WG-II-2014

Final minutes

11 June 2014

Minutes of WG-II-2014

24-28 March 2014

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

Minutes of Human Health WG

WG-II-2014 (24-25 March 2014)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 7 core members present, in addition to 11 flexible members and one BPC member as a rapporteur. There were 2 accredited stakeholder organisations (ASOs) 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. 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. Administrative issues

4.1. Housekeeping issues

The Chair gave a presentation on the key aspects of the housekeeping rules including the safety and security rules.

5. Discussion of active substances[1]

5.1 CO_2 (eCA NL)

The Working Group members agreed on the evaluation of the evaluating Competent Authority (eCA). One ASO expressed their view that humaneness of the applications would need careful considerations. The eCA confirmed that the present evaluation takes into account such concerns and the eCA would ensure that the views expressed at the meeting are also reflected in the evaluation. The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

5.2 OIT (eCA UK)

This was an early WG discussion with an intention to agree on the effects assessment ahead of the full evaluation. The effects assessment was concluded.

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

5.3 Copper pyrithione (eCA SE)

The discussion had already been finalised at the Technical Meetings but was reopened at the WG to solve three points of disagreement. Two of these were agreed by the WG, but an *ad hoc* follow-up was regarded to be necessary for the third one. The results of this *ad hoc* follow-up were provided on 25 April and these will be forwarded to the BPC together with the updated CAR.

5.4 Dinotefuran (eCA UK)

All open points were closed and the eCA can prepare the updated CAR and proceed to the BPC.

5.5 C(M)IT/MIT (eCA FR)

There will be a need for an additional round of peer review and another WG discussion. The eCA and ECHA will agree on the timing and exact format of the peer review.

6. Technical and guidance related issues

6.1 Recommendation of the Ad hoc WG on Human Exposure: Hand disinfection (PT 01) - Harmonisation of exposure determinants for professional users

One Member asked why the values reported in the WHO Guideline were not taken into account to derive the determinants for professional exposure. It was clarified that WHO Guideline provides general recommendations and does not prescribe a defined number of hand hygiene actions. In the light of this, the exposure determinants for professional users identified in the recommendation are based on consumption and observation data. Those aspects are reflected in the text of the recommendation.

The approach proposed in the recommendation was supported by the WG and the recommendation was agreed.

Conclusions and actions

The recommendation was agreed by the WG.

6.2 Recommendation of the Ad hoc WG on Human Exposure: Application duration to be used in wiping and mopping (PT2)

No discussion took place on the recommendation and the document was agreed by the WG.

Conclusions and actions

The recommendation was agreed by the WG.

6.3 Guidance development

The Chair presented the state of human health related and horizontal guidance documents under development.

7. Any other business

7.1. R4BP 3

SECR presented the most relevant changes in the R4BP 3.1 with respect to the current 3.0 version.

7.2. Lessons learned

The Chair pointed out the need for the CAs, applicants and ASOs to provide documents in time to have them included as meeting documents, stressing also that confidential documents should be clearly marked as confidential.

The response to comments tables (RCOMs) should always be provided as one document, even when there are multiple applicants and/or several product types. Comments on confidential issues should be in a separate confidential RCOM. When commenting, each comment should be made only once and they should not be repeated for various parts of the CAR. In the comment it is possible to indicate if the comment is relevant elsewhere as well. When producing the RCOM, it is also very important to indicate for each comment whether it is closed or open.

The discussion tables were considered very useful in preparing for the discussion as they help the members in focusing in the essential aspects of the evaluations. It was proposed and agreed that the discussion tables should always include the reference values regardless of whether the foreseen discussion concerns these.

Minutes of Analytical methods and physico-chemical properties WG

WG-II-2014 (25-26 March 2014)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 5 core members, 2 alternate core members, 5 flexible members and one representative of the BPC rapporteur present at the meeting. There were no Accredited Stakeholder Organisations (ASOs) present at the meeting. One applicant was present for his substance discussions.

Participants were informed that the meeting is recorded solely for the purposes of writing the minutes and that this recording will 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 was declared.

4. Administrative issues

4.1 Housekeeping issues

The Chair gave a presentation on the key aspects of the housekeeping rules including the safety and security rules.

5. Establishment of a reference specification

5.1 Reference source for biocidal active substances under the Biocidal Products Regulation (BPR) (EU) No 528/2012

The chair gave a brief presentation on the reasons for drafting the document 'Reference source for biocidal active substances under Biocidal Products Regulation (BPR) (EU) No 528/2012' and explained that the documents tries to achieve a common understanding on the terminology and the approach to be taken in particular for the assessment of technical equivalence and chemical similarity check.

The major discussions points were to agree on the definitions of the terminology used.

In summary the following definitions have been agreed:

- A source is defined by the following information:
  - the applicant
  - the manufacturer
  - the manufacture location/plant location
  - the manufacturing process

- The specification is set by the applicants and should be in general derived from a 5-batch analysis. Quality control data might be used to refine or support the specification set by the applicant. In specific cases it might be possible to refer to specifications set by other pieces of legislation e.g. the pharmacopeia or specifications used for food additives. But nevertheless these specifications need to be supported by certificates of analysis.

- Reference specification can be defined as the specification compared to the test substance used for the provided studies and adjusted by the experts of toxicology, ecotoxicology and chemistry taking into account the content of the different constituents in the (test) substance. Hence it can be regarded as a scientific refinement of the specification.

  - The experts can narrow or expand the specification based on quality control data, the composition of the test substance or expert judgement based on the physico-chemical, toxicological and eco-toxicological properties of the substance. A sound scientific justification should always be provided when the reference specification deviates from the specification.

  - There should always be one reference specification for one application. This also applies for an application which includes several applicants, e.g. task forces. In cases of several applicants with their own active substance dossier, the reference specification with the lowest purity is taken for the inclusion in the Union list.

  - For technical equivalence assessments and chemical similarity checks, the 'new' specification needs to comply at least with one reference specification for being regarded as technically equivalent or chemically similar.

- Reference source is the combination of a source and the set reference specification considering the provided studies (including the composition of the test substance). Each applicant (including consortia and task forces) might have its own reference sources.

Conclusions and actions:

Based on these definitions, the document on 'Reference source for biocidal active substances under Biocidal Products Regulation (BPR) (EU) No 528/2012' will be updated by ECHA and distributed to the members of the WG for comments.

5.2 Requirements for technical equivalence/chemical similarity checks for the evaluation of multiple dossiers for the same active substance

The WG discussed whether it is necessary to perform a chemical similarity check (technical equivalence assessment) for multiple dossiers of the same active substance in

cases, where the applicants have provided their own complete and compliant data packages which allow full evaluations of the substance. Hence the applications refer to their own reference sources. With the consequence that assessments of technical equivalence / chemical similarity checks are not necessary as sufficient information is provided to support the approvals of the active substance.

Conclusions and actions:

It was agreed that in the above mentioned situation the assessment of technical equivalence / chemical similarity check is not regarded as necessary. However, it was also concluded that these approach should only be used when the evaluations result in the same inclusion criteria (e.g. same risk mitigation measures). If this cannot be guaranteed further discussion is necessary.

ECHA will inform the Commission, BPC and CAs on the outcome of the discussion.

5.3 Glutaral – deriving theoretical dry weight specifications

In the context of the evaluation of Glutaral, the WG discussed the more generic issue of the need of deriving dry weight specifications and the preferred calculation method.

The WG discussed whether a dry weight composition needs to be calculated and included in the CAR. If yes, which calculation method should be used? For Union list inclusion it was agreed that the REACH guidance for identification and naming needs to be followed and the purity might not always refer to the dry matter depending on whether the solvent(s) can be removed without affecting the stability of the substance.

Conclusions and actions:

It was agreed that a dry weight specification is needed for technical equivalence assessment/chemical similarity check. But the substance identification for Union list inclusion is based upon the guidance for identification and naming of substances under REACH and CLP. Hence for Union list inclusion the actual content of the substance is to be considered.

WG members could not comment on the calculation methods presented in the room document hence an e-consultation will be launched to agree on the suitable method for dry weight calculation.

6. Technical equivalence assessments

6.1 Prallethrin (eCA EL)

The WG discussed the document prepared by the eCA summarising the information provided by the applicants on prallethrin. The document, as highlighted by the eCA, did not present a technical report on equivalence but gave an indication of the possible outcome of a technical equivalence assessment.

The WG discussed the available draft specification, the specific methods of analysis required and the method of manufacture.

The eCA proposed to request the missing information from the applicants to fill in the gaps in the dossier. The way forward proposed by the eCA was supported by the WG.

Conclusions and actions:

The eCA will request from the applicants where relevant the following information which is required for the assessment of the active substance:

- 5-batch analysis
- Analytical specific methods
- Information on the manufacturing process

6.2 Basic copper carbonate (eCA FR)

The working group agreed with the conclusion made by the eCA. Hence the specification and justification provided by Spiess Urania for basic copper carbonate are acceptable and comply with the reference specification used for approval of the active substances.

Conclusion:

The source of Spiess Urania is a reference source.

The specification and justifications provided by the Copper Task Force for basic copper carbonate have been regarded as not acceptable and not complying with the reference specification used for approval of the active substance.

No reference source could be set for the Copper Task Force dossier.

6.3 Copper hydroxide (eCA FR)

The working group agreed with the conclusion made by the eCA. Hence the specification and justifications provided by Spiess Urania for copper hydroxide are acceptable and comply with the reference specification used for approval of the active substance.

Conclusions:

The source of Spiess Urania is a reference source.

6.4 Copper (II) oxide (eCA FR)

The working group agreed with the conclusion made by the eCA. The specification and justifications provided by the Copper Task Force for copper oxide have been regarded as not acceptable and not complying with the reference specification used for approval of the active substances.

Conclusions:

No reference source could be set for the Copper task force dossier. In consequence, no reference source for copper (II) oxide is available.

7. SID data requirements for in situ generated substances

7.1 In situ substances - summary

The chair gave a brief presentation on the in-situ generated substances outlining the criteria of 'in-situ' and the different cases of precursors. It was also highlighted that not all in-situ substances are equilibria and not all equilibria are in-situ substances. But equilibria should rather be regarded as UVCB substance than well-defined substances as the equilibria might depend on several parameters which might not be possible to control.

This implies that the naming convention of UVCB substances needs to be followed. However as the starting material might have also active properties it was concluded that this type of UVCB substance should be named as equilibrium of S_A and S_B and …. with P_A and $P_{B.}$ [S = starting material; P = product].

7.2 Peroxyoctanoic acid (POOA) (eCA FR)

The WG discussed a common approach to assess the substance identification of this type of substances. It was agreed that for Union list inclusion the entry should be generic 'equilibrium of…'. Further conditions of the equilibrium should be indicated for Product authorisation.

The identity package needs to identify sufficiently this type of substances. The WG agreed on the following information requirements to set reference specification for this kind of substance:

- Manufacturing process including conditions and their variation.
- Information on the starting materials and reaction products (complete specification of starting materials).
- Information on the equilibrium (individual constituents measured with validated methods on one batch of the equilibrium at a defined condition).
- Quality control data as an indicator for the level of variation of the composition at different conditions: pH, temperature, dilution....

8. Discussion of active substances

8.1 Carbon dioxide (eCA NL)

No open issues indicated in the discussion table. Hence the evaluation is agreed by the WG members.

Conclusions and actions:

The eCA to update the CAR based on the conclusions provided in the discussion table.

8.2 Dinotefuran (eCA UK)

Open issues indicated in the discussion table were discussed and agreed by the WG members. Hence the evaluation is agreed by the WG members.

Conclusions and actions:

The eCA to update the CAR based on the conclusions provided in the discussion table.

8.3 C(M)IT/MIT (eCA FR)

CMIT/MIT was not agreed by the WG members as the stability of the substance without solvent needs further clarification. Hence the composition of the substance needs to be clarified.

Conclusions and actions:

Points on the substance identity remain open. The eCA to request data based on the conclusions provided in the discussion table.

9. AOB

9.1 R4BP 3

ECHA presented the most relevant changes in the R4BP 3.1 with respect to the current 3.0 version.

9.2 Lessons learned

Chair presented a summary of experience gained during WG and its preparation:

Documents need to be provided in time to have them included as meeting documents, stressing also that confidential documents should be clearly marked as confidential.

The response to comments tables (RCOMS) should always be provided as one document, even when there are multiple applicants and/or several product types.

Comments on confidential issues should be in a separate confidential RCOM.

When commenting, each comment should be made only once and they should not be repeated for various parts of the CAR.

In the comment fields it is possible to indicate if the comment is relevant elsewhere as well. When producing the RCOM, it is also very important to indicate for each comment whether it is closed or open.

Minutes of Efficacy WG

WG-II-2014 (26 March 2014)

1. Welcome and apologies

The Chair welcomed all participants to the first Efficacy WG meeting. The members of EFF WG (core and alternate) and the rapporteur briefly introduced themselves. 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. Agreement of the agenda

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

Conclusions and actions

All participants agreed on the proposed agenda. AT asked for physical meeting and development of guidance of nanomaterials and in addition proposed to discuss at AOB problem concerning harmonised evaluation of DEET. The Chair informed that physical meeting will be organized in June. In case of guidance concerning nanomaterials it is not foreseen to work now on it, as there is only one active substance included into the Union list which contains also nanoforms.

3. 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.

4. Administrative issues

4.1. Housekeeping issues

The Chair invited all members to alert SECR of any particular difficulties they have experienced.

5. Discussion of active substances[2]

5.1 CO2 (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 Chair informed that a document regarding the use of CO2 as a biocide was submitted to ECHA a few days prior to the WG meeting by Eurogroup for Animals. This document has been uploaded to CIRCABC but it was not a meeting document for discussion as it

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

was provided too late. The eCA explained that issues raised in the document had been taken into account.

WG agreed on the evaluation of eCA.

5.2 Dinotefuran (eCA UK)

The eCA proposal to include in the CAR the maximum application rate was supported and accepted by WG members.

WG agreed on the evaluation of eCA.

5.5 C(M)IT/MIT (eCA FR)

There were two points to be discussed. It was agreed that in both cases additional data has to be submitted at the product authorisation stage.

WG agreed on the evaluation of eCA.

6. Technical and guidance related issues

6.1 Work plan for Efficacy guidance

A presentation concerning the current status and work plan for efficacy guidance was given by SECR.

DE informed that after public consultation they received comments for the guidance "General principles and practical considerations for testing the efficacy of preservatives". In their opinion there would be no need to provide a revised version. The comments have been sent to the expert and some had been answered already.

UK informed that as the efficacy guidance for PT19 contains basic information only, a workshop in the UK had been planned. Now when ECHA has taken over the leading role with new guidance this workshop could perhaps be organised in Helsinki. This needs to be further discussed.

The guidance for PT 8 and PT22 will be revised by FR after the public consultation. FR asked for the possibility to organise a workshop also for these PTs. The Chair informed that Webex meetings are preferable for this kind of discussion.

SE asked about the efficacy guidance for treated articles. The Chair informed that it will probably follow ECHA's procedure, but before a decision will be taken a bilateral discussion with SE is needed.

The Chair informed also that the PT21 guidance will be revised after the parallel consultation of stakeholders and competent authorities and published on ECHA's website.

Conclusions and actions

ECHA will continue its work on efficacy guidance and update the EFF WG on a regular basis. The WG will also have a role in the preparation of guidance and will endorse guidance before they are published.

6.2 Efficacy of piperonyl butoxide (PBO) for PT18

A presentation concerning the status of PBO as an active substance was given by SECR.

The Chair of BPC informed that the status of PBO had been taken up by COM. If PBO is not regarded as an active substance a non-approval decision would be taken by COM and the substance would be regarded as co-formulant.

The applicant indicated that the definition of active substance in the BPR is not restricted to substances which have only direct effect on target organisms, but also indirectly acting substances can be considered as active substances. A full data package is available for PBO and if it would be included as an active substance it would facilitate the authorisation process of many biocidal products.

The WG members agreed that PBO is a synergist. Regarding its efficacy as an active there would be a need to look into the efficacy testing results in more detail.

Conclusions and actions

The document concerning the status of PBO will be uploaded on CIRCABC for comments by the EFF WG. The discussion will be continued in June 2014.

6.3 Possible update of the PT 14 guidance

NL briefly introduced the status of the document. This guidance deals with the evaluation methodology of efficacy tests for rodenticide biocidal products. It was endorsed at the CA meeting in 2009 but a need for revision was introduced following disagreements regarding product authorisation in the Coordination Group. The revision has been drafted by NL and was submitted via the Coordination Group/COM to ECHA.

It was generally felt that the revised documents would need to be circulated to the WG, rodenticide experts and CAs for comments. The Chair informed the WG members that the way forward after the commenting will depend on the number of substantial comments received.

Conclusions and actions

Members welcomed the initiative to update the guidance. The revised version of the PT14 guidance will be uploaded on CIRCABC for comments.

7. Any other business

The discussion concerning harmonised evaluation of DEET was postponed due to lack of time.

Conclusions and actions

ECHA will contact AT and clarify how the issue can be taken forward.

Minutes of Environment WG

WG-II-2014 (27-28 March 2013)

1. Welcome and apologies

The Chair welcomed the participants indicating that there were 7 core members present, in addition to 10 flexible members, one adviser and one BPC member as a rapporteur. No accredited stakeholder organisations (ASOs) were present at the meeting. Applicants were also present for their specific substance discussions.

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

2. Agreement of the agenda

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

There was a request by one WG member to provide information for an upcoming preservative workshop under AOB.

There was a general request to provide the agenda in doc version, so personal notes can be added to it. ECHA agreed to upload the agenda in doc version for future meetings.

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

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

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

Folpet:

There was a clarification requested for the changed introduced in the last point of the document.

Minutes were agreed.

Alpha cypermethrin:

There is need for a decided follow up to be performed by an expert group via e-consultation; ECHA will send a request for volunteers via email.

The justification for the change of the simultaneous factor (as agreed in WG-I-2014) was explained, since it was not clear from the minutes.

The text on the realistic use was revised and extended with a proposal made during the meeting, and agreed in the last day of the meeting.

The minutes were agreed.

Since not comments have been received on the minutes of the other points discussed at WG-I-2014, these have been considered as being agreed.

5. Administrative issues

5.1. Housekeeping issues

The key aspects of the housekeeping rules including the safety and security rules were presented.

6. Discussion of active substances[3]

6.1 CO2 (eCA NL)

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 Dinotefuran (eCA UK)

All points were agreed by the WG. The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

6.3 Copper pyrithione (eCA SE)

The discussion had already been finalised at the Technical Meetings but was returned to a WG to solve one point of disagreement which consists in fact of three related sub-points. The point of disagreement was solved and agreed by the WG. The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

6.4 C(M)IT/MIT (eCA FR)

All points were agreed by the WG. The eCA can prepare the updated Competent Authority Report (CAR) and proceed to the Biocidal Products Committee (BPC).

7. Technical and guidance related issues

7.1 Cut off criteria for groundwater assessment of biocides (UK)

Conclusions and actions

The paper prepared by UK was agreed by the WG. A minor textual amendment was agreed that this only is valid for active substances and metabolites fulfilling both criteria.

7.2 Proposals for standard scenarios and parameter setting of the FOCUS groundwater scenarios when used in biocide exposure assessments (DE)

The document and its background were presented by DE.

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

Conclusions and actions

It was agreed to include the results of the e-consultation summarised in the document of DE including the following conclusions of WG-II-2014 into MOTA v7. The outcome of agreed follow ups (see below) will be presented at WG-III-2014.

General comments:

Point 1 - FOCUS groundwater models: the proposal by DE was agreed without further discussion.

Point 2 – Plant uptake factor: the proposal by DE was agreed without further discussion.

Application on soil via manure/slurry and sludge:

Point 3 – Default crops for arable land: it was agreed that one application to maize in spring plus two applications to winter cereals in autumn and spring, respectively, should be used.

Point 4 – Application date: for arable land the proposal of DE was agreed. For grassland no application date could be agreed; this point will be **followed up by an e-consultation** involving Peter Okkerman, an expert from RIVM, James Hingston, Eleonora Petersohn, Anne Straczek and a Focus expert (Michael Klein).

Point 5 – Application method and depth: for **manure/slurry** application to arable land it was agreed that 20 cm incorporation depth should be used (according to the ESD for PT 18). For manure/slurry application to grassland it could not be agreed if 5 cm incorporation depth or surface application should be used. Therefore, as **follow up,** DE agreed to perform example calculations in order to identify the worst case of both calculations. The worst case will then be noted in MOTA.
For **sewage sludge** application the TGD should be followed (i.e. 10 cm incorporation depth should be used for grassland application and 20 cm incorporation depth for application on arable land).

Point 6 – Aerial deposition: this point could not be agreed, it was concluded that there will be a bilateral **follow up between NL and DE**; ECHA and FR should be included in the email exchange.

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

Some equations in the document (eq. 1 and 2) were changed; therefore MS expressed the need to re-check the document with their experts. In preparation of the follow-up discussion, NL will provide the main points for discussion and summarise questions to member states. NL will provide feedback to ECHA for which subsequent WG meeting the discussion should be scheduled (WG-III-2014 or WG-IV-2014). ECHA will provide NL with deadlines for providing the discussion table related to the respective WG-process flow.

Conclusions and actions

The document was not agreed by the WG and will be re-scheduled for discussion at one of the next WG meetings.

7.4 Volume IV Part B: Guidance on Environmental Risk Assessment – Active Substance (ECHA)

It was further explained that in WG-IV-2014 the prioritisation of points to be considered in the first revision of Vol. IV Part B will be discussed and agreed.

Conclusions and actions

The guidance document was agreed and adopted by the WG including the changes that where indicated in Appendix 1 to the discussion table.

It was recommended to use Vol. IV Part B only when the final version is uploaded on the ECHA website.

7.5 Scenario for the biocidal use and emissions from oil platforms PT11/ PT12 for PEC calculation (NL)

SE noted questions on the calculation procedure and propose to consult the MAMPEC software with regard to the calculation of a geographic mean. However, MAMPEC calculates a steady state situation whereas in the document of NL pulse injections are considered. SE further state that a high particle concentration is considered in the open ocean (5 mg silt/L) which is a factor of 10 higher than the value used in MAMPEC and the value proposed by the Norwegian Research Council. NL agreed to adjust this value.

SE further reflects on the procedure to pump in biocides in the ocean floor, which are not further considered in the assessment after they have entered the geological cycle. This exposure pathway is not considered in the TGD.

SE mentioned further editorial issues which they will send to NL.

DK further mentioned the DREAM model which is also used for risk assessment purpose which could be helpful for the scenario proposed by NL. NL agreed to cross-check this model.

Conclusions and actions

The document was agreed by the WG; however there will be a follow up between SE and NL.

7.6 Update on guidance development (ECHA)

The Chair presented the status on guidance development and indicated that that the member states responsible for the respective documents will be contacted after WG-II-2014 in order to clarify which documents could be discussed at WG-III-2014.

8. Any other business

8.1. R4BP 3

SECR presented the most relevant changes in the R4BP 3.1 with respect to the current 3.0 version.

8.2. Lessons learned from WG-I-2014

The Chair pointed out the need for the CAs, applicants and ASOs to provide documents in time (i.e. at least 10 days before the meeting) to have them included as meeting documents. It was also stressed that confidential documents should be clearly marked as confidential.

The response to comments tables (RCOMs) should always be provided as one document, even when there are multiple applicants and/or several product types for the same active substance. When producing the RCOM, it is also very important to indicate for each comment whether it is closed or open. Comments on confidential issues should be in a separate confidential RCOM. When commenting, each comment should be made only once and they should not be repeated for various parts of the CAR. In the comment, it is possible to indicate if the comment is relevant elsewhere as well.

The WG members provided some feedback to ECHA. In particular, some members reported that the discussions tables are very useful for the preparation of the meeting. In this connection, it was requested that some more background is included in the tables.

In general, it was considered relevant to have only one RCOM even when more applicants and PTs are under discussion for the same active substance.

Some members requested to have more time to reflect during the meeting and to introduce some breaks between the discussion points. This would give them more time to check the 'Open/closed point/Conclusions column' of the discussion table.

It was suggested to reduce the number of columns of the discussion table; this would make it easier to show the discussion table during the meeting.

In general, the 'Lesson learned' discussion was considered useful and it was suggested to keep it in the agenda of the next meetings.

The feedbacks received will be further considered by ECHA.

8.3. Announcement of preservative workshop by DE

DE informed the WG on the upcoming "Workshop on the leaching behaviour of biocides from preservatives" related to a BAM/UBA project running since 2011. The workshop will be organised by the Federal Institute for Materials Research and Testing (BAM) in collaboration with the Federal Environment Agency (UBA) on 3 – 4th of July 2014 in Berlin.

List of Attendees (Annex 1)

Human Health WG:

Core members
BRESCIA Susy (UK)
DE LENTDECKER Chloe (FR)
DE SAINT-JORES Jeremy (FR)
GHITULESCU Rita-Elena (RO)
HOLTHENRICH Dagmar (DE)
NIKOLOPOULOU Dimitra (GR)
RITZ Vera (DE)
Alternate core members
FASTIER Antony (FR)
BOSMAN Saskia (NL)
Flexible members
BOYE PETERSEN Annika (DK)
HÄMÄLÄINEN Anna-Maija (FI)
HYVÄRINEN TUIJA (FI)
REY Marion (FR)
LAUMONIER-MAXIMILIEN Elisabeth (FR)
CRESTI Raffaella (IT)
HUSZAL Sylwester (PL)
LÅSTBOM Lena (SE)

ECHA Staff
AIRAKSINEN Antero (Chair)
ESTEVAN MARTINEZ Carmen
JANOSSY Judit
MYÖHÄNEN Kirsi
PECORINI Chiara
RUGGERI Laura
Accredited Stakeholder Organisations
LEROY Didier (CEPE)
WAGNER Kristina (Animal Welfare Organisations)
Rapporteur
LEBLOND-GOUR Annabelle (FR)
BPC Member
IAKOVIDOU Mary (SE) (24.3)
Applicants
KANE David (LKC Ltd)
GALE Eric (LKC Ltd)
WATT Ian (Dow Chemical)
QUEROU Rodolphe (Dow Chemical)
HINDLE Stuart (Dow Chemical)
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