



## Biocides Technical Meeting 05-09 October 2009

### MICRO-ORGANISMS

#### 1. Evaluation of micro-organisms

COM started the discussion on the general principles that should be applied in the evaluation of micro-organisms in the Biocides Review Programme. The basis for this was the letter sent by COM to the MSs, dated 28/08/2009. This letter contained six proposals that were discussed one by one.

**Proposal 1** was agreed without changes: *“The Annex I inclusion should be for a specified strain, and the method of analysis should be provided for unequivocal identification at the strain level. For specific reasons and with proper justifications, this requirement might not be applicable for some micro-organisms.”*

**Proposal 2:** NL and DE said that the proposal should be applicable only for Bt and not for micro-organisms in general. COM said that the proposal could be revised accordingly, suggesting to mention “Bacillus” instead of “micro-organism”. SE asked whether *Bacillus Sphaericus*, the other *Bacillus* in the Review Programme also has a toxin, which DK confirmed. The proposal was then agreed with this change, and the wording could be as follows (changes indicated): *“When international units (IU) are applicable (e.g. for bacillus), the amount (content) of micro-organism should ideally be expressed both as 1) IU ~~international units (IU)~~ which is related to efficacy and 2) either colony forming units (cfu) or the number of viable spores. There is no direct relation between these units.”*

**Proposal 3:** NL wanted to include a clarification that normally 5 batches should always be asked for in the 5-batch analysis, but 3 batches could be enough with good reasons (proper justification). FR asked whether the results should be given in IU instead of cfu, thinking that IU would be more relevant. IND said that cfu is not reflective of efficacy because there may be different quantities of toxin present. Efficacy is related to the amount of toxins. The proposal was agreed as follows (changes indicated): *“5 batches are normally required for the 5-batch analysis, but with proper justification, it could be sufficient to provide 3 ~~to~~ 5 batches for the requirement of a 5-batch analysis. The following aspects should be considered in deciding the information that is concluded*

necessary, taking into account the nature of the micro-organism and possible contaminants:

- a. IU and cfu
- b. Efficacy-related protoxin protein levels
- c. Absence of relevant entero-, endo- and exotoxins that may cause food poisonings
- d. Absence of cytolytic proteins
- e. Any other element relevant for human toxicology (e.g. presence of harmful bacteria like *Bacillus anthracis*)."

**Proposal 4:** COM suggested concentrating on the first sentence of the proposal which proposes that human exposure assessment is not necessary if a micro-organism is not infective, pathogenic or toxic. DK said that the main problem could be that it would not be possible to conclude that Bti is not a potential human pathogen. With Bti there could be a solution to the problem when looking at the small potential pathogenicity in connection to exposure. COM mentioned that this could prove to be a problem since there is no agreed methodology to perform a human exposure assessment for micro-organisms. SE agreed that there is no methodology for this, but suggested nevertheless discussing the exposure as well. NL said that if there is an agreement with the proposal, it should read: "...infective, pathogenic or toxic to humans..." DE also agreed that a rough exposure assessment should always be performed. COM asked whether the general principle could anyway be agreed now, with no connection to conclusions on Bti. IT said that it would be difficult to perform an exposure assessment, mentioning that calling it a "rough" exposure assessment would not clarify the situation. DK pointed out that even baker's yeast can be pathogenic for immunodeficient humans, and therefore it would be difficult to agree on the proposal. COM concluded to withdraw the proposal as it was not agreed by the TM.

**Proposal 5:** The proposal was agreed without changes: "*It is recommended to apply similar principles as have been applied in PRAPeR for waiving of studies, read-across between bacterial strains and extrapolation of data between routes of entry*".

**Proposal 6:** The proposal was agreed without changes: "*It is recommended to apply similar principles as have been applied in PRAPeR for waiving of studies and read-across between bacterial strains*".

There were no further comments on the COM letter.

COM asked for further issues to be discussed before starting the Bti discussion. DE said that the possibility of transfer of antibiotic resistance from one strain to another should be taken into account when testing antibiotic resistance. IND commented that antibiotic resistance is not necessarily in the plasmid, and that the transfer is possible only if this is the case. DE said that they would not require further testing but would only argue that this should be considered and mentioned. DK agreed with IND, saying that at least most of the antibiotic resistance genes are in the chromosome. It was concluded that the possibility of transfer of antibiotic resistance from one strain to another should be considered and mentioned in the CAR of a micro-organism.

## 2. *Bacillus thuringiensis* AM 65-52 (RMS: IT)

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## INTRODUCTION

The meeting was chaired by E. van de Plassche and for specific items on the agenda by A. Airaksinen, M. Bouvier d'Yvoire, P. Piscoi and E. Berggren (DG JRC), and C. Kusendila (DG ENV). E. van de Plassche welcomed the participants to the TM III 09. 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

COM added under AOB of the General Session item 7.a on Harmonised Classification and Labelling of second generation anticoagulants.

### 2. Adoption of the minutes

COM stated late comments were received from **DK** and **DE** and proposed to include these comments. Based on a comment from **FR** it was agreed to change the second sentence of the conclusion on DEET on page 15 from "When presenting the supportive plasma data, the  $C_{\max}$  is the appropriate measure to be considered." to "When presenting the supportive plasma data, the  $C_{\max}$  is the appropriate measure to be considered because DEET is rapidly eliminated." With these additions, the minutes of the Technical Meeting were adopted.

### 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 maybe at TM IV 09 or TM I 2010.

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

The addendum will be distributed by COM after this TM for written comments.

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

The **UK** recently distributed a revised document to **COM**. COM and UK will consult if another discussion at TM is needed.

4. *Request ECHA on simultaneous discussion at RAC of Annex XV dossiers for harmonised C&L for first and second generation anticoagulants*

See item 7.a of the General Session.

5. *Include TM decisions from Environment Session and prepare procedure on adoption and updating the Manual of Technical Decisions*

See item 8 of the General Session.

6. *Follow-up EUSES training: request MS to start validation exercise*

COM sent a questionnaire to MS on the use of EUSES and the willingness to cooperate in a validation exercise. COM will present an overview at TM IV 09.

7. *Possibility of teratogenic effects due to the presence of cases of spina bifida and hypoplastic tail in the rabbit teratogenicity study at maternal toxicity doses: is it a true developmental defect which cannot be dismissed on the ground of maternal toxicity?*

**DE** stated no reaction was received from **NL** and **SE**. Applicant sent additional historical control data to **DE**. Based on these **DE** included a statement against C&L was included and the Draft Final CAR was finalised. If needed, **NL** and **SE** can make comments in the commenting period on the Draft Final CAR.

#### **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**

##### **2009**

TM IV	30 November - 4 December	CA	15-18 December
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##### **2010**

TM I	15 – 19 February	CA	9-12 March
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TM II	14 – 18 June	CA	25-28 May
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TM III	4 – 8 October	CA	21-24 September
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TM IV	22 – 26 November	CA	14-17 December
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<b>TOXICOLOGY SESSION</b>
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**1a. DCOIT (RMS: NO)**

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**1b. Cu-HDO (RMS: AT)**

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**1c. ATMAC (RMS: IT)**

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**1d. BARDAP (RMS: IT)**

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**2a. Brodifacoum (Activa Pelgar; RMS: IT)**

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**3a. Metofluthrin (RMS: UK)**

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**4a. Nonanoic acid (RMS: AT)**

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**4b. ZE-TDA (RMS: AT)**

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**5a. Update DRAWG**

Point of information. The Dietary Risk Assessment Working Group (DRAWG), constituted in June 2009, has started working. The DRAWG is chaired by **DE** (Chair Isabel Guenther, co-chair Martina Rauch). **COM** informed or reminded the TM that:

- Three meetings (4 by 20/10/2009) between a delegation of the DRAWG and representatives of the EMEA CVMP have already taken place, and a document is being prepared on guidance for dietary risk characterisation of biocides and MRL setting;
- A document on the administrative procedure for biocides MRLs was voted at the last CA meeting;
- DRAWG had launched the collection and analysis of information for products possibly causing livestock exposure and animal exposure scenarios drawn from the relevant CARs,

which were kindly provided by the various MS CAs. A first draft to prepare guidance on livestock exposure methodology is under discussion.

**DE** then gave more detailed information on the progress of the work by the DRAWG, describing the issues discussed and the content of the current draft 20-page technical document under elaboration. The summarised information is attached to the present minutes in an Appendix. The document will be made available for comments by the TM as soon as a sufficiently complete version becomes available.

## **5b. Update HEEG**

### **HEEG opinion “Defaults and appropriate models to assess human exposure for dipping processes (PT 8)”**

**COM** presented the document that was based on work carried out by **DE**. **CH** asked whether all the formulations are water based. **UK** replied that for most dipping operations water based formulations are used. Where a small amount of dipping is undertaken using solvent based formulations, engineering mechanisms are employed to control exposure to the solvent. **CEFIC** asked whether the document would go to the CA meeting for endorsement, and whether it concerns only active substances or also products to be authorised. **COM** replied that an agreement of the TM only is required and if agreed could be used. The paper would not go to the CA meeting. The paper concerns active substance evaluations, but the values could be used in product authorisations as well. **UK** clarified that the problem before having this document was that the only values available were those for manual dipping. Using these values for manual dipping resulted in exposure assessments for automated dipping resulted being too conservative. **CH** asked whether possible solvent based formulations should be mentioned in the document. **COM** mentioned that this was discussed in HEEG, where the conclusion was that if there was a solvent based formulation, it would be obvious that the solvent should be assessed as well. **UK** clarified that this HEEG paper considered the active substance, and solvents would be covered by other legislation.

The HEEG opinion was endorsed without changes.

### **HEEG opinion “Default protection factors for protective clothing and gloves”**

**COM** introduced the document, mentioning that this opinion was requested by TM II 2009, and was mostly prepared by **UK** with much help from **NL** and other MSs. **NL** mentioned that there are some differences when compared to a similar table from TNO.

**NL** asked:

- 1) Whether the impermeable coveralls refer to the code CEN 3 or CEN 4,
- 2) Whether the 90 % protection of the gloves is for non-solid substances only,
- 3) Whether only dry substances are considered in the value given for the non-professionals wearing long-sleeved shirts and trousers or skirt with shoes, without gloves.

1) **UK** described the data that was available, saying that it was found impossible to connect the default values to detailed specifications for coveralls.

2) **UK** said that an actual study was made for vacuum pressure impregnation, where roughly 90 % protection was observed. **NL** mentioned that a value of 80 % has been used for solid substances and 90 % for non-solid substances, and this division is not given in the document. **UK** agreed that this point could be addressed in the document.

3) **UK** said that the value 50 % is given in the TNsG; it was not clear what data this value was based on. It could be used for dry substances and perhaps also for light sprays.

**COM** suggested the HEEG opinion could be discussed again based on **NL** comments, and a revised HEEG opinion would be brought to TM IV 2009. **NL** could give the comments to HEEG in a written format, and perhaps provide further input. **CEFIC** said that the

nomenclature is unclear in the document, asking why specific definitions of coverall types are not given, like categories 1-3 or types 1-6. **COM** said that this was suggested by **DE** and then discussed in **HEEG**, but specific definitions were not included because it was very difficult to combine the data to specific types of coveralls. Any help in doing this would be welcome. **CEFIC** will check whether they can provide input, sending any comments to **COM**. Conclusion: **NL** and **CEFIC** will send comments to **COM**, and the document will be revised for **TM IV 2009**.

#### **Values for the assessment of professional human exposure in disinfectant dossiers.**

**COM** informed that the database has been put together by **FR** and has been uploaded in **Circa**, and is now usable.

#### **5c. Developmental Neurotoxicity for Pyrethroids**

(TMIII09-TOX-item5c-Proposal **NL** to initiate a state of the science evaluation of DNT for pyrethroids.doc)

(TMIII09-TOX-item5c-Publication\_RayandFry\_2006\_PharmTherReview.pdf)

*Note: this item was discussed before agenda item 3, metofluthrin toxicology session, due to its potential relevance for the discussion of metofluthrin.*

Background: Since the late 80's some doubt has existed on the potential Developmental Neurotoxicity (DNT) of pyrethroids. Because the Review Programme includes a significant number of pyrethroids (20 identified substances) to be examined in upcoming TMs, **NL** proposed a co-ordinated approach of the DNT of pyrethroids across rapporteur Member States. **NL**'s proposal was made available as a room document and on **CIRCA**.

Discussion: **NL** explained their proposal and the rationale supporting it. DNT of pyrethroids was discussed at TMs in 2005, and since then a new OECD guideline on testing for DNT properties was issued (TG 426). Later, the various RMS involved in assessing pyrethroids acted individually together with their Applicants, and several CARs are now almost ready for TM discussion. Some of them contain DNT studies. **NL** proposes to examine together all the relevant DNT information from the available pyrethroids dossiers, in order to come to a state-of-the-art, homogeneous, co-ordinated evaluation of the DNT risk assessment of the pyrethroids included in the Review Program. Therefore **NL** had prepared a template for collecting the available DNT information, including that from non-TG 426 studies and from dossiers with no specific DNT study, and asked the MS CAs to send to **NL** the corresponding information. The TM agreed on the principle of collecting the DNT data available. **DE** mentioned the existence of a recent review by the US EPA of the potential for DNT of pyrethroids, and the need to take also this information into account, avoiding to duplication of their work.

*Note post TM: 2 references of recent reviews are:*

*US EPA review: Shafer TJ, Meyer DA, Crofton KM. Developmental Neurotoxicity of Pyrethroid Insecticides: Critical Review and Future Research Needs. Environ Health Perspect. 2005 Feb;113(2):123-36.*

*Other review (neurotoxicity in general): Ray DE and Fry JR. A reassessment of the neurotoxicity of pyrethroid insecticides. Pharmacology & Therapeutics 2006 Jul; 111(1):174-93.*

The TM agreed to send comments on the proposed template to **NL** within 4 weeks of the TM, and **NL** mentioned that they could start analysing the collected data at the beginning of next year. **COM** mentioned that some information was also available from the PPP area and from recent substance evaluations made by the US EPA, including for some of the

substances of the Review Programme. **COM** stated that a clear position of the TM on the rather confused issue of DNT was indispensable, and therefore welcomed the initiative by **NL** to propose a systematic analysis of the available information. **IND** (Applicant for metofluthrin) mentioned that as an Applicant they had more than 10 pyrethroids in the Review Programme, and that a DNT study was not part of the core data requirements of the current biocides guidance, and expressed high concern if a retrospective requirement were imposed. **IND** also added that the original data indicating a possible concern had been generated with pyrethroids structurally close to the allethrins ("allethrin class" pyrethroids), that many pyrethroids now differed from those, that it had not been conclusively shown that these new pyrethroids caused the muscarinic receptor density changes seen with allethrins, and that the validity of the studies which had given the alarm had to be called into serious doubt for many reasons, including the high doses of pyrethroids administered by oral route. Furthermore, the toxicological significance of the observed muscarinic receptor density changes was not established. **COM** replied that the biocides Competent Authorities were aware of the difficulties of interpretation of the existing literature on the subject, that for hazard identification high doses were not a criteria for invalidation, that it could not be ignored that all pyrethroids acted on the same biological target, and that the question of toxicological relevance was also discussed at length in the recent published reviews on the subject. Altogether, although on the one hand the existing evidence was certainly not sufficient to consider DNT as a class hazard of the pyrethroids, on the other hand it was not possible to dismiss the concerns without precautions. This is why it was proposed to analyse the available evidence in a co-ordinated manner before making decisions on the DNT potential of the biocidal pyrethroids, as a whole and as individual substances, in the interest of all stakeholders.

Conclusion: It was decided that the MS would give feed back to **NL** on the data collection template within 4 to 5 weeks, and would then use the finalised template to provide **NL** with the relevant information. An analysis of the information will then be performed by **NL** as soon as possible, resources permitting, and discussed at TMI or TM II, 2010.



<b>GENERAL SESSION</b>
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### **1. Update from 34<sup>th</sup> CA meeting**

**COM** informed the meeting about the outcome of the 32<sup>th</sup> CA meeting. Reference is made to the minutes of this meeting published on CIRCA.

**COM-JRC** added with respect to the note from the Commission on multiple dossiers, there will be discussion for a second time at the 35<sup>th</sup> CA meeting, that the preferred way of working at the TM would be to first discuss and agree on the intrinsic properties based on the data from all Applicants as described in DOC II A and III A resulting in a combined LOEP, and second to discuss at another TM the exposure assessment and risk characterization described in separate DOC II B (and III B) and II C per Applicant.

### **2. Biocides-REACH Interlinkage**

**DE** introduced the document. **COM** asked to highlight more clearly the use of the guidance on PBT/vPvB assessment within the peer review process of active substances under the BPD. **AT** objected the reference to the proposal for the new Regulation. Following comments from **AT**, **DK** and **NL** it was decided to remove to a footnote the reference to the proposal for the new Regulation for guidance documents 3, 8 and 20. **COM** will consider if the document will need to be endorsed at the CA meeting.

### **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.

#### **4a. Cu-HDO (RMS: AT)**

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#### **4b. ATMAC (RMS: IT)**

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#### **4c. BARDAP (RMS: IT)**

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#### **5a. Brodifacoum (Activa Pelgar; RMS: IT)**

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#### **6a. Metofluthrin (RMS: UK)**

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## **7a. Nonanoic acid (RMS: AT)**

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## **7b. ZE-TDA (RMS: AT)**

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## **8. Update MOTA**

**COM** informed that the first version of MOTA was published on the biocides web-site of JRC-IHCP and on the confidential site of CIRCA. On the latter also a response to comments document was uploaded based on comments received on the last draft version. The section on environment still has to be added to the MOTA.

## **9. Evaluation of efficacy tests for PT 18**

**NL** informed they received after TM I 09 comments from nine MS and industry on the draft guidance. The revised document will be submitted for discussion at the next TM.

## **10. The role of efficacy in the BPD evaluation process**

**COM** and **UK** introduced the document. **COM** stated the document describes the current practice in the Review Program. **FIN** stated they agreed with the content of the document and in fact do work already according to these principles. **NL** commented, referring to the conclusions on page 10, that for some active substances it is difficult to prove efficacy as these substances are used only in combination with other actives or need a special formulation. In these cases an efficacy test for the active may be waived if a test on the biocidal product is available. **NL** commented on the following on page 10: "Where the innate activity of both the active substance and biocidal product against the target organisms has been demonstrated, a recommendation should be made for Annex I inclusion. In cases where activity has been demonstrated for the biocidal product, and where those activity levels would not be high enough for a Product Authorisation, Annex I inclusion should still be recommended and the efficacy more fully addressed at the Product Authorisation stage." According to **NL** for Annex I inclusion at least for one biocidal product for one use efficacy will have to be demonstrated. **AT** agreed with **NL**, referring the conditions for Annex I inclusion ("sufficiently effective" as laid down in Article 5). **DK** agreed with this. **DK** commented that for an active substance or product to be deemed efficacious an efficacy test is required to demonstrate sufficiently high efficacy for the applied use as most substances may show some level of effect on organisms depending on concentration alone. **COM** suggested to include more clear definitions on what efficacious and effective is and proposed a written commenting round.

**Conclusion:** comments on the document will be sent to **UK** by October 30.

## **11. Standard Operating Procedure TM**

**COM** introduced the revised SOP and the cover note highlighting the change from 3 to 5 weeks for the consolidated RCOM and the removal of documents from CIRCA once the Final CAR is submitted. Following a question by **SE**, **COM** clarified the submission of two versions: with and without track-changes. Following a question by **IE**, **COM** stated a section on multiple dossiers will be added once the Commission Note on Multiple Dossiers is agreed at CA level. No further comments were made on the revised SOP. **COM** concluded the revised SOP is approved by the TM and will send the document to CA for endorsement.

## **12. AOB**

### **12a. Harmonised classification and labelling of first and second generation anticoagulants**

**COM** reminded the relevant RMS of the request from ECHA to agree on a suitable date for the simultaneous discussion at the RAC of these substances, now all RMS have filled in the Registry of Intentions. **NO** proposed August 2010 as the ultimate date for submission of the Annex VI. This has as an advantage that no study summaries in IUCLID5 are required by ECHA as the exemption period is extended to 1 January 2011.

**COM** concluded that the proposed date is August 2010 and asked MS to inform, where relevant, with their C&L colleagues if this is possible and subsequently inform ECHA. .

<b>ENVIRONMENT SESSION</b>
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**1. SUBSTANCES in PT 08:**

**First discussion for the following substances**

**1a. BARDAP (RMS: IT)**

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**1b. ATMAC (RMS: IT)**

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**2. SUBSTANCES in PT14**

**First discussion for the following substances**

**2a. Brodifacoum (Activa Pelgar; RMS: IT)**

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**3. SUBSTANCES in PT18**

**Second discussion for the following substances**

**3a. Bendiocarb (RMS: UK)**

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**First discussion for the following substances**

**3b. Metofluthrin (RMS: UK)**

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**4. SUBSTANCES in PT19**

**First discussion for the following substances**

**4a. Nonanoic acid (RMS: AT)**

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**4b. ZE-TDA (RMS: AT)**

## 5. SUBSTANCES in PT21: Risk assessment for sediment

**UK** introduced the paper on the risk assessment for antifouling products (PT21) in sediments produced by the **UK** and **CEPE (IND)**. Comments received from **DK**, **NL** and **SE** were appreciated, and **UK** highlighted three main issues to be taken into account in the exposure assessment for sediments. First, the time taken for suspended sediment with the active substance absorbed to it to be deposited needs to be considered, second, an allowance for degradation processes during the settlement time should be made, and third, the long term steady state sediment concentration should be considered. Based on a tiered approach suggested by **NL**, a modified tiered approach was proposed by **UK** and **IND**:

- 1<sup>st</sup> tier: use the  $PEC_{\text{suspended matter}}$  and  $PEC_{\text{water, total}}$  (both only if the substance absorbs to suspended matter). Then if a problem is apparent, the following should be applied:
- Higher tier: use the  $PEC_{\text{sediment, 10yr}}$  and/or  $PEC_{\text{water, dissolved}}$  based on organic carbon provided that consensus can be reached on the input parameters for a realistic worst case scenario.

**SE** did not agree with the conclusion in the paper by **UK** and **IND** that exposure for sediment dwelling organisms, exposure to suspended matter or freshly deposited matter therefore should be looked upon as a continuous process.

1<sup>st</sup> Tier: **NO** and **FI** could agree with  $PEC_{\text{suspended matter}}$  and  $PEC_{\text{water dissolved}}$  as a first tier, because using the dissolved concentration is in line with TGD. **COM** clarified that the proposal for the first tier, consists of a comparison between  $PEC_{\text{water, total}}$  and the  $PNEC_{\text{water}}$  obtained from the ecotoxicity test, which in principal should reflect dissolved concentrations. The use of  $PEC_{\text{water, total}}$  would therefore be a worst case approach. **NO** highlighted that the difference between  $PEC_{\text{total}}$  and  $PEC_{\text{dissolved}}$  is so small that it will never result in a different PEC/PNEC. **FI** agreed with **NO** and additionally asked for clarification of input parameters especially the organic carbon (OC) degradation rate. **IND** stressed that physical/chemical properties of the substances need to be taken into account. **COM** clarified, on a comment by **DK**, that the fraction OC in suspended matter of MAMPEC is used; **DK** commented that there is a difference of 100 between fraction OC in the TGD and MAMPEC.

2<sup>nd</sup> Tier:

**NL** supported by **FI**, proposed that the  $PEC_{\text{sediment plateau}}$  should be used, especially for "open sea" and "shipping lanes", while for "marinas" and "commercial harbours" the situation is different with a shorter exposure since sludge will be removed. **IND** did not agree with the use of the  $PEC_{\text{sediment plateau}}$  because the assumption is made on relatively few data points, and the implications of using the  $PEC_{\text{sediment plateau}}$  for future antifouling substances. **NO** commented that the degradation rate of OC is set by default to 0 (zero) which is a best case situation, therefore more realistic data are needed on degradation rates of OC. **IND** argued that experimental degradation rates are quite low. **NO** supported by **FI** remained of the opinion that a more realistic value for degradation rate of OC should be used. **IND** explained the origin of some input parameters and offered to perform a literature search on realistic degradation rates for OC. **NL** asked for more information on input parameters and more information on how MAMPEC calculates PEC values, since at the moment MAMPEC works as a "black-box".

**COM** stressed that a way forward should be found and asked for a distribution of tasks to further develop this MAMPEC scenario. **IND** was asked to provide a document with more data on the discussed input parameters for MAMPEC to be discussed in the e-consultation group on antifouling substances and the next TM. Also **MS** will check if they have data available on these parameters.

### **Conclusions:**

- The **TM** agreed on the use of  $PEC_{\text{suspended matter}}$  and  $PEC_{\text{water dissolved}}$  as a 1<sup>st</sup> tier.
- For the 2<sup>nd</sup> tier there remained a need to define the settings of the MAMPEC scenario if the sediment concentration is used, i.e. fraction of OC in suspended matter and sediment, net sedimentation velocity, sediment layer thickness in the different scenarios, derivation of degradation rate in suspended matter, degradation rate of OC in sediment, and the derivation of the degradation rate in the water phase.
- **IND** will provide a background paper within 4 weeks which will be discussed in the email-consultation group for antifouling and the next TM.

## **6. AOB**

**DE** announced a workshop focussing on the characterisation of the leaching behaviour of product types in main group 2 which will be organised on 21<sup>st</sup> January 2010 in Berlin. Invitations will be sent by email to members of the TM, which are also invited to present their experiences with leaching tests for main group 2.

**PL** requested if it is possible to have a special session on the harmonisation of emission scenarios for substances in PT6 during TMI 2010. **COM** will await the outcome of the meeting on this subject between **PL**, **DE** and **AT** (FREG meeting) before scheduling such a session.