EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Chemical Assessment and Testing

Biocides Technical Meeting
01-03 December 2009

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 L. van der Wal (DG JRC), and C. Kusendila (DG ENV). E. van de Plassche welcomed the participants to the TM IV 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

The agenda was endorsed without any changes.

2. Adoption of the minutes

COM clarified their position following a request from the UK on the need for risk assessment for companion animals (see page 29 of the draft minutes). It was stated by **COM** that the risk to companion animals should be taken into consideration, but that quantitative risk assessment to pets was not recommended on a routine basis at Annex I inclusion level. It should be assumed that the hazard characterisation for pets is covered by the hazard characterisation done for human health, and that risk management measures via labelling of the products, decided at national level at the product authorisation stage, were the most appropriate, also because many aspects were country-specific. **UK** added that this was the most effective way to cover the issue in the various countries, and proposed that where appropriate (i.e. whenever companion animal exposure appeared possible) a statement could be included in the Assessment Report reminding the MS at the product authorisation stage that they should consider the corresponding risk and take the necessary risk management measures at national level. (Comment post-TM: **COM** proposes to use the following standard form of words for the Assessment Report and in DOC IIC Section 4 under "Measures to protect man, animals and the Environment: "If it is foreseen that use of a biocidal product within a Member State entails significant risks to companion animals

Joint Research Centre · I-21027 Ispra (VA), Italy · TP 582
Telephone: direct line (+39)0332/786716 · Telefax: (+39)0332/789963
E-mail: erik.van-de-plassche@ec.europa.eu
http://ihcp.jrc.ec.europa.eu

then – at the product authorisation stage – the Member State can introduce risk mitigation measures to alleviate the risk".)

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 in the first half of 2010.

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

   See agenda item 7 of the Environmental Session.

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

   See agenda item 8 of the Environmental Session.

4. *Inform ECHA on simultaneous submission of Annex VI dossiers for harmonised C&L for first and second generation anticoagulants by 31 August 2010 by filling in Registry of Intention*

   See item 7c of the General Session.

5. *Include TM decisions from Environment Session in the Manual of Technical Agreements (MoTA).*

   See item agenda item 4 of the General Session.

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

   See agenda item 6 of the Environmental Session.

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

2010

TM I	15 – 19 February	CA	9-12 March
TM II	14 – 18 June	CA	25-28 May
TM III	4 – 8 October	CA	21-24 September
TM IV	22 – 26 November	CA	14-17 December

TOXICOLOGY SESSION

1. Risk characterisation of local effects

COM introduced the document provided by COM on RC of local effects. The central question would be whether irritation effects could in some cases be a sufficient reason for possible Annex I non-inclusion, and the answer suggested by the COM note is that this should not be the case.

FI supported developing further the guidance document on RC of local effects, as proposed in the COM note. The note was providing some new elements that should be taken into consideration in developing the guidance. FI agreed with the main conclusions, but had some reservations concerning the detailed proposals. **UK** agreed with FI, supporting the main conclusions and having some issues that should be clarified in the document. **NO** welcomed the document and supported further work on developing the guidance.

The four proposals of the document were discussed one by one:

Proposal 1: "Minor irritant effects, even if exposure exceeds the calculated AEC, should not as such result in Annex I non-inclusion. Instead, this information (exposure estimations exceeding AEC, and RMMs and the PPE proposed) should be clearly indicated in Doc I, *Elements to be taken into account by Member States when authorising products*. This proposal is based on the nature of the effect: Minor irritant effects would not constitute an unacceptable risk to humans, which is the BPD requirement for Annex I non-inclusion. The conclusion that the risk is acceptable would require that 1) reversibility of the effect can be assumed, 2) the intervals of exposure allow complete healing before further exposure occurs (and/or exposed individuals would be able to take measures when irritation occurs). Lastly, consideration should be given to whether exposure is primary or secondary, as in the latter case the exposed persons might not be aware of the possibility of exposure."

FR commented that in the COM note it is mentioned that it is not practicable to perform a full RC of local effects for all substances that cause local effects, because sufficient information is not systematically available. However, FR considered that a repeated-dose study with appropriate dilutions should be required whenever local effects are suspected and there is no other possibility to derive an AEC. An irritation threshold (NOAEC) should be provided. **COM** clarified that a repeated-dose study would in this case always be required when there is irritation, which **FR** confirmed. **NO** said that because of animal welfare reasons, such studies might be questionable for all substances with irritative and corrosive nature. **COM** said that the added value of such experiments might not be sufficient to justify further studies on animals. **IND** commented that irritation is very dependent on the formulation, and therefore the studies might anyway not be representative of what the workers will ultimately be exposed to. There are so many variables in the assessment that it would be better to perform the assessment in a qualitative way. **COM** asked whether the TM could agree that minor irritation would not be a sufficient reason for Annex I non-inclusion, suggesting leaving the details to be discussed in the working group. **PT** agreed with this. **AT** asked whether it would be enough to use PPE and RMMs for professionals, so that irritation would not be an issue for Annex I inclusion. **COM** replied that the problem comes when even after RMMs and PPE, there is a risk of irritation for the professionals, and therefore it needs to be decided what should be done about that risk, and whether such a risk could in some cases result in

a non-inclusion decision. COM clarified that the current note does not need to be endorsed, but based on the suggestions and the discussion at the TM, a working group will be formed that will draft a proposal for the next TM. **COM** concluded that the TM agreed with the principle of the proposal, and the exact wordings will be formulated within the working group that will be formed.

Proposal 2: "Exceeding the calculated AEC would result in an unacceptable scenario when 1) the local effects cannot be identified as reversible, or 2) if a serious health effect is considered possible as a consequence of exposure. In the absence of such concerns, Proposal 1 would apply."

FI asked whether exceeding the AEC in this case means exceeding it even after using all the PPE and RMMs, which **COM** confirmed. **FI** agreed with the principle, but was hesitant to support a conclusion on the exact definitions and wordings at this stage. **COM** clarified that the TM does not need to decide on exact wordings now, but instead this should be a general discussion on the principles, and the wordings would be proposed later by the working group, and discussed again in the next TM. There were no more comments and **COM** concluded that the TM again agrees on the principle of the proposal.

Proposal 3: "When a substance causes both systemic effects and local effects in repeated-dose studies, RC should be performed separately for systemic and local effects. Thereafter it can be assessed whether systemic AELs or local AECs are more critical. A brief initial assessment may often be sufficient to identify the more critical approach which should then be followed."

FR said that it could be included in the text that if systemic effects are observed at lower doses than local effects, then local effects will not be taken into consideration. **IND** supported the proposal but pointed out that it is not always easy to determine which effect will be the most critical, because it is not easy to compare the values obtained in an irritation study and with a systemic study. **NO** agreed with IND, pointing out also that the AFs can be different for local and systemic effects, and that the probability of local effects compared to systemic effects depends also on the exposure pattern. **FI** agreed that sometimes it might be necessary to perform a RC separately for local and systemic effects. FI however had some doubts about the meaningfulness of a quantitative RC based on dermal effects, because at least for some cases the tools that are available might not be good enough. **NO** agreed with FI, saying that the exposure data may not be really suitable for performing the RC. **COM** agreed that the problems mentioned should be included in the document that will be drafted by the working group. It was concluded that the principle of the proposal will be taken up by the working group in drafting the revised document.

Proposal 4: "Medium- and/or long-term exposure are assessed in the RC of local effects, not acute exposure."

This is a clarification to the earlier document, and it was agreed without comments.

NL asked on point 3 of the conclusions, asking which other frameworks should be included in the paper. **COM** replied that other frameworks should maybe not be included in the document, but the working group should just perform a comparison with other frameworks, e.g. REACH, to see what kind of differences there might be.

NO asked for a clarification to point 2 of the conclusions, as the CLP issues should be kept separate from RC of local effects, and the reference values should not be the same as those for classification. **COM** agreed that this point could be understood as linking the reference values with CLP, but this is not the intention. The three points under the Conclusions section should be taken only as COM proposals for the working group to try to take into account when drafting the document.

The working group was formed by the following volunteers that will draft a proposal for the next TM on the RC of local effects: FI, UK, NL, FR, NO, DE, SI, PT, AT, CEFIC. **COM** will coordinate the e-mail working group, as no MS volunteered to take the lead in the group.

2. SUBSTANCES in PT 08.

2a. DCOIT (RMS: NO)

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2b. Flufenoxuron (RMS: FR)

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3. SUBSTANCES in PT18

3a. Flufenoxuron (RMS: FR)

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3b. Fipronil (RMS: FR)

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3c. Abamectin (RMS: NL)

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4. AOB

4a. Update DRAWG

4a.1. COM informed the TM of the progress of the joint work between the DRAWG and the EMEA since last TM. In addition to informal communications, two 2-hour teleconference work meetings of the joint group formed by members of the DRAWG and members of the EMEA CVMP were held, on 20 October and 26 November. The efforts focused on the preparation of a guidance document entitled "*Risk Characterisation and Assessment of MRLs for Biocides*". The document should be available for a first round of comments in the first quarter of 2010. Among important issues discussed:
i) It is recognised by the group that the methodology for dietary risk assessment (e.g. method for setting the ADI, food basket used for the risk assessment), at least at Annex I inclusion stage, must be harmonised. Therefore the current position is to require an early involvement of the EMEA in the process, and the application of the reference methodology already in use at the EMEA. Taking into account this need has implications on the procedures to be followed by the various actors (RMS, Applicants, EMEA). In case Member States, due to national specificities, would have concerns on the methodology or

would need adjustments to apply risk management measures, these should be addressed at product authorisation stage.
ii) The justification of the trigger used for dietary risk assessment of biocides is being reviewed, with a view to establish its robustness beyond the current position of simply adapting EFSA practice to the biocides situation.

4a.2. DE (chair of DRAWG) informed the TM of the progress of the work of the DRAWG itself. In addition to informal communication, a meeting by telephone conference was held on 12 November to advance the development of the Technical Draft Guidance on Livestock Exposure Estimation (TDG). The current version was further discussed and elaborated, and remaining tasks were distributed, relating to step 2 of refined exposure assessment, default values, and additional examples. Finally, the timeline of the document was discussed.
An agreement of the participants was achieved on most comments and examples in the TDG. More details were given by **DE** on the following:
i) Step 2 of exposure estimation:

- The section of the TDG dealing with refined exposure estimation (Step 2) still needs considerable improvement.
- It was agreed that due to the complexity of this step, it is not possible to describe methods for all imaginable scenarios. Consequently, rather than methods, principles for exposure estimation will be provided as a guide.
- A proposal for this section is under preparation in November 2009. All DRAWG members will review and contribute this proposal.

ii) Default values:

- A number of default values have yet to be defined.
- A list of default values was compiled and parameters were distributed among group members, who will search for appropriate data and circulate them to the group in December 2009.
- The results will be discussed in a telephone conference in mid December 2009 and / or in January 2010.

iii) Timeline:
The initial aim to finish the document by the end of 2009 was too ambitious. It is now planned that a draft will be available for presentation at next TM (TMI_10).

4b. Update HEEG

COM mentioned that the UK room document was briefly discussed in HEEG, where there was general agreement on the UK conclusion. Since no decision is needed by the TM, it was brought to the TM as a room document. **UK** introduced the room document, mentioning that with ConsExpo it has to be kept in mind that the chronic exposure value is a year-averaged dose (total dose divided by 365). The TNO has been consulted, and they agreed with the conclusion. **COM** said that this will be included in MOTA.

GENERAL SESSION

1. Tracking System

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2. SUBSTANCES in PT 08:

2a. Flufenoxuron (RMS: FR)

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3. SUBSTANCES in PT18

3a. Flufenoxuron (RMS: FR)

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3b. Fipronil (RMS: FR)

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3c. Abamectin (RMS: NL)

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4. Update MOTA

COM informed the TM that decisions reached in HEEG will be included in MOTA. The ENV decisions are also to be included in MOTA.

5. Evaluation of efficacy tests for PT 18

NL introduced the document by saying that it has been thoroughly revised after the numerous comments received. One of the main points under revision concerned the level of efficacy where different views were expressed by MS. Presently rather high level of efficacy are agreed upon, with the specification that if the level of efficacy of the product is lower, a proper justification has to be submitted. This has been accepted in order to ensure the necessary flexibility. NL asked the TM if this draft is to be accepted or a new round of comments is necessary.
UK asked that submission in writing of new comments should be possible. **IND** and **SE** also requested more time for additional comments. **DK** commented that in regard to possible occurrence of resistance, since a product may also be applied by professionals, sufficient indications should be provided for the latter category to avoid the development of resistance. **AT** asked if the document covers only products under PT 18 or both PT18 and PT19. **NL** clarified that both PT18 and PT19 are covered..
NL asked the TM if paragraph 1.3.12 regarding testing should stay in this guidance or its place is in a more general document. **COM** is the opinion that indeed the generality of

paragraph qualifies it for TNsG level. Also several issues regarding the wording will have to be addressed (just new actives mentioned, unclear what the meaning of "a full scale field test" is).
COM concluded that one month will be allowed for submitting the comments and depending on these a decision will be taken if additional discussion at the TM level will be necessary.
Conclusion: a commenting round of one month was agreed by TM

6. The role of efficacy in the BPD evaluation process

DK raised the point that the efficacy data is also relevant for the risk assessment as the outcome of the efficacy tests on products influence the calculation of the exposure level. If lower concentrations are accepted for risk characterization, where the product is safe, the product might not be efficacious. If the concentration is raised in order to make the product efficacious, the risk of it may become unacceptable. **NL** supported DK by saying that if efficacy needs a higher concentration and risk assessment is done on a lower concentration it might be the case that there is no safe use. Therefore the efficacy should be proven for the concentration that indicates no risk. If this condition is not met as a consequence the whole process of Annex I inclusion would be worthless, since no safe and efficacious uses may be found. **COM** noted that in practice if a MS will identify such a case, a discussion with the Applicant should clear the matter. The paper presented tries just to formalize the way the TM is already working. **UK** supported this approach. **AT** supported NL by bringing the same arguments.
FI asked if "label claim" would include the advertising material and accompanying leaflets or different types of information that come with the biocidal product. **UK** confirmed that indeed the intention was to include all the information regarding claims. **FI** said that under current legal framework such data is not revised by CA in the enforcement process. **AT** clarified that according the BPD, Article 20, "label" would include all the information that accompanies the product. AT recommended rewording of chapter 2.3.1 in order to take account of this.

Conclusion: the document has been endorsed by TM, with the recommendation of clarifying chapter 2.3.1

7a. Progress on revision of efficacy guidance for PT 08

FR introduced the paper by saying that they have started the revision of the PT 8 guidance with the help of EWPM and some of the MS. Some of the recommendations of EWPM regarding the application rates will have to be discussed therefore MS are invited to participate. An initial period of electronic consultation has been proposed by FR to be possibly followed by a workshop.
Conclusion: the document will be sent for a commenting round as soon as a new version is available with the comments compiled (comment FR post-TM : normally in March).

7b. Report on meeting OECD Biocides Task Force October 2009

The chair of the OECD Biocides Task Force informed on the outcome of the last meeting. **COM** reminded MS to send nominations for the revision of the OECD ESD for PT 08 and the project on the evaluation of the leaching rate determination for wood preservatives.

7c. Harmonised classification and labelling for second generation anticoagulants

COM reminded the involved MS to fill in the registry of intentions of ECHA as soon as possible.

7d. Evaluation of efficacy for PT 21

COM informed that CEPE offered to review the current section in the TNsG of Product Evaluation on efficacy evaluation of antifouling products. CEPE does not foresee major comments on this section. CEPE will forward their review to the TM in the first half of 2010.

7e. Modification RCOM Table

NL stated that after the consolidated RCOM is uploaded on CIRCA it is not always easy to solve issues in bilateral consultation as the contact person for a certain aspect is difficult to find. NL suggested adding a table at the top of the RCOM table where contact points can be listed by the RMS. It was agreed that **NL** will send a proposal template to COM.

ENVIRONMENT SESSION

1. SUBSTANCES in PT 08:

1a. Chlorfenapyr (RMS: PT)

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1b. Flufenoxuron (RMS: FR)

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1c. Cu-HDO (RMS: AT)

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2a. Environmental risk assessment PT 18 following peer-review First Draft CAR Bendiocarb (RMS: UK)

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2b. Flufenoxuron (RMS: FR)

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2c. Fipronil (RMS: FR)

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2d. Abamectin (RMS: NL)

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3. Substances in PT21: risk assessment for sediment

COM introduced this item, and stated that several comments by **FI**, **NO** and **SE** were received regarding the questions on MAMPEC put forward in the CEPE-document. During the last TM, degradation rate constants of organic carbon in sediment were discussed. Taking into account that discussion, CEPE has now prepared a document, proposing a default degradation rate value of k= 0 day^{-1} (i.e. current default value) for the 1st tier assessment, for higher tiers a rate constant of 0.0001 day^{-1} (for sediment mixed layers of 10-20 cm) and finally a degradation rate constant, k=0.0002 day^{-1} for freshly deposited sediment (e.g. 3 cm). Additionally, a room document was prepared by **UK**.

The discussion started on the CEPE-document, to which **SE** commented that due to the lack of time to evaluate the document **SE** preferred to send comments in writing after the meeting. **NO** commented that with a degradation rate of k= 0 day^{-1} for carbon degradation, the first tier will actually reflect a lower concentration of the active substance than a next tier where degradation of carbon is considered and thus the concentration of the active substance is higher, which would be a strange tiered approached; **COM** agreed. **FI** asked for clarification on how the PEC would be expressed (i.e. organic carbon normalised, dry weight or wet weight). **NO** clarified that so far PEC values have been expressed as dry weight sediment concentrations and not as carbon normalised. **FI** then commented that

taking into account carbon degradation does not seem to have an effect when compared to concentrations expressed on a dry weight basis. **COM** proposed to discuss the CEPE-document at another moment, since the representative of CEPE was not present and due to the late submission of the document. **NL** mentioned the release date of a new MAMPEC version which will contain more extensive documentation, and commented that it may be more effective to await the release of the new MAMPEC version. **COM** commented that a lot of time has been spent already and that the discussion on the sediment scenario should be held in a parallel process, furthermore, the document produced by UK provides a practical approach on how to deal with the current MAMPEC model at this time.

UK introduced the document and remarked the need for additional sediment testing, as well as the possibility within MAMPEC to derive concentrations within the different sediment layers. **SE** proposed, before stepping away from the approach suggested in the TGD (which was revised from $PEC_{whole\ sediment}$ to $PEC_{suspended\ matter}$ in 2003) and use sediment instead of suspended matter concentration, a more thorough discussion is needed. **SE** further argued (considering UK's proposal that $PEC_{suspended\ matter}$ should be compared with $PNEC_{suspended\ matter}$ and $PEC_{whole\ sediment}$ should be compared with $PNEC_{whole\ sediment}$) that a $PNEC_{sediment}$ should be representative for all species in the sediment compartment, and that 90% of the species present in that compartment are exposed to suspended matter. **NO** commented that it is not practical to use different PNEC values for sediment and suspended matter. **NO** highlighted that unacceptable risks will probably arise when concentrations in suspended matter are used instead concentrations in sediment. **SE** expressed that the rationale of refining scenarios is primarily to make the assessment more realistic, not to reduce the risk. If a risk is identified and no refinement increasing realism is at hand, the issue should be addressed at CA level. **NO** additionally asked why EPM was mentioned since sediment testing is a PT 21 specific data requirement and thus there is no need for the EPM. **COM** proposed to further discuss this issue between several MS and CEPE in order to generate a full proposal. **NO** asked for a deadline, to which **COM** proposed that comments will be sent directly to CEPE respectively UK before the end of 2009

Conclusions:

- **MS** will send their comments on the respective documents to CEPE and UK before the end of 2009.

4. Harmonisation of the exposure scenario for PT 6

PL introduced their proposal regarding the harmonisation of exposure scenarios for PT 6, also provided in a room document, and requested MS to return the questionnaire in excel-format before the end of 2009. **COM** this issue has been discussed on several occasions without much success, although agreements were reached on some principles, i.e. in-can preservatives categorisation in different use categories. However **COM** would be hesitant to further develop the emission scenarios for the various categories of in-can preservatives. **DK**, **AT**, **FI, NL**, **DE**, **FR**, **UK**, **SE**, **SI**, supported the **PL** proposal. **SI** additionally expressed concern regarding the time-frame to reach harmonisation which was also a concern of **COM**. **COM** concluded that the participating MS will send the questionnaire to **PL** before the end of 2009, with the remark that if MS want to pursue with their dossier these MS will not be stopped from submitting their dossier.

Conclusions:

- MS will send the excel sheet provided by **PL** back to **PL** before the end of 2009.

- MS that want to pursue with their dossier for PT 6 will not be stopped from submitting their dossier. The harmonisation of the exposure scenario will take place in parallel.

5. Addendum ESD for PT13

COM introduced the discussion on the ESD for PT 13 (metalworking fluids), initiated by a question from **DK** on the volume of processed liquid treated in a recovery plant for metalworking fluids. **NL** proposed to keep the parameter as set in the ESD. Several MS (**DK**, **SE** and **FR)** carried out some additional research, but no additional information on this parameter was obtained, therefore **COM** proposed to use the value as stated in the current ESD. **COM** further remarked that the following or a similar sentence could be included when a risk for metalworking fluids had been identified, "The release of biocides used as metalworking fluids has to be considered by the relevant national authorities when issuing permits for recovery plants". **DE** commented that it also sent comments which were not included in the revised document and asked **COM** to add these amendments. **DE** agreed with **NL** and **FR** to use the mentioned parameters in the current ESD. **DE**, supported by **DK,** further commented to be critical regarding the proposed non-inclusion of the waste life stage in the assessment, since **DE** is not so familiar with waste legislation and is of the opinion that the emissions during recycling or waste stage are very relevant when compared to the use stage of PT 13. Furthermore, **DE** and **DK** requested more information regarding the criteria for case-by-case decision making. **COM** clarified that at this point of time no more realistic values for the parameters in the ESD can be defined regarding the waste life stage of metalworking fluids. **DE** commented that it would prefer to clearly state the identification of a risk for a certain use in the CAR, and subsequent possibilities for risk mitigation. **COM** could agree with the comments by **DE** and **DK** and will reconsider their proposal and discuss this further at CA level.

In addition the environmental risk assessment for the waste stage in general was discussed. **NL** remarked that the guidance document issued by ECHA (for waste dumps and incineration installations) is not sufficient and more discussion is needed to obtain better guidance. **COM** responded to **NL** that it is up to the TM to decide to use this guidance by ECHA. **BE**, supported by **UK**, remarked that earlier discussions during TM resulted in not assessing the waste stage since it is not part of the Biocidal Product Directive. **DE** informed the TM that ECHA is working on a revised guidance document and did not agree with **BE** and **UK** that the waste stage should not fall under the BPD, because of the relevance of emissions during this life cycle stage. **COM** supported this last comment by **DE**.

Conclusions:

- The volume of processed liquid treated in a recovery plant for metalworking fluids as stated in the current ESD will be used in the risk assessment of PT 13.
- When a risk for metalworking fluids has been identified, the following or similar sentence should be included under elements to be taken into account: "The release of biocides used as metalworking fluids has to be considered by the relevant national authorities when issuing permits for recovery plants". **COM** will further consult with DG ENV on how to deal with metal working fluids regarding recommendations for elements to be taken into account for product authorisation.

6. EUSES

COM thanked all MS who expressed their interest in participating in the validation exercise of EUSES 2.1. Some changes were made to the distribution of PTs (i.e. **AT** changed to PT 10, **DK** received PT 7 and **SI** changed to PT 11). **NL** informed the TM that a bug was discovered in the EUSES scenario for PT 11 and that there is ongoing work by RIVM on the black list which contains the latest issues/bugs for EUSES. RIVM will be contacted by **COM** for information on the latest version of the black list and the scenarios to be distributed in the validation exercise. The validation exercise will exist of one scenario which will be distributed by **COM** to the participating MS in the first half of 2010, who will then return the outcome of the exercise within 3 months. A revised distribution list will be send around by **COM** to the participating MS.

Conclusions:

- **COM** will send a revised distribution list to the participating MS.

7. Addendum TNsG data requirements biodegradation

COM introduced the addendum to the TNsG for data requirements, which was necessary due to discussion on substances with low Kp values and the requirement for water-sediment studies. **DE** and **NL** expressed their support for the addendum, where **DE** commented to also include the amendments under the water section of the TNsG for which **DE** will provide a proposal. **SE** had some detailed comments (i.e. unit change in the introduction to 3 hours instead of 3 days, adding more detail on the background of amendments) which will be send by **SE** to **COM** for incorporation in the document.
No further comments were received and the addendum was endorsed by the TM.

Conclusions:

- **COM** will amend the addendum with the comments made by **DE** and **SE**, **SE** will send their comments to **COM**.

8. Guidance document leaching rate PT 07, 09 and 10.

After a previous discussion**,** regarding leaching rates for PT 07, 09 and 10, during TMIII-08, comments by MS were incorporated in a guidance document produced by the **UK** which will be distributed on the **COM** website. **NL** commented that for biocides no regional assessment but only a local assessment is performed and therefore **NL** proposed to delete the reference to a regional assessment. **DE** commented that the lack of harmonised data for the service life time (TIME2) for PT10 should be mentioned specifically in the document; and that the discussion on adequate leaching tests for the emission estimation of preservatives should advance. **DE** reminded MS the possibility to attend the workshop on leaching rates in Berlin on the 21 of January 2010. **FI** asked to add more clarification regarding PT 7 (tonnage approach or an approach where leaching rates to soil are calculated similar to the procedure for PT8 i.e. the use of TIME1 and TIME2) and **NO** provided clarification that TIME1 and TIME2 were used for these calculations. **NO** would prefer not to remove the regional assessment since this value is used as background. **NL** argued that no verification of background levels is possible and that the level of regional background is not of significance when compared to the local assessment. **COM** concluded that the regional assessment will be deleted from the document while the lack of harmonised data for the service life time (TIME2) for PT10, as well as the clarification regarding PT 7, will be included.

Conclusions:

- Regional assessment will be excluded from the guidance document.
- Lack of harmonised data for the service life time will be specifically mentioned in the guidance document.
- A clarification with regard to PT 7 will be included in the guidance document.

9. AOB

9a. Evaluation of mesocosm tests in the Review Program

COM introduced the issue brought up by **IND** regarding the evaluation of mesocosm studies in the biocidal review program (i.e. quality criteria assessment of this type of study, how to interpret these studies in relation to PNEC derivation). The proposal was supported by **UK**, after which **COM** proposed that **IND** will produce a document to be discussed at a later stage. **IND** highlighted the need for guidance and agreed to produce a document regarding the use and application of mesocosm studies which will be presented to **COM**. **UK**, **NL**, **DE**, **SE** and **FR** expressed their interest in participating in the discussion of the document. Further discussion will be scheduled between **IND**, interested MS and **COM** after receipt of the document.

Conclusions:

- **IND** will produce a document regarding the evaluation of mesocosm studies in the biocidal review program and provide it to **COM**.