Final Minutes of the Biocides Technical Meeting TM I 09
16-20 March 2009

INTRODUCTION

COM reminded that it is necessary that the participants register in time for the TM, and especially for those that will be reimbursed by COM. If registration is done after the deadline, reimbursement cannot be made.

1. Approval of the agenda

A room document from FR will be discussed as AOB item 5d.

2. Adoption of the minutes

The minutes were adopted without changes.

3. Action List TM

1. *Development of refined marina scenario for PT21 to be used in product authorisation*

   The first version is expected from CEPE.

2. *Paper on evaluation of tests on nitrogen and carbon transformation in soil*

   An e-mail consultation from FR is ongoing.

3. *Prepare addendum to the TNsG on data requirements section 7.0.2.3.2 on requirement of water-sediment study depending on Kp value.*

   The addendum will be discussed in TM II 2009.

4. *Manual of Technical Decisions: COM to present first draft*

   First version is available on Circa and will be discussed in the General Session of this meeting.

5. *Update guidance document "Risk mitigation measures for anticoagulants used as rodenticides: after Annex I inclusion of chlorophacinone with respect to tracking powder*

   This is ongoing work that will be done during the first half of 2009.

6. *Distribute questionnaire resistance via web-site CPSQ*

   DE will send the questionnaire to COM.

7. *Finalisation document groundwater assessment (harmonisation input parameters sorption and degradation)*

   The document has been finalised and is available from the JRC biocides web pages.

8. *Finalisation thought-starter leaching rate for PT 07, 09 and 10*

The document has not been finalised yet.

9. *Update document on framework food risk assessment*

   This document will be discussed in the General Session of this meeting, item 8.

10. *Discussion document on assessment factors for local effects*

    This document will be discussed in the Toxicology Session of this meeting, item 1.

11. *Discussion document for CA meeting on use of new and old TNsG on human exposure including endorsement of the new TNsG*

    This document was endorsed by the CA meeting.

12. *Submit entry in registry of intention for Annex XV dossier for harmonised C&L for first and second generation anticoagulants*

    COM has not received the information from all MSs on whether they have filled in the ECHA registry of intentions. Information has been received from NL concerning flocoumafen, from FI concerning difenacoum and from NO concerning difethialone. Other MSs were asked to send this information to COM as soon as possible.

13. *Inform ECHA on request extension transitional period for IUCLID 5 submission of Annex XV dossiers*

    The letter has been sent to the Director of ECHA, and the item will be discussed in the REACH CA meeting in March 2009.

14. *Inform NL on participation in working group project "Harmonisation of efficacy data requirements for PT 02*

    Proposal has been endorsed at the CA meeting, and the project will start with several MSs and COM involved in the working group.

15. *Analysis of use of REACH guidance under BPD*

    This DE document will be discussed in the General Session of this meeting, item 2.

16. *Proposal sediment risk assessment using MAMPEC for PT 21*

    The document will be discussed in the Environmental Session of this meeting.

17. *RMS for PT 06 active substances to send the relevant information from their received submission on the categorisation and the emission factors to FR*

    This will be discussed in the Environmental Session of this meeting under AOB.

4. Members of the Technical Meeting and the e-consultation group

COM asked to inform by E-mail on any changes.

5. Next Technical Meetings

TM II 09	8 - 12 June	CA	12-15 May
TM III 09	5 -9 October	CA	15-18 September
TM IV 09	30 November - 4 December	CA	15-18 December

Note from the Commission

COM said that from now on there will be many more CARs to be discussed, and the way of working will need to be adapted to allow this to happen. There needs to be communication between the commenting MSs and the RMS on the issues raised in order to avoid unnecessary discussions at the TM. This communication can occur either before or after submitting the RCOM, and if done before, then the result of this communication can be included in the RCOM. The aim should be to resolve as many outstanding issues as possible before the first discussion at the TM. COM referred to the SOP that is available from the JRC biocides web pages, noting that the procedures given in that document are not being followed by all MSs.

NL commented that many MSs are understaffed, and it is practically impossible to react to the RCOM before the deadline of the documents. NL urged that no further documents should be sent after the deadline, because it is not possible to take all of those into account. **COM** responded that the deadlines should be respected, but on the other hand, the relevant information should also be distributed.

COM asked for two points to be taken into account for all substances:

1. There has to be communication between the RMS and the commenting MSs to solve part of the issues before the TM.
2. When a point is closed, it has to be clear that it will not be discussed again in the TM.

TOXICOLOGY SESSION

1. Risk characterisation of local effects

COM presented the document that was drafted by the e-mail working group formed by UK, FR, NL and DE, concerning the risk characterisation of local effects. **AT** agreed with the proposal, but wanted to remind the TM that uncertainty is very high when using or adjusting AFs for local effects, and therefore caution should be be applied when considering the most appropriate AF for a particular scenario. Recent studies have indicated that even much higher AFs than the currently used default values might be necessary, but it would be very difficult to put such factors into use in the approaches that are currently usable. **NO** welcomed the document and the efforts to harmonize the approach for risk characterisation of local effects. As for the performance of quantitative risk assessment of local effects, not only difficulties in establishing external reference values based on the available studies could be encountered, but also limitations in the available exposure data. NO, agreed with AT that reducing the AFs should be done with caution. NO asked whether other MSs agree to the possibility of reducing the intraspecies AF to 3.2, since according to the REACH guidance this reduction is not possible. **FR** said that it would not be logical to take into account the toxicokinetic variability in intraspecies variability if it is not taken into account in interspecies variability. **COM** clarified that in the proposal, the general rule would be not to modify the intraspecies AF, but in exceptional cases, like for a simple irritant effect, this could be done.

IND agreed that the principle of quantitative risk assessment based on systemic effects is not suitable for substances that primarily demonstrate local effects. Nevertheless, the vast majority of the available data concern systemic effects, and the exposure data is also not well suited for assessing local effects. The risk characterisation currently involves using systemic AELs, and the exposure models available for most PTs are not suitable for the purpose of relating exposure to an AEC_{dermal} or $AEC_{inhalation}$. In consequence, this approach would require the actual exposure data. Finally IND argued that if this methodology is adopted, then it should be used as a harmonised approach and not just for individual chemicals. **COM** confirmed that harmonisation is the intention of the document and asked IND to clarify whether they support the document and whether they would recommend any specific changes to it. **IND** replied that they agree to the scientific basis, but wanted to point out that the exposure data that is needed to perform the assessment is not always available.

FR commented that unlike mentioned under the title “Dermal route”, a dermal toxicity study can be very relevant for exposure that occurs under gloves. This text should be corrected. Furthermore, FR asked about the usability of the irritation studies as a source of information on dermal effects. **COM** proposed to change the text so that such information could be used if relevant effects are seen, and **FR** agreed.

DE asked whether this document is an official guidance document that goes to the CA meeting for endorsement, to which **COM** replied that it would not have the status of an official guidance document, but it is just the TM opinion on how we should proceed. It will be placed on the JRC web pages, and in the Manual of Technical Decisions.

PT said that because of the lack of exposure data, it will usually not be possible to perform a quantitative risk assessment, and therefore a qualitative one will normally be performed as the first option. This would not refer only to classification and labelling. **COM** clarified that the paper concerns the situation when there are only local effects, not

systemic ones, and thus the risk characterisation has to be based on the local effects and only then the methodology outlined in this paper will need to be considered.

FR considered the following sentence (under Interspecies AF – Toxicodynamic AF 2.5) misleading, because local metabolism belongs to the kinetic part: "…if the mechanism is not known, or if local metabolism may have a role, then the factor 2.5 is applied." **AT** disagreed, saying that the toxicokinetic AF is more related to systemic effects, since it is largely based on parameters like liver weight, liver plasma flow and renal plasma flow and local metabolism on skin could be mentioned in the context of toxicodynamic AF. **FR** asked whether local metabolism should be considered as part of the global metabolism, as in their opinion it should be. **COM** said that this is the case, but pointed out that the kinetic component relates to the systemic metabolism and does not take local skin metabolism into consideration, just as it is not taken into account in allometric scaling. COM therefore agreed with AT. **FR** then agreed that local metabolism can be considered as a special case and be included into the dynamic component. **COM** said that the current phrasing of the document would then be accurate, saying that there seems to be an agreement that the local metabolism does not belong to the kinetic component, and asked whether it should be included in the toxicodynamic component or added as a separate, third point in addition to the toxicodynamic and toxicokinetic components. This would not result in an additional AF, but just another point to be considered. **FR** agreed with the current text, suggesting it just to be mentioned that although local metabolism is not really part of the toxicodynamic component, it can nevertheless be included in this AF. **COM** clarified that local metabolism is problematic because it does not really belong to either of the components, but it has to be taken into account somehow. It was agreed that the document is considered endorsed by the TM, and the final changes on it, as discussed in this TM, will now be discussed among the same group of countries that participated in drafting the document, in order to find a suitable wording that all could agree on. It will then be uploaded to the JRC web pages and into the Manual of Technical Decisions.

2. SUBSTANCES in PT 08

2a. Copper (II) carbonate; Applicant WPCTF, copper (II) oxide; Applicant WPCTF (RMS: FR), copper (II) carbonate; Applicants Spiess Urania (RMS: FR) and copper (II) hydroxide; Applicant Spiess Urania (RMS: FR)

-

2b. Alkyldimethylbenzylammonium Chloride (ADBAC); Applicant Lonza GmbH, Stepan Europe and Field Fisher Waterhouse LLP (RMS: IT)

-

2c. Didecyldimethylammonium Chloride (DDAC); Applicant Lonza GmbH, Stepan Europe and Field Fisher Waterhouse LLP (RMS: IT)

-

3. SUBSTANCES in PT 19

3a. DEET (RMS: SE)

-

4. SUBSTANCES in PT 18

4a. Diflubenzuron; Applicant Chemtura (RMS: SE)

-

4b. Diflubenzuron; Applicant Safepharm (RMS: SE)

-

4c. Bendiocarb (RMS: UK)

-

5. AOB

5a TNsG on Human Exposure: report from 32nd CA meeting

COM informed that following the discussion on the legal status of the TNsG on Human Exposure, COM sent a proposal to the CA meeting that then considered the TNsG as endorsed.

COM informed that the HEEG opinion on the use of the old version (2002) and new version (2007) of the TNsG on Human Exposure, endorsed in the previous TM, was now endorsed by the CA meeting as well.

5b. Workshop Human Exposure to Biocides: report from 24-26 Ferbruary workshop in Oslo

COM reported on the exposure workshop in Oslo. This was a 3-day workshop where the first day was for general issues, the second day a training workshop on BEAT, and the third day was a training workshop on ConsExpo.

On the first day there were presentations on Guidance on human exposure, databases used for human exposure, and then case studies presenting problematic issues. Finally there was a general discussion on using the guidance.

Based on the discussion at the workshop, COM interpreted that:

1. The experts agree with the HEEG proposal (endorsed by TM and CA) on using the old and new guidance.
2. Validation of the new guidance is not really possible, but it would be possible to compare results using old and new guidance. It would be very desirable to perform an exposure assessment using both the methodologies to compare the results. Everything that is known points to the same direction: results obtained using the new guidance should be considered more trustworthy, as there is more data available.
3. The biggest difference in possible outcomes of exposure assessment when using TNsG 2002 *vs*. TNsG 2007 could be that the new guidance (with BEAT and ConsExpo) gives

more accurate results. To know more about the possible differences, it is necessary to compare the two approaches in an exposure assessment. It also depends to a large extent on the way the exposure assessment is performed, as e.g. it is not necessary to use the Bayesian probabilistic approach when performing an assessment with BEAT.

According to COM, the overall conclusion of the workshop was that the new guidance is superior and should be used where possible, considering e.g. what guidance was available when submitting the dossier. For the substances on the 3rd list, it would be useful if some exposure assessments were done using both the old and the new guidance. The experts did not see any scientific reasons for not using the new guidance.

UK commented that it would be very useful to compare the exposure assessment using the old and the new guidance for e.g. antifoulants, and assessing just one substance with both methods would give an indication of the possible differences.

FR agreed with COM conclusions, pointing out that flexibility in the approach was agreed by all. BEAT is a good tool in that it enables more flexibility for the experts, allowing more expert judgment to be included in the exposure assessment.

5c. HEEG opinion on Choice of secondary exposure parameters for PTs 2, 3 and 4

FR presented the document, concluding that both ConsExpo and SOP are applicable and valuable tools, and the choice between them depends on the scenarios and the parameters available in the dossier.

NL considered it a very useful document, asking whether models or worked examples are available in the TNsG 2007. **FR** replied that these are not included in TNsG 2007.

AT said that 3 models are discussed here (ConsExpo, SOP and HESI), so why is HESI not mentioned in the conclusions? **COM** replied that in point 1.2.4 it is mentioned that the calculation is the same as the SOP model, so it could be mentioned in the conclusions as well, although this would not bring much new information to the document.

Conclusion:

The HEEG proposal was endorsed by the TM.

5d. Discussion of Room document provided by FR: Waivers based on US-EPA reports as the only source of information: acceptable or not?

-

GENERAL SESSION

1. Update from 32th CA meeting

COM informed the TM on the outcome of the last CA meeting. 14 substances were included in Annex I. COM withdrew the dossier on brodifacoum for the vote on Annex I inclusion. The following substances were discussed for the first time: aluminium and magnesium phosphide, flocoumafen and tolylfluanid. During the meeting the revised draft guidance document prepared by CEFIC regarding *in-situ* generated active substances and their evaluation under the BPD was discussed. The guidance documents on evaluation of efficacy testing for rodenticides and on TWA were endorsed. NL presented a proposal for a project on harmonisation of efficacy data requirements and performance standards for disinfectant products PT 02, which was endorsed.
Further detailed information can be found in the minutes of the 32nd CA meeting.

2. Biocides-REACH Interlinkage

DE introduced the document prepared by the DE CA concerning the applicability of the different REACH guidance documents with respect to the BPD. **DE** proposed that the document be used as a reference when no guidance has been developed on a specific issue under the BPD. **DE** pointed out that guidance documents No. 8 on requirements for substances in articles and No. 3 on data sharing, could be of interest if these topics will be addressed in the revision of the BPD. **NL** questioned the relevance of guidance documents No. 3 and 8 for the BPD as presently they specifically refer to obligations under REACH. **NO** commented that guidance document No.14 is relevant for the BPD for PBT identification. **COM** supported **NO. UK** mentioned that in case a socio-economic analysis must be carried out, guidance document No.17 could be applicable. **SE** supported **UK**.
FR pointed out that the guidance No. 6 on PPORD could be of interest even if not completely fitting with the BPD. **AT** commented that the guidance on data sharing is relevant with regard to non-active substances. **AT** said also that the guidance on polymers could be helpful with the necessary adaptations. **AT** noted that the guidance on articles could be useful as well, since treated materials are addressed in article 5 of BPD. **IND** commented that it should be clarified if the evaluation on the REACH guidance documents was carried out in detail and what the implications are if a guidance document is relevant. **DE** informed that only on guidance No. 20 an in-depth evaluation was carried out and that the document should be regarded as a first indication.
COM suggested that an explanation on what is stated in the document with regard to the relevance of the single guidance documents should be added. **COM** agreed that this should be regarded as a background information paper. **COM** asked the TM to send written comments within 4 weeks and invited **DE** to revise the paper for the next TM.

3. Tracking System. Progress reports

COM informed the TM that the progress report is available on CIRCA and invited the MS to send written comments via the generic biocides e-mailbox.

4. SUBSTANCES in PT 08:

4a. Creosote (RMS: SE)

-

5. SUBSTANCES in PT18

5a. Diflubenzuron; Applicant Chemtura (RMS: SE)

-

5b. Diflubenzuron; Applicant Safepharm (RMS: SE)

-

5c. Bendiocarb (RMS: UK)

-

6. SUBSTANCES in PT19

6a. DEET (RMS: SE)

-

7. Evaluation of efficacy tests for PT 18

NL introduced the document. The project started in 2006 where two workshops were organised with experts from IND and MS being present. Some key issues were:

- Initially it was decided to prepare a set of rigid data requirements for product authorisation to aid the inexperience in several MS in dealing with this PT. However, on the other hand it was felt that flexibility shall be introduced if a product applied for at product authorisation does not fit in the type of products described in the guidance document. Therefore, the guidance offers precise and flexible information.
- A relatively high performace criterion of 90% killing rate is required in the guidance document. However, also here flexibility shall be allowed where a lower rate can be considered acceptable if justified. One example may be biocidal products of natural origin (biological products) with a low hazard profile or an insecticide used for ants where not the ant nest is treated but direct spraying of ants (so not a complete destruction of the ant population).
- Not for all insect groups experts were present at the workshops. Subsequently, additional information on insect groups not included in the document are welcomed.

Conclusion:
MS will sent written comments by April 30 to NL with a copy to COM.

8. Food risk assessment

Background: the purpose of the session on food risk assessment at TMI_09 was i) to discuss the new version of the draft framework document "*Stepwise approach on data requirement for the estimation of residues in food of animal origin and the need to*

perform risk assessment" and ii) to discuss the threshold values to be used for triggering step 2 and later steps of the food risk assessment of biocidal products, according to the principles agreed at TMIII_08.
COM started the session by a slide presentation to provide a basis for discussion. The scope of the document was defined: food of animal origin is defined as food derived from livestock exposed to biocidal products by oral route, dermal route or inhalation. The current state of the document was summarised, and the calculations made for the threshold values were presented.

Discussion:
A long discussion (**DE, NL, FR, IE, AT, COM, EMEA, EFSA**) took place, and a number of questions were raised, some of which already expressed in the pre-TM comments, in particular by **NL** and **DE**.
The most salient issues were:

- determining where the responsibilities would lie for ADI and (if necessary) AEL setting;
- determining where the responsibilities would lie for food (or "dietary", as proposed by **NL**) risk assessment (hereafter **DRA**);
- Separating clearly the processes of DRA and MRL setting;
- Determining which studies could be requested by the RMS and which were to be requested under the responsibility of EMEA;
- whether a single framework document or separate documents should be made available for DRA in the case of food of animal origin and for other types of DRA.

Conclusions:
It was agreed that:

- The process of DRA for food of animal origin will be clearly separated in 3 major steps:
    - Step 1 of initial external animal exposure estimation;
    - Step 2 of refined external animal exposure estimation;
    - Step 3 of dietary risk characterisation.
- A risk management process of MRL consideration / setting may follow as necessary according to the conclusions of the DRA.
- For food of animal origin, the proposed value of the threshold for triggering step 2 of refined animal exposure assessment, and step 3 of dietary risk characterisation, was accepted by the TM. The value is directly derived from EFSA practice, who use a trigger of 0.1 mg of substance per kg of dry feed. The trigger for biocides is therefore set as an acute (over one day) **external exposure**, summed over all routes (oral, dermal, inhalation), of the food-producing animal to **0.004 mg of substance per kg of body weight of food-producing animal**. If in the future EFSA were to change their trigger value, the trigger for DRA of biocides in food of animal origin would evolve in parallel.
- It will be the responsibility of the RMS to request from the applicant additional studies aimed at performing Step 2 of refined animal external exposure assessment.
- It will be the responsibility of the RMS to set an ADI and, where necessary, an ARfD for the substance considered, which should be discussed and agreed with EMEA. A clear wish for methodological harmonisation was expressed by **IND**.
- The step of dietary risk characterisation will be done in close co-operation between the RMS and EMEA. The exact modalities and responsibilities have to be established by further discussion between the TM working group on food risk assessment and EMEA. However, it is already acknowledged that, in order to avoid as much as possible spreading the request for studies over time, the

request for specific studies at this stage should be done, as a principle, only with the agreement of EMEA.

- The process of MRL consideration and setting will be under the responsibility of the EMEA, in cooperation with the RMS. Where adequate resources are available, MRLs may be proposed by the RMS.
- The proposal for inclusion of a substance should not be delayed on the sole basis of dietary risk assessment issues. Where necessary, the biocide DRA or at least its initial steps should be performed by the RMS based on existing methodology, available data and scientific common sense. Depending on the situation, it may be necessary to indicate in the Annex I inclusion proposal, together with possible risk mitigation measures, that further refinement of the dietary risk assessment is necessary before allowing safe product use. The dietary risk assessment should then be finalised as soon as appropriate data or methodology become available.
- Methodologies to refine dietary risk assessment, particularly related to exposure, should be developed as soon as possible, in order not to overload the product authorisation stage with dietary risk assessment issues.
- It was recognised that some work of DRA will inevitably have to be done at the product authorisation stage. In particular, if further or an entirely new DRA is needed at product authorisation level, due to new use modalities, this will have to be done at national level, building on accumulating experience.
- In line with the above objective, a dietary risk assessment expert working group (*Note post-TM: provisional acronym **DRAWG**, may be modified later*) will be formed on a voluntary basis out of the TM. **DE** kindly accepted to take the leadership of this working group, and nominations were invited (to be forwarded to **COM**). A close co-operation with **EMEA** and **EFSA** will be established. The initial objectives of this group are:
- To collect, develop and evaluate external animal exposure scenarios;
- To define data requirements for step 2 of refined external animal exposure scenarios;
- Jointly with other actors (EMEA, COM, EFSA), to establish detailed procedures for DRA co-operation.
- The framework paper for biocide DRA of food of animal origin will be re-drafted after the DRAWG has made some progress, in co-operation with EMEA. In principle next draft is scheduled for discussion at TM III_09. It should be kept in mind that the purpose of the framework document is to define the general procedure for biocides DRA at Annex I inclusion stage, rather than provide detailed technical guidance.
- Other types of biocide DRA: The document relative to DRA for food of animal origin will be further progressed before deciding on other types of DRA. Meanwhile, reflection should continue on other types of dietary risk assessment and management:
    - For food of plant origin, the principles should be similar and the approach will have much in common; the relevant body for MRL setting is likely to be EFSA. The issues will be treated either in a separate document or by extension of the document on food of animal origin.
    - The direct exposure of food products of plant or animal origin to biocides, e.g. by contact with treated surfaces in food-processing facilities, will also have to be considered.

9. TNsG Analytical Methods

COM introduced the document being the revised TNsG for Analytical Methods following the public consultation. A Response to Comments Table was prepared by **COM** for the agenda item.

FIN commented that the SANCO document revision number should be specified in the references. **NL** proposed to keep the range of acceptable recovery as 70-110%. **FIN** asked for clarification with regard to the need of independent laboratory validation studies. **DE** commented that stability is not part of the minimum data requirements for the analytical methods under BPD. **COM** will change the text referring the issue to the OECD guidance document on pesticide on residue analytical methods. **FIN** proposed to add recovery rate to the last bullet point of section 5.1 of the TNsG on Annex I inclusion.

Conclusion:
COM will amend the document that will be sent to next CA meeting for endorsement.

10. Manual of Technical Decisions

COM presented in a closed session the first version of the Manual of Technical Decisions, document developed by the **COM**. The first version of the document contains decisions taken at TMs on general and toxicological issues. The title is open to debate or other suggestions. The scope of the document is on technical decisions related to the scientific and technical evaluation of the active substances discussed at TMs and the present structure comes from all the previous minutes of the meetings. The environmental part will be added in a future version. **COM** proposed to the meeting a brief discussion on the follow up procedure, about the structure and the content of the document and secondly about the endorsement/adoption of it. For the first version a commenting period of two months was proposed. **COM** argued that formal endorsement at CA level is not needed, as long as the document is based on extracts from the minutes containing all the decisions of the TMs, which are endorsed at the CA level. In the proposed form, the document allows the possibility to check the decisions in the corresponding minutes, reflecting only the discussions from the TM. **DE,** supported by **FI** and **UK,** thanked the **COM** for the useful document, considering it very helpful for the completion of the CARs and expressed the interest for the further development of the environmental part. **DE** underlined that the endorsement of a living document, to be updated very often, is not necessary at CA level. In addition, only individual cases would need to be brought to the CA level. **DE** proposed the addition to the text of a remark on the issues endorsed at CA level, and the naming of the corresponding CA meeting. Furthermore, **DE** also agreed on the proposal of two months for the commenting period. **NL** appreciated that due to the methodology issues contained in the document, which in general require the approval at CA level, the document should be endorsed. **AT** considered the CA endorsement possible mentioning a case where different decisions were taken at TM and CA level on technical equivalence. **COM** replied that in such cases only the final CA descision will be incorporated in the Manual of Technical Decisions. **COM** concluded that no CA endorsement of the document would be necessary and proposed a two months commenting period for the first version. After the finalisation, the document will be available for consultation. **CEFIC** considered the document very useful and expressed the high interest for the next version and the wish to consult the available version as soon as possible. This was confirmed by COM.

Conclusion:

- **Comments on the document to be send to the COM by May 22;**

- **COM will reconsider the title of the document and include the environmental part. No endorsement of the document is needed at CA level.**

11. AOB

11a. Identity and technical equivalence of polymers

-

11b. Synergist or active substance

-

ENVIRONMENT SESSION

1. SUBSTANCES in PT 08:

1a. Alkyldimethylbenzylammonium Chloride (ADBAC); Applicant Lonza GmbH, Stepan Europe and Field Fisher Waterhouse LLP (RMS: IT)

-

1b. Didecyldimethylammonium Chloride (DDAC); Applicant Lonza GmbH, Stepan Europe and Field Fisher Waterhouse LLP (RMS: IT)

-

2. ESD for PT 2, 3 and 4

The ESDs, further developed under a contract by DE, was introduced by the consultant. Thereafter, each ESD was discussed.

DK requested that the tonnage scenario be incorporated in all ESDs. The consultant replied that this is an area for more research as more data need to be available to develop these scenarios, for example in order to decide on the default value for the fraction of the main source released.

ESD PT 02

- **NL** will clarify by e-mail their comment on the institutional scenario.
- In section 2.1.4.2 the use in institutional areas is described using a scenario from Van der Poel (2001) which is in fact based on the number of households feeding one STP. So the scenario is not really appropriate for institutional use (comment **NL**) and this will be clarified. The relevance of the survey on the frequency of disinfectant, detergent and cleaning applications for households (as in institutional areas disinfectants are most likely used more often compared to households) in the ESD be explained. However, as the relevant data are not available the consultant suggested to keep the scenario and recommended this as an area for further research. This was agreed.
- In section 2.2.4.1 emission to air is described for air-conditioners based on the ESD for PT 08. The consultant will check the A-tables in the TGD (comment **NL**) and the exposure assessment for human health for PT 11 (comment **SE**) to determine if the scenario described is appropriate.
- **NL** provided an alternative scenario for air-conditioners based on a higher tier scenario for PT 11. It was agreed to stick to the scenario described in the current document which is more suitable for a first tier approach. The scenario provided by **NL** will be included in the recommendations for further research.
- In section 2.4.4 a scenario is described for chemical toilets. **FIN** stated that the tank volume can be as high as 20 m^3. It was agreed to stick to the value of 2 m^3 per day as otherwise the dimensions of the STP would have to be changed as release of higher volumes would affect the STP with a size of 10,000 inhabitant equivalents
- **FR** will send comments in writing on the terminology of Vform.

ESD PT 03

- **DK** asked that that a scenario for use in aquaculture be included It was agreed to add this under further research. Although there were no uses idenitified in aquaculture in the summaries provided for the PT1-6 workshop such applications may occur, for example for the disinfection of equipment (comment **NO** where a national regulation on cleaning and disinfection of equipment in aquaculture is in place). The borderline with the Veterinary Medicine Directive may have to be checked (comment **BE**– NO replied that the use covered by their national regulation is within the scope of the BPD).
- **NL** asked to include example calculations using a standard application dose. This could be used to evaluate which animal groups would be most critical in the evaluation. It was decided to not include this information at this time but mention this as an item for further work.
- **FR** will send a comment in writing on the calculation of the Qai in Table 4.
- For hatcheries an additional scenario will be included which was developed by the German UBA based on an application received.

ESD PT 04

- For food, drink and milk industries it was decided to move the scenario described in section 2.1.4.1 to an annex. This scenario shall only be used when the more specific scenarios (described in 2.1.4.2 and 2.1.4.3) cannot be applied due to lack of data. The consultant will provide more information on the scenario described by Bakker in section 2.1.4.2 as values from some default parameters are missing. No preference could be made between both scenarios.
- For information a table will be reintroduced in the document on large, medium and small plants in section 2.1 (comment FIN).
- In section 2.2 for the scenario for large scale catering kitchens FR doubted if the default of 1 kitchen connected to a STP is correct. The consultant will check this using the number of people which can be served by such a kitchen and the number of inhabitants connected to a STP.

The consultant highlighted the areas for further research which will be described in the revised documents.

Conclusion:

- **The ESDs will be revised based on the discussion at the TM. These ESDs will be forwarded to the CA meeting for endorsement;**
- **Minor comments can be sent in until April 21. Major revisions, for example additions of new scenarios, are not possible within the scope of the current project.**

3. SUBSTANCES in PT19

3a. DEET (RMS: SE)

-

4. SUBSTANCES in PT18

4a. Bendiocarb (RMS: UK)

-

5. SUBSTANCES in PT21: Risk assessment for sediment

UK introduced the CEPE document and asked for comments to be sent to **UK** within 1 month after this TM. **DK** stated that the current document is too general and asked for a more detailed revised document.

Conclusion:
Comments to be send to UK and COM by April 20.

6. Project plan proposal for revision ESD for PT 14

COM introduced the project proposal and asked for expert from **MS** and **IND** to participate in the working group which will convene in 2-3 meetings to complete the work. **IR**, **UK**, **FI**, **NL**, **NO, DE** and **IND** would like to participate. Other **MS** have 1 month after this TM to express their participation. **NL** asked if the risk assessment for birds and mammals could be extended to other PTs, but **COM**, **NO** and **IND** stated that the focus will be on PT 14.

Conclusion:

- **The project plan will be revised and forwarded to the CA meeting for endorsement;**
- **MS and IND to nominate experts for the working group by April 20.**

COM additionally informed the TM that a revision of the ESD for PT8 will be performed in collaboration with **OECD**. **MS** will be kept informed by **COM**

7. AOB

FR received answers and comments from several **MS** regarding PT6 issues discussed at TM IV 08, and asked for assistance in compiling an overview document. **PL** offered to contribute. **FR** will submit the results from the questionnaire as soon as possible.

AT asked for the inclusion of references in meeting documents, **NO** additionally asked for track changes in the draft agenda for clarity.