Final Minutes of the Biocides Technical Meeting TM II 08 in Arona, 10-12 June 2008

INTRODUCTION

1. Approval of the agenda

The meeting was chaired by E. van de Plassche and for specific items on the agenda by K. Aschberger, G. Deviller and A. Airaksinen (DG JRC), and C. Kusendila (DG ENV). E. van de Plassche welcomed the participants to the TM II 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.

The TM was informed that:

- The Human Exposure Expert Group is now coordinated by A. Airaksinen (TCS).
- General session: Item 7e (Inventory of efficacy test methods) will be skipped since it was discussed in the Product authorization and mutual recognition facilitation group.
- Environment session: Item 1b (Groundwater assessment) will be skipped since the document could not be provided in time.

IND asked about the documents that were not endorsed in the last CA meeting, and whether an indicative timetable could be given about the handling of the documents by the TM. **COM** clarified that the two documents in question were the "TNsG for Risk Characterisation for human health" and the "Workshop on environmental risk assessment for PT18". Written comments have been received from MSs and based on these COM will decide whether they will have to be taken up again at the TM, or whether a written procedure can be used. **DK** preferred to have a TM discussion on the "TNsG for Risk Characterisation for human health".

2. Adoption of the minutes

There were no comments to the Minutes of TM I 08, and the minutes were endorsed.

3. Action List TM

With respect to the Action List the following was concluded:

1) **COM** needs to formally inform OECD of the agreed change in the marina scenario for PT21.

2) **IND** will present a proposal for a new marina scenario in the beginning of 2009, while NL has indicated that they will not have the resources to participate in this work. **COM** welcomed any input from the MSs to this work.

3) There has been no progress yet on the paper on evaluation of tests on nitrogen and carbon transformation in soil.

4) **FR** has sent to DE the information from PBT WG on the assessment of the bioaccumulation criterion for pyrethroids.

5) The addendum to TNsG on data requirements will be brought to TM III 08.

6) The Manual of Technical Decisions will be brought to TM III 08.

7) CIRCA has been restructured. This is an agenda point to allow questions and suggestions to be made.

8) The final revision of Mixing & Loading Model 7 has been agreed upon, and was placed on CIRCA.

4. Members of the Technical Meeting

PL has informed of changes and the list will be revised.

5. Next Technical Meetings

The next TMs are:

TM III 08	14-17 October 2008	CA	17-19 September
TM IV 08	9-12 December 2008	CA	25-28 November
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

1. SUBSTANCES in PT 8.

First discussion for the following substances

1a. Creosote (RMS: SE)

Second discussion for the following substances

1b. Dazomet (RMS: BE)

2. SUBSTANCES in PT14

First discussion for the following substances

2a. Flocumafen (RMS: NL)

Second discussion for the following substances

2b. Chlorophacinone (RMS: ES)

3. AOB

3a. Use of ConsExpo for professional human exposure assessment

The TM was asked for its opinion on the HEEG proposal on the use of ConsExpo for assessing exposure for professional users. The HEEG suggested that although the models and default values are presented for consumers, ConsExpo can be used to assess professional exposure as well, provided that some basic differences between the professional and non-professional users, indicated in the proposal, are taken into account.

SE agreed with the proposal, but asked how to choose the default values for professionals if there are no measured values. **FR** suggested that this information should be given by the applicant, and only applicant can give such information. **DK** proposed that this kind of information should be gathered in a data base, and the approach should be harmonised if possible, as was done for rodenticides. **NO** supported the DK suggestion. **SI** would prefer to use the flow chart in p. 32 of the new TNsG for human exposure assessment, which is meant for exposure assessment of professionals. **COM** suggested making a questionnaire on the default values and sending it to all MSs who could introduce the values from the disinfectant dossiers

that have already been submitted. These would then be taken together in order to harmonise the approach in TM III or TM IV of 2008. **COM** will draft the questionnaire and send it to MSs during the summer.

Conclusion:

HEEG proposal was accepted, and COM will draft a questionnaire to build a data base on the default values.

3b. Exposure Scenarios In-can Preservatives

COM introduced the paper by SI and UK asking the TM opinion to achieve harmonised approaches for the exposure assessment within PT 6 (In-can preservatives).

Q1: Should exposure be assessed for STEP A, as this can be considered equivalent to the manufacture/formulation?

NL considered Step A as mixing and loading of the formulation, and it should thus be assessed. **FR, FI** and **SE** agreed with the SI/UK suggestion not to assess it. **NL** was concerned that if Step A is not assessed, then in-can preservatives might not fall under BPD. **FR** clarified that Step B concerns the use of the biocidal product and that will be under BPD. **IND** considered Step A to be part of the formulation, whereby it does not need to be assessed. The TM agreed not to consider Step A in the exposure assessment.

Q2: Should we also address exposure to the in-can preservative for those wearing the washed clothes or can a waiving argument be used instead such as: exposure will be so low for those wearing the washed clothes, compared to exposure for those washing the clothes, that exposure will be negligible?

Q3: Would we also need to address exposure of those eating food which has been placed in the washed dishes? If so then presumably we can use waiving arguments rather than undertaking exposure calculations, or reverse reference scenarios, for exposure of individuals eating out of washed dishes?

Q2 and Q3 were discussed together. **FR** suggested that this should be considered as indirect exposure following the use of in-can preservatives, and it should be assessed with ConsExpo. **DE** reminded the TM that this has been discussed in the TM before, suggesting that at least the first step should be assessed, i.e. using the product containing the in-can preservative. For example, exposure of the person washing the clothes should be assessed, but not necessarily the person who puts on the washed clothes. **SI** agreed with DE, mentioning that waiving arguments should be possible as well. **AT** opposed waiving of exposure, claiming that if there is no data, then nothing is known of the possible exposure.

Q4: Would the TM agree with this approach of waiving the exposure assessment for the uses that are assumed to result in lower exposure?

Q5: Due to the presence of a particular in-can preservative in a so wide range of products, does a 'combined exposure' assessment need to be undertaken for in-can preservatives? And if this is the case, what guidance should be followed?

Q4 and Q5 were discussed together. **AT** asked whether in the Annex I inclusion there would be specific use patterns, or would the substance be accepted in general as an in-can preservative, without specifying the acceptable uses. In case several uses are included, would exposure for all uses be assessed, and would cumulative risk assessment be performed? **COM** reminded the TM that in the CA meeting it was considered unrealistic for the applicants of all substances to perform cumulative risk assessment. This is therefore not mandatory, but **COM** said that there are well-justified cases where cumulative risk assessment is necessary, and the MSs can perform it where they consider it justified. **COM** estimated that more systematic cumulative risk assessment could be done either at the product authorisation phase, or after the Review Programme has been finalised. COM suggested assessing the worst-case scenario and not all the uses that are foreseen. **AT** saw a danger in assessing only some uses, since this might allow an applicant to choose use patterns with smallest exposure, thereafter applying it in uses with higher exposure. **AT** suggested that it should first be discussed how the Annex I inclusion decisions could be formulated, and what should be included.

NL had concerns that the paper is guiding the Review Programme in a wrong direction: just because cumulative risk assessment is difficult, it should not be disregarded. It should therefore be encouraged, and only if it becomes evident that it is not possible, it should be left out. **IND** reminded that the main objective of the Review Programme is harmonisation of the market, and only at the product authorisation phase will there be information on all the products that there are in the market. **IND** also noted that in the CA meeting it was suggested to leave cumulative risk assessment for the reauthorisation of the Annex I entry. **ES** agreed in the need to assess the exposure in all the different uses, and suggested assessing the combined exposure from the different uses that one person might perform. **ES** suggested clarifying that cumulative exposure is a broader term that refers to all exposure to a chemical, while combined exposure assessment can be done for certain uses within a PT or across PTs. **COM** pointed out that from a practical point of view, assessing the cumulative exposure in all uses of a product would be at present an impossible task, which would delay the Review Programme by years. **PT** suggested that e.g. reverse reference scenario could be tried in assessing exposure over the different uses, and such approaches should be tried before deciding to skip the assessment. **COM** concluded that cumulative risk assessment can be done although it can not be done systematically for all substances at this point of time, and that **COM** expects the first such assessment to give further insight on the task.

AT commented that after Annex I inclusion there would be no control since for the products where the in-can preservative is used, there is no product authorisation. **IND** disagreed saying that if a biocidal active substance is used in formulating a product, then this needs to be authorised in the product authorisation stage, for all uses within the PT. This information will then become available. **AT** opposed this view, saying that the products can include a PT6 biocide if it is in Annex I, and there will be no product authorisation. **IND** pointed to Q1 of the paper, where TM agreed that Step B, but not Step A, will be assessed. This is the point where product authorisation occurs,

thus there will be control, and exposure to the product containing in-can preservatives will be assessed.

AT suggested that the issues on PT6 should be brought to the CA meeting, asking also for a harmonised approach to treated textiles. **COM** agreed, saying that the issues will be first discussed within COM (together with DG ENV). **IND** mentioned that a solution to handling treated textiles has been suggested in the last CA meeting, which is to assess treated articles (end use) at the biocidal product authorisation stage.

3c. AT e-consultation C&L skin sensitisation Decanoic Acid

3d. BEAT and ConsExpo (Room document)

COM introduced the paper that was provided to give background information to the MSs on the BEAT model. **COM** mentioned that there have been requests for training and workshops on BEAT, and this is being considered.

3e. HEEG opinion on amendment of TNsG on human exposure to biocidal products – Antifouling painting model (Room document)

FR introduced the HEEG opinion, which is an amendment in the TNsG, following the identification of an error in the body exposure value given in the table. In addition to the correction, some clarifying information was included in the table. The TM agreed to modify the TNsG as suggested.

GENERAL SESSION

1. Update from 29th CA meeting

COM gave an update from the last CA meeting. Detailed information can be found in the minutes of the 29th CA meeting. COM informed that the "TNsG on Human Health Risk Characterization", which was not endorsed at the CA meeting, will be discussed at TM III 08. With respect to the "Workshop report on environmental risk assessment for PT18", which was not endorsed at the CA meeting, **COM** will consider if the comments received from SE can be dealt with in a written procedure. **COM** urged MS not to re-open technical issues at CA level. Although due to the parallel process of the finalisation of the Draft Final CAR and the AR technical issues may still have to be resolved after the last TM discussion, the aim shall be to resolve all issues before the CA meeting and not re-open technical issues which were agreed at TM level.

1a. Biocides-REACH Interlinkage

COM informed that consultation between ECHA, DG JRC and DG ENV has lead to the following working procedures which will in the near future be laid down in a Memorandum of Understanding:

1) *Pre-registration*

For pre-registration the contact details of the applicants in the Review Program were made available to ECHA. ECHA will have to forward these contact details to a potential registrant in a SIEF in case of an inquiry to the applicant.

2) *Inquiry*

If there is an inquiry for an active substance ECHA will contact JRC. JRC will then submit the information on the substance composition, as ECHA needs to establish technical equivalence, and the data available in the dossier submitted to ECHA. If ECHA considers the substances to be equivalent, and data can be shared, the contact details of the applicant will be made available to the inquirer. Following a question by **IND**, **COM** clarified that no IUCLID files will be made available to ECHA. In addition, with respect to an overview of the information available in a dossier submitted by an applicant, **COM** clarified that the results of the completeness check or the reference list will be made available to ECHA. However, ECHA will not make this information available to an inquirer. **COM** stated that the only case where 'actual data' (for example a study summary in IUCLID) may be made available by ECHA to an inquirer (or to a potential registrant in the case of pre-registration) is in the case of a disagreement over data sharing. This will have to be further clarified between DG JRC, DG ENV and ECHA.

3) *Provisions on submission of confidential information to ECHA*

These provisions will be laid down in a specific Memorandum of Understanding as this concerns not only information on active substances submitted under the BPD but also information handed over by JRC to ECHA from the "old legislation" on industrial substances.

4) *Dissemination of data*

On the web-site of ECHA no data on active substances submitted under the BPD will be published. Instead a link will be made to the web-sites of DG Environment and JRC where the Assessment Reports are published.

5) *Classification and labelling*

Under REACH an Annex XV dossier will have to be prepared for harmonised C&L to be submitted to the Risk Assessment Committee (RAC). The Annex XV dossier has

to be prepared in IUCLID5 by the RMS. Guidance was prepared by ECHA on how to prepare such a dossier which will be distributed by **COM**. Following a question by **FR**, **COM** clarified that the relevant parts of the CAR can be attached as a Word file in IUCLID5, where in IUCLID5 only the identity of the RMS needs to be added and information on substance identification (EINECS, CAS and substance name for example). **COM** informed that Annex XV dossiers can already be submitted to the RAC. **COM** will consult with ECHA on the time-lines required within the biocides framework and on whether the applicant can participate in the RAC meeting (this will also be clarified for the MSC for PBT/vPvB identification). **COM** will update the current document on C&L procedures for the next TM.

6) *PBT and vPvB identification*

Under REACH an Annex XV will have to be prepared by the RMS for PBT/vPvB identification to be submitted to the Member State Committee (MSC). A sub-committee (comparable to the current PBT WG) will be established under the MSC, which will deal with PBT/vPvB identification. **COM** informed that it has to be clearly mentioned in the submission that a check on the PBT/vPvB properties is requested as an Annex XV dossier can also be submitted for the identification of a Substance of Very High Concern or a restriction proposal. Following a question from **IND**, **COM** clarified that biocidal use is exempted from authorisation for substances listed on Annex XIV of REACH. **COM** informed that the guidance on PBT/vPvB identification based on the criteria laid down in Annex XIII was recently published by ECHA. **COM** will prepare a paper for the next TM on the procedure to be followed including the guidance to be followed.

2. Tracking System. Progress reports

COM asked MS to inform them if the information needs to be updated.

3. SUBSTANCES in PT 8:

First discussion for the following substances

3a. Creosote (RMS: SE)

4. SUBSTANCES in PT14

First discussion for the following substances

4a. Flocumafen (RMS: NL)

Second discussion for the following substances

4b. Chlorophacinone (RMS: ES)

5. TNsG on Product Evaluation: revision of Chapter 6.2 Resistance

COM introduced the document and thanked **NL** for commenting on draft versions. **AT**, **SE**, **DE** and **FR** stated they agreed to change the current TNsG based on the proposal. IND asked to delete reference to names of individual active substances. **AT** asked to modify in Section 6.2.3.4 in the middle "It would be … selection pressure stops". **AT** argued this is a research need which may be carried out in order to take a decision, based on the outcome of the research, if an active substance, being currently ineffective, should be rejected or withdrawn from an authorization. This was agreed and **COM** asked **AT** to prepare a text proposal. **DE** proposed to make the questionnaire, used for the document prepared by **DE** in 2006, available. **COM** will add this questionnaire to the JRC-IHCP web-site. **DE** informed about a meeting in Germany on monitoring principles and resistance management for rodenticides. It was decided to make this document available to the TM. **FR** stated that for micro-organisms some other definitions may have to be used. **FR** will send a text proposal to **COM**. **DK** noted that it was decided earlier that the evaluation by RMS of resistance development for disinfectants will wait until the SCENHIR opinion on "Potential antimicrobial resistance effect of biocides" is available. **COM** will check on the timing of this opinion. **SI** stated they will send some minor comments.

Conclusion:

- **FR and SI will send written comments on terminology for micro-organisms to COM before July 7.**
- **AT will send a text proposal on a revised paragraph in Section 6.2.3.4 to COM before July 7.**
- **COM will revise the document for endorsement and subsequently public consultation at the CA meeting.**

COM informed that **NL** is working on a document on the evaluation of efficacy tests for insecticides. **COM** informed the meeting about a meeting 1-3 July in the Wisconsin, USA entitled "Efficacy methods and standards workshop", where a draft version of the document will be discussed.

6. Residues in Food for Biocidal Active Substances – Framework Approach

COM introduced the agenda item and proposed to agree on the principles laid down in the document. **COM** mentioned that the term "appropriate bodies" cannot be specified at this moment, as this may either be EMEA or EFSA. **NL** stated that a food risk assessment needs to be performed for these active substances before a decision on Annex I inclusion, including the derivation of an ADI and MRL and the necessary data. **NL** proposed to derive a provisional MRL and request afterwards EMEA or EFSA to establish the MRL. **AT** and **DE** agreed with **NL**. IND asked to introduce the consequences of a food risk assessment. For example, if a MRL is available but due to biocidal use the MRL is exceeded. **FR** agreed with **NL** and stated that if a risk is identified in step 1, metabolism and residue studies in livestock animals shall be requested. If the results from these studies still lead to risk, a MRL will have to be derived. **AT** stated, referring to experience from the PPP area, that standardised exposure studies and methods need to be developed starting from the recommended

use pattern for the biocidal product. **FR** agreed with this. **NO** agreed with the stepwise approach presented and stated the crucial question is when and in which cases a MRL needs to be established. In addition, **NO** asked why PT 2 was included in the document. **COM** agreed that PT 2 shall be removed. **IND** stated that for biocides the exposure will in almost all cases be indirect, in contrast to for example pour on applications of insecticides being a veterinary application. **DK** replied that if this is the case than this shall be clarified in the current guidance on "biocidal products and veterinary and human medicines", as for example a scope discussion is ongoing on active substances used in ear marks. **AT** asked to invite experts from EMEA and EFSA to present and explain the MRL setting by these bodies. **COM** disagreed to this proposal. **DK** stated that the document shall first be rediscussed at TM level before it is forwarded to the CA for endorsement. **AT** stated the wording of significant residues (before a MRL is requested) is misleading, referring to permethrin where a MRL has been set of 50 µg/kg food item being a low concentration but significant. AT reiterated that the need for an MRL shall always be evaluated taking into consideration the ADI and the food consumption pattern. With respect to the question "where a MRL is needed", AT stated that it was already decided that an MRL is "needed for food and feed placed on the market by third people" (for example no MRL is needed in case of contamination of food because of spraying an insecticide in a kitchen). The RMS need the MRL for monitoring purposes.

Conclusion:

- **The dead-line for sending comments to COM on the document "TMII08GEN-item6-Residues in Food Framework.doc" is 31 July.**
- **The document "TMII08GEN-item6-Residues in Food Framework.doc" will be modified by COM for TM III 08.**
- **At TM III 08 a discussion will be organised on the step 1 focussing on criteria for requesting an MRL. COM will contact some MS and IND on contributions to this discussion. COM will consider if experts on MRL setting from EMEA or EFSA will be invited to participate.**

7. AOB

7a. ES e-consultation Phys/Chem properties of AEM 5772 PT02

7b. New CIRCA structure

COM stated the CIRCA structure was changed. **COM** clarified following a question from **FR**, if there will be a common DOC IIA or IIIA over the PTs this will be moved to the same 'level' as the LOEP.

7c. Application Codes PT 18/19/20

DE introduced the document where application codes were added for PT20. **NL** stated that the list will be included in the discussions in the workshop referred to under item 5 of this TM. **COM** clarified, following a question from **IND**, that the application codes are to used under product authorisation and not at Annex I inclusion stage.

Conclusion:

- **MS will send comments on the application codes to DE before August 31;**
- **Based on the comments received a revised document will be presented at TM III 08.**

ENVIRONMENT SESSION

Introduction

COM informed on the outcome of the last meeting of the PBT working group in March 2008. The discussion on second generation anti-coagulants concluded that these substances can be regarded as potential PBT substances. The main issue was the B criterion and the technical difficulties to evaluate it. The need for further testing in fish to determine a BCF was questioned, because according to the use pattern these substances will mainly end up in the terrestrial food chain. **NO** will prepare the wording of the outcome of this PBT working group to be used in all PBT factsheets. For chlorfenapyr a testing strategy for a potentially PBT metabolite was decided upon. It was concluded that flufenoxuron is a PBT.

1. SUBSTANCES in PT 8

First discussion for the following substances

1a. Creosote (RMS: SE)

1b. Groundwater assessment

This item was not discussed and moved to the next TM.

2. SUBSTANCES in PT 14:

First discussion for the following substances

2a Flocoumafen (RMS: NL)

Second discussion for the following substances

2b Chlorophacinone – tracking powder (RMS: ES)

3. AOB

3a. Data requirements biodegradation

COM introduced the agenda item, consisting of four questions raised by **DE**, which was not finalised at TM I08. In addition, **DE** prepared a document related to questions one and three. **DE** introduced the first question. **FR** shared the concerns of **DE**. The main concern of **FR** would be the formation of metabolites in a STP not identified in a water-sediment study, due to other degradation pathways in a STP. The question would be if this is acceptable? **SE** agreed with **DE** and referred to a similar situation where **SE** suggested to carry out a simulation study, although a water-sediment study

was available, to refine the risk assessment. **NL** and **ES** stated that due to higher microbial mass in a STP the approach to use the water-sediment study as a worst-case is appropriate. **ES** recommended using the whole system mineralization rate based on the CO_2 measurements. **NO** and **DE** stated that is it might be very complex to calculate the biodegradation rate constant, even if the whole system value is used, applying the FOCUS guidance. In addition, **DE** stated regarding the mineralization rate, that CO_2 levels in the water-sediment test are not high for these pyrethroids. **FR** agreed and stated that using the whole-system mineralization rate may underestimate the persistency of a substance in sediment (for a substance which degrades in the water column but not in the sediment) or be too conservative for the water phase due to other dissipation processing occurring. **FR** and **NO** stated that more guidance is needed. **NO** referred to a rapidly degrading substance with known metabolites from a water-sediment study, where the rate constant was not extrapolated to the STP (for example using 1 day^{-1}) due to the information on these metabolites. **ES** argued that the only possible extrapolation would be for primary degradation and mineralization. **DE** stated they would ask for the STP simulation study for these substances. **COM** agreed with this way forward and concluded that at this moment there are no substances for which both studies are available. For some substances, referred to by **SE** and **NO**, this will become available in the near future.

Conclusion:

- **DE will require a STP simulation test for these substance;**
- **If information becomes available for substances for which a water-sediment and STP simulation study is carried out, the question will be revisited at the TM.**

DE introduced the second and fourth question related to the Annex I criteria for persistence and bound residues (see Annex VI of the BPD and also Chapter 5.3 of the TNsG on Annex I inclusion). According to **DE** simulation studies have to be required for non ready biodegradable substances to allow a decision on if these criteria are fulfilled, regardless of the risk identified. If it is decided to not require these studies, **DE** stated the substances shall be regarded as P for the PBT assessment and it cannot be checked if the Annex I criteria are fulfilled. **DE** presented a decision making scheme. **DK** disagreed with DE and stated a test shall be required in case of significant exposure. Only if the exposure is negligible the test can be waived. **COM**, **FR** and **SE** agreed with DK. **NL** asked if the exposure is negligible if the substance shall than be regarded as P in the PBT assessment. **DK** stated the substance shall then be regarded as a potential P. **SE** asked to refine the scheme proposed by DE to include the concept of negligible exposure for not requiring a test. This decision also depends on information on abiotic degradation processes and the use, where the use of only low amounts could be an argument for not requiring the test. **FIN** stated to require a simulation test based on the identified risk, although it is difficult to assess the risk of the bound residue. For the rodenticides **FIN** did not require the test but used the defaults from the TGD. In addition, **FIN** questioned if tests shall be required for metabolites which would lead to an increase of the tests required. **FR** stated that a test for the metabolite(s) may be necessary, although also the ecological relevance of the metabolite shall be considered. **NO** stated to be in general line with FIN to only ask a simulation test in case of an identified risk. **NO** asked other MS if they required simulation tests for disinfectants in PT 1, 2 and 3 for non-ready biodegradable substances, where exposure occurs to these compartments. **FR** stated they asked for

the water-sediment study but not for the soil simulation study because of the uncertainty of the position of other MS on these studies and because of the physico-chemical properties of the substance. **DE** stated they would ask for a water-sediment study. **DE** reminded that under product authorisation these studies may be needed, but preferred to obtain this information for the Annex I inclusion of the active substance stating that only data for one representative product may be available to assess if exposure is negligible. **DK** stated this is the reason why the tonnage approach is to be used for Annex I inclusion and reminded the meeting of the "unless clause", where it will only be possible to consider this clause at the Annex I inclusion stage: tonnage data for all uses of the active substance can only be requested at this stage. **FR** agreed with this and reminded of the relatively high volumes for disinfectants compared to rodenticides and wood preservatives. **DK** reminded that the ESDs for PT 07 and 09 are based on the tonnage approach. **NO** asked for a recommendation on how to proceed with respect to disinfectants released to the aquatic environment via an STP. **FIN** asked for guidance on what can be considered as negligible exposure. **DK** stated a simulation for soil would be required as mentioned in Annex VI of the BPD, but for the sediment there is no exact wording in Annex VI of the BPD in contrast to the TNsG which is however not legally binding. **DE** reminded of the discussions within REACH on this issue where it was concluded that it is almost impossible that there will be no exposure to a certain compartment. **COM** referred to a proposal for a revision of the current Annex XI of REACH dealing with criteria for "negligible exposure" and proposed to await this discussion which will be finalised in the coming months. **DK** agreed with this. **DE** stated they would consider the comments made at the meeting and decide on the need for testing before the next TM. **NO** asked if, for disinfectants, where significant exposure to water occurs, a simulation test should be required in case of non-readily biodegradable substances. **COM** confirmed this.

Conclusion:

- **The need for simulation studies with respect to the Annex I inclusion criteria is in principle exposure driven**
- **Based on the ongoing developments within REACH this will be discussed at TM III 08, especially related to the criteria for exposure based waiving.**

3b. Penetration rate or application factor used in ESDs

This item was not discussed and moved to the next TM.

3c. ESD PT13

This item was not discussed and moved to the next TM.

3d. UK Thought Starter: Leaching Rate PT07, 09, 10

This item was not discussed and moved to the next TM.

3e. Draft Workshop Report PT 1-6

This item was not discussed and moved to the next TM.