc EE WG
- Each open issues to be assigned to one Ad hoc EE WG member - in charge to prepare the Draft Recommendation
- Draft Recommendation will be distributed by ECHA to Ad hoc EE WG for commenting (via CIRCABC)
- Comments received from Ad hoc EE WG members to be included in Draft Recommendation by the Ad hoc EE WG member in charge
- Draft final Recommendation to be agreed by the Ad hoc EE WG
- Draft final Recommendations to be endorsed by the Environment WG

To be noted:

In specific cases ECHA may also be in charge of open issues/preparation of recommendation and acts as Ad hoc EE WG member.

The Draft final Recommendations should be uploaded to CIRCABC for discussion at the Environment WG around 10-15 days before the WG meeting.

Action: ECHA will set up a Newsgroup in order to collect feedback on the proposed working procedures.

7.5.2a PT 1 - Ad hoc EE WG consultation on default values for professional hand disinfection (ESD for PT 1, Emission scenario for calculating the releases of disinfectants used for skin and hand application in hospitals based on an average consumption)

A consultation of the Ad hoc EE WG on the default values for professional hand disinfection in PT 1 was launched on 01/10/2014 since for two active substances to be discussed at WG-V-2015 no default values are provided in the pick list (Table 3.8) of the ESD for PT 1 for $Qsubst_{pres\_bed}$ and $Qsubst_{occup\_bed}$. The outcome of the consultation was discussed at the meeting:

- Is there a need to revise the default values provided in the current ESD for PT 1 for the scenario of hand disinfection (in hospitals)?

  Conclusion: The WG agreed that there is a need to revise the scenario by adding a second method (beside the pick list) to derive a value for *Qsubst*.

- Amount of disinfectant used in each application: is 3 g of disinfectant protective enough? Does this value cover the different formulations?

  Conclusion: For the amount of disinfectant used, the efficient dose rate provided by the applicant should be used. If not available, a default value of 3 g should be used. If the amount is expressed in volume, the density of the product is set by default to 1, if no density is provided by the applicant.

- Number of applications per day: can the values proposed for the Human Health (HH) exposure assessment also be used for the environmental exposure assessment? Which values should be used for the food processing industry?

  Conclusion: For the number of applications/FTE/d the default values proposed in the recommendations of the Ad Hoc Working Group on Human Exposure will be used (i.e. 10 applications/shift for hand wash and 25 applications/shift for hand rubs. N.B.: The expression "per shift" in the last two lines was only used for consistency reason with the recommendations of the Ad Hoc Working Group on Human Exposure!).

- Hospital beds per hospital/per 10,000 inhabitants: Has any monitoring activity been performed on this issue on national level following the discussions on Iodine during TM II 2012 that could be used to revise the existing default value? Should the data from EUROSTAT (27 Member States) be considered, although not considered acceptable during TM II 2012?

  Conclusion: The use of the existing default value of 400 beds and occupational rate of 75% (= 300 beds) was agreed by the WG.

- Number of people using the disinfectant product?

  Conclusion: As a default value for the number of people using the disinfectant a value of 1.5 FTE/bed was agreed.

- Is it acceptable to provide a different scenario (e.g. based on food processing industry) as first tier?

  Conclusion: If it is not specified that a use is specifically and exclusively for food processing, the hospital scenario should be used for the emission estimation as first tier.

- Should the leave-on products be assessed similarly to the disinfection soaps? Is this worst case assumption excessively unrealistic?

  Conclusion: It was agreed that as a worst case, leave-on products could be assessed as disinfection soaps/hand raps if no information is available on a potential volatilisation or degradation on the skin. Removal processes could be accepted based on data, such as vapour pressure, to reduce the release to STP.

The following equation for the calculation of $Qsubst_{pres\_bed}$ and $Qsubst_{occup\_bed}$ was proposed:

$$Qsubst_{pres\_bed} = N_{FTE/bed} * Q_{form} * F_{form} * RHO_{form} * N_{appl}$$

$Qsubst_{pres\_bed}$ = *Consumption of active ingredient per bed [kg/bed*d]*

$N_{FTE/bed}$ = *Number of hospital personal per bed [FTE/bed] (Default: 1.5 FTE)*
Q_{form} = *Efficient dose rate of the hand disinfectant (Default: 0.003) [kg]*
F_{form} = *Fraction of active substance in the hand disinfectant [--]*
RHO_{form} = *Density of the product (Default: 1) [kg/L]*
N_{appl} = *Number of disinfection events/FTE/day (Default: 10 (liquid soaps) or 25 (hand rubs)) [1/FTE*d]*

To be noted:

- Q_{form}*:* The value for the efficient dose rate should be provided by the applicant. Only if no information is provided by the applicant, the default value should be used
- RHO_{form} is only relevant if the application rate of the product is provided as volume
- The same equation would also apply for the calculation of $Qsubst_{occup\_bed}$.
- *Post WG-V-2014*: *Cform* was changed into *Fform* in order to be consistent with the units.

Conclusion: The equation as proposed was accepted by the WG. It was further concluded that for surgical hand disinfection, a fraction of 10% using the product should be added to the equation.

7.5.2b PT 18 - Ad hoc EE WG consultation on the relevant depth to be considered

It was discussed if on the relevant depth for PT 18, the 10 cm depth or the 50 cm depth should be supported for direct release to soil in rural areas.

Conclusions and actions

The WG agrees to harmonise the procedure with other product types and use the 50 cm soil depth when considering restricted areas (e.g. around houses, terraces…) in PT 18.

In general the issue will be also taken up under the umbrella of the protection goal discussion.

Because the change triggers the need for a change in risk assessment, ECHA will check if this point needs to be confirmed by the CA meeting.

7.5.2c PT 18 - Ad hoc EE WG consultation on the exposure assessment for manure application

Not discussed, further discussion needed.

Action: ECHA to set up a telcon for further clarification and discussion of the issue after the meeting.

8. Any other business

8.1 Lessons learned

Specifically highlighted was the revised peer review in closing points in RCOM in the Revised Working Procedures (WP) for active substance approval (uploaded to CIRCABC for agreement in BPC-8 in December):

- **Updated RCOM:** *The eCA marks all points as closed or open: those marked as open will later be included in the discussion table by SECR (step 17). Issues that are bilaterally/trilaterally agreed but are of special relevance for the assessment (e.g. changes in reference values, additional studies required) are marked as open and will be agreed by the relevant WG*.
- **Disagreement in closing a point:** *When the updated RCOM is provided via CIRCABC indicating a point to be closed by the eCA, the other MSCAs have one week to request re-opening the point for discussion at the WG. The request will be directed to the SECR, informing the eCA. It is important to note that the timeline for this must be strict because of the preparation of the discussion tables. If disagreement to closing a point is not communicated within one week, this will be considered as tacit agreement to close it*.

On the RCOM and updated RCOM the following was further noted by ECHA:

There should be a more active roles of eCA and commenting MS in trilateral discussions to close points by e.g. setting up teleconferences to close open points. SECR is happy to support the eCAs on request.

The status should be clearly stated in the updated RCOM as open or closed points. Referring to the new working procedure, peer review of closing points can only work if the proposal is clear. If the RCOM is not clear on closing points, ECHA may reject them in the future.

Each comment should be included only once in the RCOM, if necessary indicate where else it may be relevant.

The following points were contributed by WG members and ASOs:

- One WG member requested to have the agenda uploaded to CIRCABC in Word version, instead or in addition to the pdf version.
- Draft new working procedures: two WG members would prefer having two weeks instead of one for checking the updated RCOM table. A possible option for this extension would be finishing the trilateral discussions one week earlier.
- Draft new working procedures: The ASO present requested a clarification on the possible RCOM rejection.
- A request for clarification and harmonisation was raised as to by when the following should be applicable and be considered in the CAR: new default values/new scenarios/new ESDs/new guidance => to be clarified by the BPC/CA meeting (immediately/after a transitional period/at product authorisation stage/at renewal stage?)
- A request for clarification was raised to the BPC until when new data can be accepted.

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List of Attendees (Annex I)

Analytical methods and physico-chemical properties WG

Core members
MUEHLE Ulrike (DE)
HUSZAL Sylvester (PL)
WARBURTON Anthony (UK)
SANDERS Marion (NL)
Alternate core members
WEBER Philippe (FR)
Flexible members
TADEO Jose L. (ES) Rapporteur
FUERTES Pedro (ES)
GONZALEZ Lorena (ES)
KARHI Kimmo (FI) Rapporteur
KORKOLAINEN Tapio (FI)
HYVARINEN Tuija (FI)
SCHMIDT Marianne (DK) Rapporteur
CATALDI Lucilla (IT)
CEBACEK Petra (SI)
Stakeholder(s)
MIHAI Camelia (CEFIC)

ECHA Staff
KREBS Bernhard (Chair)
RODRIGUEZ UNAMUNO Virginia
TAPIO Susanna
AIRAKSINEN Sanna
LISBOA MARTO Susana
Applicant(s)
BASF
Evonik Industries
Lanxess
Solvay

Human Health WG

Core members
HOLTHENRICH Dagmar (DE)
RITZ Vera (DE)
DE LENTDECKER Chloe (FR)
DE SAINT-JORES Jeremy (FR)
BOS Carina (NL)
Flexible members
SCHMIDT Marianne (DK) Rapporteur
BOYE PETERSEN Annika (DK)
DONOSO-CARRERO Rosa (ES)
ESTEVEZ Jorge (ES)
GONZALEZ Lorena (ES)
MARTINEZ Marta (ES)
HÄMÄLÄINEN Anna-Maija (FI)
HYVÄRINEN Tuija (FI)
KARHI Kimmo (FI) Rapporteur
PALOMÄKI Jaana (FI)
REY Marion (FR)
UJMA-CZWAKIEL Monika (PL)
CEBASEK Petra (SI)
WANG Camilla (SE)
Rapporteurs
VILANOVA Eugenio (ES)

ECHA Staff
AIRAKSINEN Antero (Chair)
ESTEVAN MARTINEZ Carmen
JANOSSY Judit
PECORINI Chiara
RUGGERI Laura
Accredited Stakeholder Organisations
MIHAI Camelia (CEFIC)
Applicants
BASF
Evonik Industries
Lanxess
Lonza
Thor GmbH

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
CAZUC Viorel (RO)
Flexible members
FRANK Ulrike (SE)
FONNESBECK VOGEL Birte (DK)
GONZALES Lorena (ES)
Rapporteurs
KAHRI Kimmo (FI)
HYVÄRINEN Tuija (FI)
MARTINEZ Marta (ES)
FONNESBECK VOGEL Birte (DK)

ECHA Staff
THUVANDER Ann (Chair)
SZYMANKIEWICZ Katarzyna
SCHAKIR Yasmin
Applicants
BASF
Kemira
Lanxess
Solvay
Evonik Industries
Accredited Stakeholder Organisations
MIHAI Camelia (CEFIC)
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)
Flexible members
DE LA FLOR TEJERO Ignacio (ES)
AHTING Maren (DE)
NIEBRZYDOWSKA Agnieszka (PL)
COSTA Lenia (PT)
Ad hoc EE WG members (2nd day)
STRACZEK Anna (FR)
LOZACH Jerome (FR)
DIAS Victor (FR)
MUNCH CHRISTENSEN Anne (DK)
GONDOLF Anette (DK)
SMIT Els (NL)
Van VLAARDINGEN Peter (NL)
PERSSON Johan (SE)
HAHLBECK Edda (SE)
WALTON Chris (UK)

ECHA Staff
SCHIMMELPFENNIG Heike (Chair)
GUTIERREZ Simon (Vice Chair)
SAEZ RIBAS Monica
Rapporteurs
LARSEN Jorgen (DK)
PENTTINEN Sari (FI)
RAMOS Carmen (ES)
Stakeholder observer
MIHAI Camelia (CEFIC)
Applicants
CEFIC Peroxygens Sector Group, Subgroup Hydrogen peroxide
LANXESS Deutschland GmbH
BASF SE