Final Minutes of the Biocides Technical Meeting TM IV 08
9-12 December 2008 in Paris

INTRODUCTION

The meeting was welcomed to Paris by Mrs. Odile Gauthier, the deputy director of Risk Prevention at the French Ministry of Environment.

The meeting was chaired by E. van de Plassche and for specific items on the agenda by M. Bouvier d'Yvoire and A. Airaksinen (DG JRC), and C. Kusendila (DG ENV). E. van de Plassche welcomed the participants to the TM IV 08. Representatives from the MS, NO, CH, CEFIC and Industry were present at the TM. For specific items of the agenda, the interested companies were invited to attend.

1. Approval of the agenda

IE suggested including in the agenda a discussion on phenothrin, and this item was included in the AOB of the General session. Another agenda point was added in the same AOB as suggested by **AT**: "Relevance of the REACH guidance documents for dossier evaluation under 98/8/EC?"

2. Adoption of the minutes

DK asked whether it would be possible to split the adoption of minutes by sessions, so that the TOX session would adopt the TOX minutes, and then GEN and ENV sessions their parts of the minutes. **COM** replied that the reason to have it as a first agenda point is that it can then be used as a reference document for the meeting.

DE said that two comments have not been taken into account in the Minutes. On Aluminium Phosphide, DE asked for some explanation about further actions on the code of good practice. On the reporting of the creosote stakeholder consultation, DE would like to have it mentioned in the minutes that the outcome of the consultation is very one-sided since only very specific stakeholders took part in the consultation. **COM** agreed to include these points.

With the DE points to be added, the minutes of TM III 08 were endorsed.

3. Action List TM

COM informed the TM on the following points:

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

   The scenario is under development, and will be dealt with during the first half of 2009.

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

   There has not been a response from DE yet, and this will be discussed with DE.

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.*

   This has not been done yet.

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

   This will be presented during the first half of 2009.

5. *Investigating the possibility for training on BEAT*

   This training will be organised on 24-26 February 2009, and more information will be given in the TOX session.

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

   DG ENV will be contacted.

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

   DE has been contacted, and this will be discussed with DE.

8. *Revision of TNsG risk characterization for human health and submission to CA*

   The document has been endorsed in the CA meeting.

9. *Revision framework food risk assessment including trigger values*

   This will be moved to TM I 09.

10. *Finalisation document application codes for PT 18/19/20 including cover note on aim application codes*

    Some changes have been received, and this will be uploaded on the CPSQ website.

11. *Investigation of possibility to incorporate application codes in IUCLID5*

    The OECD will be contacted.

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

    Some comments were still received from NL. These will be checked and then the document will be uploaded on the CPSQ website.

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

    The MSs that expressed their interest to finalise this document will be contacted to publish the document as soon as possible.

14. *Finalisation Workshop Report PT 1-6 including cover note on cumulative risk assessment*

    This was endorsed at the CA meeting and will be published on the CPSQ website.

15. *Distribute proposal for emission volume for metal working fluids*

    This will be done during the first weeks of 2009.

16. Revise erratum ESD PT13

This will be done during the first weeks of 2009.

DK pointed out that for point 8, the TNsG was endorsed by the CA meeting and then released for a 6-month consultation period.

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

COM asked the MSs to send any changes in the members and addresses to COM. For Norway, the new generic e-mail address is biocides@sft.no.

5. Next Technical Meetings

TM I 09	16-20 March	CA	17-20 February
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

TOXICOLOGY SESSION

1a Bifenthrin (RMS: FR)

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1b. Copper (II) carbonate, copper (II) hydroxide and copper (II) oxide (RMS: FR)

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

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

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1e Creosote (RMS: SE)

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2a Acrolein (RMS: UK)

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3a. Spinosad (RMS: NL)

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3b. CO2 (RMS: FR)

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4. AOB

4a. Use of old versus new TNsG on human exposure

COM introduced the document by FR and COM, mentioning that it would be desirable to be able to agree on the principles on when to use the old and new TNsG on human exposure. It was suggested that in principle, the old TNsG (2002) should be

used for the lists 1, 2 and 3, while the new TNsG (2007) should be used for the 4th list and for new active substances.

UK supported the suggestion, considering it a rational approach. Harmonisation would be gained, saving resources and money. UK suggested not to use the 2007 guidance for the first three lists, but to learn the methodology by using it for the fourth list only.

NO asked whether we should take into account the new exposure data included in BEAT for the first three lists, noting that the outcome of the risk assessments could very well be influenced by this choice, e.g. for PT21 where much higher exposure values were reported for a specific task than in the 2002 guidance. **UK** considered that we should accept that there is always new data available, but we should work in a structured way and use the same guidance for the same lists of substances. This would be good for the harmonisation, and fair for the industry. **AT** supported using the new and more realistic data, and suggested an occasion to be organised for all the MSs to learn about the new guidance, and what has been changed. **COM** replied that the Oslo workshop[1] is intended to be such an occasion, and all MSs can participate there. **AT** suggested that we should not make a decision on when the old or new guidance is used before this workshop. **UK** said that we do not know what the problems are going to be in using BEAT, but we should try to learn that when performing the assessments of the 4th list chemicals. The proposal given in the paper would seem the only rational way forward. **COM** suggested that the TM could be informed of the discussions held at the workshop, after which the next steps at the TM level could be decided. **NO** suggested that we should be able to use the new guidance to complement the old guidance when deemed necessary, asking the TM for a decision on whether this can be done. **COM** said that this would result in problems of non-equal treatment for some substances.

NL said that the TNsG 2007 has actually not been endorsed by the CA meeting, so it is still a preliminary version. NL also pointed out that decisions on the guidance can not be made at the TM, but only at the CA level. **NO** commented that on the front page of the written part of the TNsG 2007, published on the web site, it is stated that the document was endorsed at the 25th CA meeting. However, there might not be a specific decision on using BEAT. **COM** said that the document was endorsed during the summer 2007, and the date of January 2008 on the web page only indicates the time when the document was put there in the present format. **NL** cited the minutes of the CA meeting, where no endorsement is indicated. **COM** said that it should be considered that the TNsG has been endorsed since the TNsG was accepted at the TM and then brought to the CA meeting, where it was not sent back to the TM. This would imply that the document was endorsed. **UK** was of the opinion that it is an issue of legality of the guidance, and was not sure whether a refinement on an endorsed guidance again needs an endorsement. UK suggested the TM to make a decision that the CA meeting would then either endorse or not. **AT** supported UK, but said that the decision on the guidance to be used should be made not now but in TM I 09 in March, after having in February both the CA meeting's endorsement of the guidance and the Oslo workshop. **NL** said that the status of the TNsG is not clear, and that it should be endorsed by the CA meeting.

[1] "Human Exposure to Biocides" – a series of workshops covering BEAT, ConsExpo and general aspects of human exposure to biocides, Oslo 24-26.02.2009

DE supported the text of the proposal, adding that it also concerns ConsExpo and not only BEAT, and thus asked the TM to ask for the CA endorsement of that approach. **FR** reiterated the motivation for the proposal, saying that the exposure assessments for many substances will be started immediately after the TM, and it is necessary to know which guidance should be used. On the other hand, dossiers of the 4th list have been received and it will now be decided whether they can be considered complete or not, when the new guidance has not been used. FR suggested that if the TM can not make a decision, then the TM opinion should be handed to the next CA meeting for endorsement. **DE** supported FR suggestion, adding that the new guidance is *de facto* accepted: it has been published and it is mentioned in that document that it has also been endorsed, and therefore it has already been used by at least some applicants. The TM should send a clear recommendation to the CA meeting that the new guidance should be used for the 4th list dossiers. **NO** supported the DE opinion and the proposal and emphasised the importance of having a decision/recommendation as soon as possible on which guidance to use for the different lists. **AT** pointed out that we do not know yet what data is different between the old and new guidance, and it will be problematic to solve the differences: which values are more correct and should be used. **DE** said that we need some experience in working with the guidance to see the possible disadvantages, adding that if the CA meeting is asked for an opinion on the principles of using the new guidance, they should also be asked about using that guidance for the product authorisation step already from the beginning. **AT** and **PT** said that a general problem in the new TNsG for human exposure is that it has never been properly discussed at the TM.

COM asked whether the approach should be flexible also for the 4th list, or whether the new TNsG should always be used for that. **UK** suggested that if there is a 4th list dossier with exposure assessment performed using the old TNsG, then the RMS could do the exposure assessment again using the new guidance. This way all the 4th list dossiers would be brought up to the new standard, while at the same time getting material to compare the results obtained using the old and the new TNsG, with BEAT and ConsExpo. This would also mean a kind of validation of the new methodology. **NL** supported using the new guidance for the 4th list dossiers, using the old guidance only if for some reason the new guidance is not usable. **IE** supported the principles suggested, asking also IND to comment. **IND** agreed that the TNsG is not formally endorsed, but the more important question is whether it is evaluated. IND supported performing the exposure assessments using both old and new TNsGs to get an overview of the differences. **AT** pointed out that as the new TNsG has not been evaluated, it needs to be made sure that any mistakes found can be corrected, and we would not be stuck to guidance with known errors. Therefore the evaluation should be made now, discussed in the Oslo workshop, and decided after that. **COM** suggested to send the current proposal and a letter to the CA meeting, clarifying in the letter that the principles have to be applied for the dossiers on a flexible basis since the status of the new guidance has not been clear, and since BEAT was not available and/or usable immediately after the new TNsG was considered to be endorsed. The CA meeting should also be asked for either the endorsement of the new TNsG or the recognition that it is (or can be considered) endorsed. The TM agreed.

GENERAL SESSION

COM welcomed the participants and opened the general session. After a short view of the agenda points, **COM** proposed two new items to be added to AOB, consisting in a question raised by **IE** about a specific substance, to be discussed in a closed session, as agenda item 7c, and a discussion of the room document distributed by **AT**, *the Relevance of REACH Guidance Documents for dossier evaluation under 98/8/EC*. **COM** also informed on the distribution on CIRCA of the draft final CAR for **difenacoum** for PT 14 (RMS: FI), from the third applicant, after a written procedure instead of a discussion at TM level. The final draft CAR is now distributed for the 60 days commenting period. The dossier will be submitted to the next CA meeting for Annex I inclusion.

1. Update from 31th CA meeting

COM reported to the TM on the last CA meeting that took place on 27-28 November 2008 in Brussels. The minutes from that meeting will be available shortly. At the CA meeting, prior to the Standing Committee (SC), final discussions on three substances took place (**potassium sorbate**, **tolylfluanid** and **coumatetralyl**).

It was decided to forward **tolylfluanid** in PT 08 and **coumatetralyl** in PT 14 to the SC for Annex I inclusion. Bilateral consultation between the RMS and **JRC-IHCP** will have to take place on the environmental risk assessment of potassium sorbate in PT 08. Several documents forwarded by JRC-IHCP were endorsed: workshop reports for the environmental risk assessment for PT 01-06 and PT 18 and the revised TNsG for risk characterization for human health, of which the latter will be published on **DG ENV** website for public consultation. Furthermore, a proposal on the development for technical guidance in 2009 was discussed. Proposed revisions of the ESDs for PT 08 (in collaboration with OECD) and PT 14 were endorsed. A proposal of further development of OECD guidance on efficacy testing for treated articles will first be discussed at the TM. In addition, specific guidance on the application of IUCLID5 for industry and MS under product authorization, where IUCLID 5 is accepted to replace DOC III A and B, was considered essential. **JRC-IHCP** will investigate this and see if further collaboration with **ECHA** is necessary.

COM also informed about the discussions on the Manual of Decisions with respect to laundry disinfection products, fuel additives and food extracts. COM referred to the discussion on the document raised by **IND** on the status of the products in the supply chain, a subject also raised in the previous CA meeting, and indicating who in the supply chain has to apply for the authorisation.

Another subject discussed in the CA meeting was on data protection; a simplified document outlining 5 key issues which need full attention during the revision, was presented by the **COM** in the CA meeting.

In the SC a proposal for non-inclusion for six active substance/PT combinations for which no dossier was received was voted upon and accepted unanimously.

COM also informed on the Product Authorization and Mutual Recognition Facilitation Group which took place prior to the last CA meeting. One of the main

issues resulting from this meeting was the need for additional discussion on technical and scientific issues at TM level on product authorization (for example on data requirements and the use of the calculation method coming from C&L). This request was discussed and reconfirmed at the CA meeting. Subsequently, a special session on product authorization will take place during the next TM in March 2009. **COM** requested MS to volunteer for the preparation of this meeting as JRC-IHCP will only facilitate special session. **DE** welcomed the initiative and informed about the start of a similar action at national level. **DE** attempts to put together a national guideline for product authorization, aiming to offer to the applicants the necessary instruments. The compiled guidance document is foreseen to be finalized next January in German. **DE** will also ask the other MS for comments considering mutual recognition, when the English version is finalised. **DE** stated that this document could be discussed at this special session. **COM** and **DK** welcomed the initiative. **DK** expressed the concern that such a document could be too broad. They would propose to follow rather a step by step procedure and answer first to the **IND** questions on wood preservatives including how to deal with products containing more than one active substance. **COM** mentioned that **IND** prepared a test-case for product authorisation for wood preservatives containing several sub-applications. These test-cases could also form the basis for discussion at the special session. In addition COM noted that for each product type, there are most likely specific technical issues to be discussed. **DE** referred to their guidelines which cover rodenticides and wood preservatives. **AT** supported and welcomed the **DE** initiative. **AT** added the proposal to split up the special session according to the TM Session on physico-chemical properties and efficacy, on toxicological aspects, and on ecotoxicological aspects. **COM** will discuss further with MS and **IND** about the practical arrangements.

2. Biocides-REACH Interlinkage

DK underlined that at the last TM it was agreed that **COM** would take up the question of the requirement of ECHA on Annex XV dossiers for harmonised C&L in IUCLID 5. **COM** informed that the concern of the MS was raised at the REACH CA meeting (also for the pesticides). **ECHA** required a proposal from the MS on a prolongation of the transitional period to be exempted from using IUCLID 5. A decision will subsequently have to be taken by the REACH CA.

Several MS reiterated their concern about using IUCLID 5. DK proposed an extension of the transitional period up to the end of the Review Programme. **AT** asked **COM** to make such a request to **ECHA**, on behalf of all the 27 MS CAs working on biocides, instead of doing it individually. COM stated that they will inform ECHA about this request. **COM** reminded MS however that subsequently all national CAs on biocides should contact their national representatives in the REACH CA as a decision will be taken at that level.

COM informed next that when it comes to procedures in the RAC or MSC, MS are advised to contact their national representatives in these committees.

Regarding PBT identification, **ECHA** will need a formal letter from the **COM** for this issue, as formally PBT identification coming both from the biocides and the pesticides area was not under the remit of **ECHA**. As for an Annex XV dossier for harmonised C&L ECHA requires the dossier to be submitted in IUCLID 5.

The next item discussed was a document from **NO** on harmonized C&L for first and second generation anticoagulant rodenticides. **NO** highlighted the background of the document. The request to coordinate the submission date of Annex XV dossiers for all first and second generation anticoagulant rodenticides to ECHA in order to have a simultaneous discussion at the RAC in ECHA was welcomed. **NO** informed that the first step is that the RMS enters the submission in the Registry of Intentions. It was decided that:

- The involved RMS will submit an entry into the Registry of Intention by 31 January 2009. A reminder will be distributed by COM.
- COM will send a request to ECHA on a simultaneous discussion of these Annex XV dossiers in the RAC.

3. Tracking System. Progress reports

COM asked MS to send in their comments to the generic e-mail address.

4a Acrolein (RMS: UK)

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5. SUBSTANCES in PT 8:

5a. Bifenthrin (RMS: FR)

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5b. Alkyldimethylbenzylammonium Chloride (ADBAC), Applicant Lonza GmbH, Stepan Europe and Field Fisher Waterhouse LLP (RMS: IT) and 5c. Didecyldimethylammonium Chloride (DDAC), Applicant Lonza GmbH, Stepan Europe and Field Fisher Waterhouse LLP (RMS: IT)

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6. SUBSTANCES in PT18

6a. Spinosad (RMS: NL)

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6b. CO2 (RMS: FR)

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7. AOB

7a. Harmonisation of efficacy data requirements and performance standards for disinfectant products PT 02

The initiative by NL was welcomed by the meeting. **NL** stated the project could start in April 2009 with the development of a framework. This could then be discussed at a workshop taking place at the earliest in June or July 2009. Following requests to include other PTs, NL stated this project on PT 02 could serve as a basis for similar projects for other PTs. Following a request from **AT**, it was agreed that cooperation with the work carried out by the OECD is essential.

Conclusion:

- The project plan will be forwarded, including the cooperation with OECD, to the CA meeting for endorsement;
- MS are required to send nominations for the working group to **NL**;
- **COM** will investigate their participation in the project;
- **IT** and **BE** will send lists of available test methods to NL.

7b. Question Italy on efficacy tests for third list

IT introduced their question requiring a discussion on minimum requirements for efficacy testing for Annex I inclusion to be set. **IT** made reference to the coming SCENIHIR opinion on resistance development caused by the use of biocides. **AT** pointed to the ongoing activities of the OECD on efficacy test method development. **NL** stated methods are available for disinfectants, referring to the CEN methods mentioned by IT. **NL** agreed that for Annex I inclusion a minimum set of efficacy tests shall be available for at least one safe use. **COM** stated it was earlier agreed that for Annex I inclusion it is sufficient to demonstrate the activity of the active substance. **DK** pointed to the fact that sometimes tests on dummy products were accepted for Annex I inclusion.

Conclusion:

COM concluded that the development of requirements for (a set of) efficacy tests is important but this shall be the done under product authorisation. **IT** proposed to send an updated list of CEN methods to be included in the next edition of TNsG to COM which was much appreciated.

7c. Relevance of REACH guidance for evaluation of dossiers under the BPD

AT raised this issue, supplying a room document, on the relevance of REACH guidance. The majority of the meeting (**DE**, **DK**, **FR**, **NO** and **IND**) indicated the need to first carry out an analysis of which guidance is available and what is or is not useful for the evaluation of active substances under the BPD. **DE** stated an analysis like this is momentarily carried out at national level. **NL** and **BE** expressed their concern on changing guidance and stated the discussion belongs to CA level. It was stated that already guidance coming from REACH is or has been used, e.g. technical equivalence and PBT identification. It may also be the case that some parts of the guidance are useful and others not, for example the guidance on interpretation of (eco)toxicological tests may be used in contrast to Integrated Test Strategies.

Conclusion:

COM concluded that the issue will be discussed at TM I 09 where **DE** will provide the analysis carried out on national level. **COM** offered to assist where necessary. Conclusions on the use of REACH guidance under the BPD will subsequently be forwarded to the CA meeting for discussion and endorsement.

7d. Progress on d-phenothrin RMS: IE; PT 18)

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ENVIRONMENT SESSION

COM informed the meeting that in 2009 two EUSES training workshops will be organised: one for industry and one for Member States.

1. SUBSTANCES in PT 8:

1a Bifenthrin (RMS: FR)

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1b. Alkyldimethylbenzylammonium Chloride (ADBAC), Applicant Lonza GmbH, Stepan Europe and McKenna, Long & Aldridge (RMS: IT)

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

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1d Creosote (RMS: SE)

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2. SUBSTANCES in PT 12

2a Acrolein (RMS: UK)

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3. SUBSTANCES in PT18

3a. Spinosad (RMS: NL)

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3b. CO2 (RMS: FR)

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4. Outcome of e-consultation photodegradation CMIT/MIT

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5. AOB

5a. CEPE response to e-consultation PT21

CEPE informed the meeting about the release of MAMPEC Version 2.5. **CEPE** explained that one of the changes compared to earlier versions is the sediment module allowing the user to calculate the concentration in sediment over time assuming a 10 year window and taking into account degradation of organic carbon. **UK** supported using the sediment instead of the suspended solids concentration, as for the short term exposure of sediment organisms this is covered via the assessment for the water column while for long term exposure the sediment concentration is more relevant. **UK** noted that sedimentation in the marine environment takes more time compared to freshwater systems as the water depth is higher, certainly in the open sea and shipping lane scenario, and in a marina the dynamics of the system lead to an increased settlement time of suspended solids due to continuous resettlement due to boating activity. Therefore removal processes during settlement of suspended solids have to be considered. **NL** stated that indeed degradation needs to be discussed in this case. However, the food of sediment dwelling organisms originates from suspended solids. **FR** stated they needed to check the revised sediment module but would be in favour of using the sediment concentration. **COM** concluded that this issue will be brought to the next TM as MS needed first to check the revised sediment module.

NL asked if CEPE could distribute the VNSI study report on protective measures in Dutch repair shipyards quoted in statement prepared by CESA.

Following a question by **NO** on "Issue 6" **CEPE** stated the text should read either dissolved or total concentration. **CEPE** argued that the decision on using one of these two concentrations depends on the characteristics of the substance and shall be a case-by-case decision based on results from for example tests with sediment dwelling organisms exposed via the overlying water or spiked sediment: if the sorbed fraction to suspended solids is not bioavailable the dissolved concentration shall be used, otherwise the total concentration.

Following a question by **NO**, **CEPE** explained their position on the use of the average concentration in the exposure assessment. **COM** stated this explanation was in line with the discussions in the working group of the ESD for PT 21. **NL** proposed to use the 95 percentile in cases other arguments than economic transportation are involved, such as marinas being a nurture ground for fish. **UK** informed about their national evaluation of several boosters where based on adequate monitoring data it could be concluded that the average concentration from MAMPEC still overestimated the actual concentration. Therefore using the 95 percentile would lead to an unrealistic estimation of exposure. **NO** stated that they could have sympathy for the average concentration as otherwise there would be almost no difference between rapidly and 'less rapidly' degradable substances. **NL**, supported by **FR**, stated that the question is if the uncertainty in the current MAMPEC scenarios is 'incorporated' in the parameters while it should be in the model scenario itself. **COM** referred to earlier discussions where it was concluded that the marina scenario cannot be considered a realistic worst-case scenario but that revised scenarios are under development to be used under product authorisation. It was concluded that, awaiting these scenarios, the average concentration will be used in the Review Programme.

5b. Exposure assessment for PT 06

FR presented the document. The following questions were discussed:

- Question 1 (page 2): the majority (**DK**, **FR**, **DE** and **NL**) agreed to assess product formulation as well as product use. **UK** referred to the low concentration of an in-can preservative in the end product compared to other Product Types, for example wood preservatives. **DK** explained that the only situation where an in-can preservative is used as a biocidal product is the use in an industrial setting, for example when the paint formulator is adding the in-can preservative, often supplied as a technical concentrate, to the paint.
- Question 2 and 3 (page 2): it was concluded that for the product formulation stage the tonnage approach has to be used for the assessment. The subsequent issue is which IC/UC category from the TGD has to be used. **DE** proposed to apply a worst-case approach based on the proposed uses (most applicants have used the categories proposed in the ESD for PT 06) by the applicant. It was realised that there may be other uses in which the in-can preservative is used. The worst-case approach then would consist of: i) considering the uses applied for; ii) investigating, for example via a sensitivity analysis using EUSES which IC/UC category leads to a worst case emission; iii) assuming the whole tonnage applied for as input value for the assessment.
- Question 4 (page 3): the categorisation presented by **FR** was much appreciated. **NL** questioned how large the group of "6.7 Other" is? It was suggested that in-can preservatives used to preserve pesticides (although it was noted that this case may not fall under the scope of the BPD), rodenticides and wood preservatives belong to this category. It was decided, following a question by **DK**, that **COM** will check if in-can preservatives used in cosmetics fall under the scope of the BPD. In addition it was agreed that all MS will check their PT 06 applications and evaluate if this categorisation can appropriately describe the uses applied for. By doing so also the extent of the group "6.7 Other" can be evaluated. The results shall be sent to FR by the 31 January 2009.
- Question 5 and 6 (page 4): **DK** questioned if all emission for these sub-categories will have to be summed up stating that for some categories, especially industrial, it is unlikely these emissions will enter the same Sewage Treatment Plant. In addition, if emissions are summed up the question is how to carry out this cumulative exposure assessment? **FR** and **DE** agreed, but noted that at this point of time there is insufficient knowledge to answer these questions. First for example emission factors, as presented in the Excel spreadsheet accompanying the document, have to be harmonised. **FR** stated that an additional step is needed to harmonise the default values used in environmental and human health exposure estimation. It was decided that all involved MS send their data on emission factor extracted from their dossiers to FR by the 31 January 2009. **AT** proposed to start a research project on cumulative risk assessment for human health and environment. **DK** noted that the consequence is that the clock is stopped for these dossiers. **COM** stated this shall be a case-by-case decision depending on the application.
- Questions 7-9 (page 5): **DK** stated that in line with PT 08, the Annex I inclusion shall only refer to PT 06 without specifying the categories as discussed under question 4. As long as there is one safe use for a certain

category the active substance shall be included in Annex I. **NL** agreed. **AT** supported also this approach stating that in the Assessment Report it shall be clearly stated: i) the categories applied for; ii) categories for which a risk assessment was carried out; iii) categories for which insufficient data were available. **NL** suggested that all RMS prepare a table of intended uses of their application to be checked by the applicant. **COM** stated the suggestions are in line with their ideas, although this is a discussion belonging to CA level.

Conclusion:

- All RMS for PT 06 active substances will send the relevant information on the categorisation and the emission factors to FR by 31 January 2009;
- The end result of this shall be a guidance document for exposure assessment for PT 06 to be submitted to CA level.

5c. Exposure assessment harmonisation for PT 04

FR presented their position. AT agreed to use one value. UK stated that the purpose of the environment (more 'broader' assessment where for assessing dispersive use the average is often used) and human health (protection of the individual) could be the reason behind the two different values. NL, supported by DE, suggested to discuss the situation with the applicant in order to set real instead of default values. It was decided to keep the value of 3 for the environmental and 4 for human exposure assessment.

5d. ESD 2, 3 and 4 finalisation

DE informed on the progress on the finalisation of this ESD. A draft will be distributed to the TM by the end of January 2009 accompanied by a document indicating the changes. A commenting phase is then started of 4 weeks leading to a final version to be submitted for TM I 09.