EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Chemical Assessment and Testing Unit

Minutes of Biocides Technical Meeting I 2013
11th -15th March 2013

INTRODUCTION

The meeting was chaired by A. Payá Pérez and for specific items on the agenda by M. Andryszkiewicz, D. Blihoghe, S. Pakalin, A. Paya-Perez and B. Raffael.
A. Payá Pérez welcomed the new participants to TM I 2013.
COM reminded to send the documents intended for TM discussion under the AOB two weeks before the TM, and those related to the CARs five weeks before the TM, as foreseen in the TM SOP.
For next TM, any request for items to be included in the agenda has to be sent not later than the 15th April, so that COM can circulate the first draft of the agenda 6 weeks before the TM.

1. Approval of the agenda

Agenda was adopted by the TM.

2. Adoption of the minutes

NO comunicated that some of their comments on the ENV part have been missed out.
COM will include the comments in the draft minutes.
COM considers the minutes as adopted after the inclusion of NO comments.

3. Action List TM

COM reported that the Action List document was uploaded on CIRCABC and explained that item 6 regarding the review of local risk assessment guidance will be followed by ECHA together with the group of local risk assessment. COM asked to MS interested to contribute to the work of the Working Group to contact ECHA.

Action list from TM I 2103 is available in CIRCABC.

3.1 Action 1: Finalisation document "Harmonisation of environmental risk assessment for PT. PL with the collaboration of DE will revise and finalise the guidance document and forward to COM for discussion by the CA meeting. At TMIII2012 DE informed on the on-going project which will be finalised in 2014.

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http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides

3.2 Action 2: *Distribute list with tasks MS in EUSES training validation exercise and prepare the exercise.*
EUSES updated version, in which some bugs are repaired, is now available. Consequently, the validation exercise will now start. COM will distribute the documents to those MS that volunteered to participate. TMI 2013: EUSES will be handed-over to ECHA.

3.3 Action 3: Consult with the applicants for PT 13 in the Review Program to obtain more information on the parameters used in the ESD for PT 13.
TM I 2013: IND/CEFIC will coordinate with Applicants of PT13 to provide some progress on this action item. NL is collecting information from applicants which could be provided to a guidance for the TM including the non-confidential information. Follow up of TM I 2013: IND will present an update in TM II 2013.

3.4 Action 4: Development of "swimming scenario" for PT 19 environmental risk assessment: comments on draft to DE. At TM III2012 DE informed that a project started on 1st October 2012. TMI-2013 (action on-going).

3.5 Action 5: *Finalise guidance documents on environmental risk assessment for PT 21.*
COM informed that UK is preparing the document and waiting for the outcome of the discussions on the various e-consultations on PT21. UK will present the document at TM II 2013.

3.6 Action 6
3.6.a Extreme sensitizers with human data.
TMI-2013: ECHA informed that a document for discussion will be ready for TM II 2013.

3.6.b Guidance on the transfer of biocides to food.
On-going.

3.7 Action 7: *Evaluation of Disinfectants by Products*
Submitted to CA49-2012-pending CA opinion. Action completed.

3.8 Action 8: IPBC discussion. DRAWG to prepare a paper identifying the worst-case dietary exposure scenarios for PT6.
TMI-2013 –On going.

3.9 Action 9: Can the TTC concept be used for the purpose of waiving nature-of-residue studies?
DRAWG to send a proposal for DRAWG opinion. TMI-2013 on – going.

3.10 Action 10 : City Scenario-Leaching from paints, plasters and fillers applied in urban areas
TM I-2013: A revised document will be submitted for discussion at TM II 2013.

3.11 Action 11: Calculation of groundwater concentration for substances leaching from wood, masonry and films (PT 07 and PT 10) to soil using PEARL.
TM I-2013: A revised document will be submitted for discussion at TM II 2013.

3.12 Action 12: Use of Koc in PEC calculations for antifoulants (SE)
TM I-2013: A revised document will be submitted for discussion at TM II 2013.

3.13 Action 13: Overview of the ESD work under the OECD Exposure Group (JRC)

TM I-2013: An update will be presented to TM II 2013.

4. Members of the Technical Meeting

No comments were raised by the TM.

5. Next Technical Meetings and CA meetings

TM II	10-14 June 2013
TM III	16-20 September 2013
TM IV	25-29 November 2013

CA I	27 February – 1 March 2013
CA II	15 -17 May 2013
CA III	10 - 12 July 2013
CA IV	25 - 27 September 2013
CA V	11 - 13 December 2013

TOXICOLOGY SESSION

START: 11th March 2013 at 14:30 hrs
FINISH: 12th March 2013 at 18:00 hrs

1. GENERAL ISSUES

1a. Preparations for the hand-over of the activities under the Review Review Programme from the Directive (BPD) to the Regulation (BPR)

COM distributed a room document presented at the last CA meeting with information on the current situation of the Review Programme. COM also distributed two tables with the guidance documents under preparation and on-going projects. COM asked MS to revise and update if needed the information on the tables during the following two days in order to have an overview discussion during the GEN session on Wednesday morning. Apart from that, COM suggested MS to complete any missing information on this topic by 19th March, as it is an important issue for ECHA in order to plan the work of the Biocidal Products Committee.

AT asked if MS could put questions on the CA document of the Review Programme. **COM** explained that the room document was intended just for information for MS to be aware of the discussions at the CA level. COM will also inform in the GEN session about the outcome of the CA discussion in other issues.
AT said that the CA document influences also the TM process, as for example the last round of comments on the final draft CARs of 60 days seems not to be necessary anymore. **COM** informed that the proposal is that after RMS has collected the information from TM and prepared the final draft CAR, the first CA discussion will take place as soon as possible, instead of having the 60-day commenting period and then the first CA discussion. This was proposed in order to speed up the process while working at two different levels in parallel. COM clarified that this procedure will not be possible for all substances, for example in cases where the finalization of the draft CAR involves the collection of information. However, for most substances it will be feasible.

COM also informed that a schedule was prepared for the foreseen CA discussion of substances for which the final draft CAR is already finished. This time planning is included in the same document.

COM reminded MS to update information on summary tables on the Review Programme status before Wednesday morning in order to complete them as much as possible.

1b. Evaluation of disinfectant by-products

COM informed that the document was presented to the 49th CA meeting by NL, after the discussion in the TM, but following the amount of comments from other MS, the document was put on hold by the CA meeting.
For the MS involved with their dossiers, COM suggested to ask the CA to finalise the discussion or to find an alternative suitable solution.
NL confirmed that they are waiting for a signal from the COM/CA before proceeding with the subject. This is an important issue to be included in the minutes.

3. AOB

3a. Update HEEG

COM introduced Alex Zenie, the new contact person for the HEEG.
Chiara Pecorini (now in ECHA), that was managing the group till the end of 2012, as part of the JRC and that will start again to manage it as from January 2014, as part of ECHA, will most probably participate to the TM II 2013.

3b. Update DRAWG

DE gave a brief update from the DRAWG representative.

3b.1. Livestock guidance
Comments from public consultation have been integrated in the document where applicable. However, discussions on when to include dermal absorption of animals in the assessment process are still ongoing. The result of these discussions should be awaited before the document is finalised.

3b.2. Food guidance
Comments from TM discussions have been integrated in the document where applicable. There is still a need to have some further discussion on the scenario of disinfectants in the food industry:
- There is a need to revise the derivation of the rinsing thresholds.
- In addition, it was identified as necessary to consult a HACCP (*Hazard Analysis and Critical Control Points)* expert to gain a better picture of the industry process before finalising the method. We currently have one nomination and are waiting for approval.
- An assessment method for PT8 biocides has yet to be developed. This is not urgent, because most PT8 products have already been/are currently being authorised. So the method won't be needed until renewal of the authorisations. Hence, it can be developed after the food guidance has been endorsed.

3b.3. Related guidance documents
- Livestock MRL guidance: The comments from public consultation are currently being discussed by the CVMP-BTM group.
- Food MRL guidance: Has yet to be initiated.

3b.4. Further actions
- DRAWG might be asked to draft another guidance document. This guidance document would address how to perform residue trials. We have however not received a mandate for this yet.
- A procedure for MRL assessments for biocides has not been developed so far. A workshop is planned to discuss this. Germany will host the workshop (venue, logistics). However, the organisation (what to discuss, who to invite, etc.) will be a collaborative effort of DE, JRC and, if interested, other DRAWG MS. So if any of you/your CAs are interested in being involved in the organisation, please contact the chair of DRAWG.
- DRAWG was asked by the TM to submit a paper on identifying worst-case uses for PT6 products. A draft has been written and is currently under discussion in DRAWG.

COM thanked DE and asked to send any comment to DRAWG chair.

Conclusion

DRAWG will follow up the issue, in particular to finalise a paper on identifying worst-case uses for PT6 products.

3c. Evaluation Manual for Product Authorisation

COM reported that a new version of document was prepared by NL and uploaded on CIRCABC for commenting.
NL introduced the changes made to the document and explained that the updated version is based on the revised MOTA and on the comments made by CEFIC that were not included in the first version.
DE reported that they have some editorial comments concerning dietary risk assessment which they submit to NL in writing. They were also of the opinion that the document should be upgraded with EFSA default values.
COM reported that there was also a written suggestion sent by the UK to consider a recent document that has come to light from the Committee of Mutagenicity regarding disinfection by-products in swimming pools and their genotoxic potential. However, it was agreed that this issue will be taken into consideration when the on-going discussion on the disinfection by-products will be finalized by the CA meeting.
SE agreed to provide their comments concerning the risk for the companion animals in writing.
NO reported that there were two HEEG opinions (one on the Links study and second one on the dipping of hands/forearms in a diluted solution) missing in the new version and they agreed to forward them to NL in writing.

Conclusion

NL will receive the above mentioned comments and include them in the package that will be handed over to ECHA for the next revision of the document.

3.d Substances of Concern

COM reported that the last meeting of the working group (WG) on the SoC took place in December 2012 and the key actions arising from that meeting were:

- To organize workshop to discuss all HH issues at TM
- UK to share a compilation document with the comments submitted by MSs for TM IV 2012 with WG and WG to reflect on these comments to better focus discussions at TM
- SE to revise a checklist document and provide some ideas for further steps following the screening list (e.g. in the form of decision tree). The updated document to be shared with WG before being sent for the next TM.

Since December meeting, two main documents have been distributed to WG for discussion:

1. SE submitted an updated version of the checklist document for screening potential SoC
2. UK sent a document compiling comments/answers received from MSs to 12 questions having been discussed at TMIV and proposed way forward for the issues.

The e-consultation is still on-going (comments have been received by few MSs and IND) and due to the time constraints it was not possible to refer any specific question to TMI for discussion. According to the outcome of the e-consultation on both documents, the WG will provide further details on the content of the workshop to discuss on the main HH issues (to be organized back to back to the TM II 2013 in June).

3e. BIP, 6.1 –Guidance for Information Requirements

The comments received during the commenting period were discussed. ECHA will provide a revised RCOM table with the conclusions of the TM for each comment and will revise the document accordingly.
ECHA informed that upon completion of the revision, the document will undergo editorial check and will then be sent for public consultation to stakeholders and CAs.
Any question or request of further information should be addressed to ECHA.

3.f. BIP 6.4 HH- Block I (Hazard, effect-, exposure, and risk assessment)

The comments received for the chapters on hazard identification, characterisation and risk characterisation were discussed. ECHA will provide a revised RCOM table with the conclusions of the TM and will revise the document accordingly.
For a number of comments from UK no discussion took place due to the absence of the UK CA but ECHA informed that will discuss bilaterally with the UK CA to agree on the way forward and then bring the revised document to TM.
ECHA will circulate the revised documents towards end of April and MS will be asked to inform if they would like to discuss it at the June 2013 TM. ECHA noted that the effort concentrates to refine existing guidance and not create extensive new text unless it is really necessary.
Any question or request of further information should be addressed to ECHA.

3g. BIP 6.7 –Cumulative and synergic effects – Mixture toxicity

FR presented the revised version of the document and the changes made following comments received. Cefic provided late comments and it was not possible to discuss them at this point in time.It was agreed that the clean version of the document will be sent to ECHA and it will be included within the development of BIP 6.7 by ECHA. ECHA noted that Cefic comments will be dealt at later stage by ECHA and will also identify necessary modification in relation to the development of similar Guidance within the ENV work area. For future developments of this Guidance, FR will be consulted being the lead country for this guidance.
The TM noted that the current document should be used already by MS when performing assessments for product authorisation to ensure harmonisation.
Any question or request of further information should be addressed to ECHA.

3.l BIP 6.8 –Giuidance on microorganisms

The item was only for information; **SE** informed the TM for an upcoming workshop in June 2013 and invited interested MS to participate.

3.h EFSA Guidance on Dermal Absorption to Biocidal products

Background
COM reminded that in 2012 EFSA issued a guidance document on dermal absorption, with values that have been endorsed by the TM IV 2012. TM should also endorse the whole document. There were many detailed comments on the Guidance from DE, which made reference to previous comments already sent to EFSA during the preparation of the guidance.

Discussion
DE acknowledged that EFSA guidance on dermal absorption provides a useful reference for the assessment of biocides, in addition to other documents. **DE** has always advocated a detailed analysis of the applicability of EFSA guidance to biocides before a decision is taken, since for some substances (such as disinfectants, or cosmetics), other guidances, like the one from OECD, might be more appropriate.

NL supported the use of the EFSA guidance as a basis as it is a harmonized guidance much similar to the OECD guidance, also because the same people were involved in the discussion of both documents. **NL** welcomed a later adoption of an EFSA guidance with a new appendix for biocides, but for the time being, the EFSA guidance should be endorsed.

DE asked if that new appendix would cover those substances where the EFSA guidance is less applicable. **SE** supported the document but requested expert judgement about the section on similarity (Section 6.2), as it is too flexible. **PT** supported this guidance, which PT had already been using. **DK** and **CZ** also supported the use of the guidance, but agreed with SE concerns on the similar products. **DE** proposed to give preference to the EFSA guidance, but in some cases where the EFSA guidance would not be clear, the OECD guidance could be used additionally.

COM informed that in view of the hand-over to ECHA, it is preferable not to start anything new, as ECHA will have different systems for the preparation of the guidance documents. Therefore, it is advised to endorse it as it is, and if there is extra work to be done in the future regarding the specific applicability for biocides, this would be done according to the new ECHA procedures.

Conclusion
The guidance was endorsed with additional reservations from some MS.

3.i. MOTA Version 5

COM reported that the new version of MOTA was uploaded on CIRCABC, but as it was not completed and one opinion agreed on at TMIV 2012 was missing, the room document including that opinion was distributed at the meeting. This opinion will be included in the document and complete version of MOTA will be uploaded on CIRCABC after the TM. The changes that had been made to MOTA version 5 concerned the inclusion of:
1) Six HEEG opinions such as:

- Opinion 11 (MOTA minutes TMIII 2010) – on the "Primary exposure scenario – washing out of a brush which has been used to apply a paint "
- Opinion 12 (MOTA minutes TMII 2011) – on the "Harmonised approach for the assessment of rodenticides (anticoagulants)"
- Opinion 13 (MOTA minutes TMIV 2011) – on the "Assessment of inhalation exposure of volatized biocide active substance"

- Opinion 14 (MOTA minutes TMIII 2012) – on the "Approach to identification of worst-case human exposure scenario for PT6"
- Opinion 15 (MOTA minutes TMIV 2012) – based on the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints"
- Opinion 16 (MOTA minutes TMIV 2012) – on the "Model for dipping of hands/forearms in a diluted solution".

2) An issue on a default value for derivation AELs and internal exposure levels.
3) An issue on the most relevant exposure determinant in the spray application scenario.
4) An issue on the derivation of dermal absorption values.
5) An issue on the possibility of waiving of the mutagenicity studies.

The written comments were submitted by UK in respect of:

- A default value for derivation of AELs where UK proposed adding the "oral absorption value' for clarity
- and
- A relevant exposure determinant in the spray application scenario where UK proposed adding "by professional operators" and refered to the Opinion that came from the discussions held at TMIII 2011 on German CAR for Cyfluthrin.

COM asked other MSs for their views on MOTA version 5.

FR had a remark about the PPP SANCO guidance document on the relevance of metabolites, mentioned by UK. **COM** mentioned that for a single biocidal active substance the limit of 0.1 µg/L should always be applied in the groundwater. However it was underlined that wherever above mentioned limit is exceeded then the PPP SANCO guidance document on the relevance of metabolites should be applied. **FR** agreed with this statement but at the same time proposed to make a remark that as an issue comes from PPP area, then MSs could have different interpretation of different steps and stages of that guidance document. Therefore it could be helpful to add a sentence explaining that all the steps and stages should be applied in the same way in order to harmonise the way of using the document.

COM asked other MSs for the views on that issue. No comments were received. COM explained that the aim of the meeting is to endorse a revised version of MOTA and as there were no further comments, the document was endorsed with the comments received during the commenting period.

Conclusion

MOTA version 5 was endorsed with the comments received during the commenting period.

SPECIAL SESSION

START: 12th March 2013 at 09:00 hrs
FINISH: 12th March 2013 at 18.00 hrs

WORKSHOP ON PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY

Conclusions on the workshop where a general consensus was reached have been forwarded to ECHA for inclusion in the ECHA guidance on the data requirements for Regulation 528/2012.
Relevant comments for the Evaluation Manual General session have been brought to the attention of the TM meeting in the specific discussion.
Full minutes of the workshop have been distributed to the participants with the possibility to submit comments by the 15th April.
The final minutes have been revised and uploaded to the dedicated workshop folder under TM I 2013. "

GENERAL SESSION

START: 13th March 2013 at 09:00 hrs
FINISH: 13th March 2013 at 18.00 hrs

1. GENERAL ISSUES

1a. Reporting on the 49th and 50th CA meeting

The 49th meeting took place in December 2012 and 50th took place in February 2013.
Two new substances (chlorphenapyr PT8 and difenothrin PT18) were voted for inclusion in Annex I.
The guidance on efficacy tests for biocidal products PT18 and PT 19, and the Evaluation Manual for Product Authorization version 1 were endorsed.
A new template for the assessment report with an updated list of endopoints was endorsed.
The guidance for testing of preservative efficacy was endorsed and released for six-month commenting period.
The document for disinfectant by-product prepared by **NL** was agreed to be pending for the CA decision.
During the CA meeting, **ECHA** explained that they would only establish technical equivalence with the reference source already approved. **COM** explained that it was possible to carry out technical equivalence between two substances provided the required data were submitted. **COM** explained that **ECHA** had the power to ask for the relevant data to be submitted. **COM** supported by all **MS** and **IND** stated that the expectation is that **ECHA** shall establish the technical equivalence as of 1st September 2013 for all substances. **COM** asked **MS** to concentrate in scientific aspects rather than in regulatory aspects.
The document on the review programme of active substances and establishment of work programme for the years-to-come was also presented in the CA meeting. DG ENV had already prepared the document on the review programme for 2013 and will be distributed to the MS.
AT asked on how to proceed with the dossiers of formaldehyde releaser in preservatives. **COM** explained that at the CA meeting the issue of DBPs was discussed, but n0 conclusion was reached, so many dossiers should be put on hold until a final decision will be taken.
NO asked if the Techical equivalence could be prepared by September. **COM** explained technical equivalence should be approved before the dossier is included.

1b. Preparations for the hand-over of the activities under the Review Review Programme from the Directive (BPD) to the Regulation (BPR)

COM asked **MS** to finalize the open issues (draft CARs, second discussions, open guidance documents). A room document has been distributed. **MS** should update the document on on-going projects and to send to COM within the 18th March.
NL said that there is a mistake as the efficacy guidance on preservatives is already endorsed. **DE** was the responsible for this guidance and will send the update.
NL would like to be added as a participant in the physico-chemical storage stability under the table of on-going projects.

NL has some disinfectants and is waiting for the solution on the disinfectant by-products documents. **COM** replied that **MS** should state in the table that substances are pending waiting for the solution of the issue.
DE said that a few guidances and documents already submitted by them had not been included and they would resubmit it in order to update the information.

1c. ECHA presentation on preparatory activities for BPR

Erik van de Plassche, Chair of the Biocidal Products Committee (BPC) in ECHA, presented an overview of the preparatory activities for the Biocidal Products Regulation, especially on the role and function of the BPC and its Working Groups. The latter will replace the current Technical Meeting under the BPD. The presentation is available in CIRCABC in the TM I 2013 space.
Any question or request of further information should be addressed to ECHA.

2. Tracking System: Progress reports

No comment was raised on the subitted progress reports.

4. AOB

4a. MOTA Version 5

Discussion
NL reported that according to the MoTA v.5 issues in relation to 3.6 Efficacy/effectiveness chapter were last discussed in 2005, remarking that after 2005 an E-consultation was launched on Efficacy and the result should be inserted in MoTA. **COM** will incorporate this point in the further revision of MoTA.

IE commented that according to the discussion made in the Workshop on Physical and Chemical properties and Storage Stability (TM I 2013), a clarification on the new regulation requirement on phys/chem test is requested. **UK** clarified that according to the new regulation Phys/Chem testing have to be conducted according to GLP or an equivalent international standards. TM asked COM to define in the guidance what stands for an equivalence international standard in alternative to GLP. **COM** answered that the issue belongs to the Guidance for Information Requirement BIP 6.1.

Conclusion
TM agreed on the way forward and the MoTA v.5 was endorsed in the General session. Point closed.

4b. Evaluation Manual for Product Authorisation

Evaluation manual version 1 was revised by **NL** including the comments received during the public consultation period. This revised version (version 1.1) was tabled at the PA&MRFG and CA meeting in December 2012.
CEFIC submitted comments on the overall document to which **NL** responded in the RCOM table. Comments received from MSs and **CEFIC** together with the revised documents were uploaded to CIRCABC for this meeting. **NL** gave an overview of the

comments and their responses. As **CEFIC** was not present to the meeting, **COM** asked **NL** to consult bilaterally on the issues presented in the RCOM table.
At the last TM, the discussions focused on the extrapolation proposal by UK, and further comments were requested to be submitted by the 18th January. **DE** and **FR** submitted comments on the extrapolation proposal. These comments were discussed at the workshop on storage stability that took place in connection with TM I 13. **NL** gave an overview of the relevant agreements of the workshop in respect to the comments. **UK** mentioned that the discussion on the surface tension and viscosity in liquid formulations will be amended to be in line with the ECHA guidance, PET and HDPE type packaging materials are not to be extrapolated between eachtother and the pack size will not be an issue. **NL** confirmed that these agreements will be included in the evaluation manual.
The full minutes of the workshop will be uploaded in the folder of TM I 2013.

Conclusions
The TM endorsed the evaluation manual version 1.1 at the General session.
As **CEFIC** was not present at the TM, they can consult bilaterally with **NL** in respect to their comments for the next revision. The current version of the manual will be send to the CA meeting.

4c. BIP, 6.1 –Guidance for Information Requirements

The comments received during the commenting period were discussed.
ECHA will provide a revised RCOM table with the conclusions of the TM for each comment and will revise the document accordingly.
On Section 7.6.4 ECHA will prepare a proposal and distribute this to the TM for a written consultation round.

ECHA informed that upon completion of the revision, the document will undergo editorial check and will then be sent for public consultation to stakeholders and CAs.
Any question or request of further information should be addressed to ECHA.

4d. BIP, 6.3 –Technical equivalence

The scope of the document has been revised, from a more scientific technical one in the beginning to a more procedural one now.
The comments received during the commenting period were discussed.
ECHA will revise the document accordingly.
ECHA informed the TM about the request from the CA meeting to consider also applications for technical equivalence before approval. If ECHA will consider also these applications ECHA will revise the document accordingly.
ECHA informed that upon completion of the revision, the document will undergo editorial check and will then be sent for public consultation to stakeholders and CAs.
The TM was asked to send written comments to ECHA by April 15.
Any question or request of further information should be addressed to ECHA.

4.g BIP 6.8 –Giuidance on microorganisms

The item was only for information; SE informed the TM for an upcoming workshop in June 2013 and invited interested MS to participate.

4f. Guidance on Efficacy of PT 8

COM explained that the draft guidance document was prepared by FR and it has already been commented on and the general opinions were discussed during the previuous meetings. As a result of those comments and discussions, the document was rewritten and the consolidated version of the proposal was uploaded on CIRCABC for commenting. The comments were submitted by NL.

FR reported that they had a bilateral discussion with **NL** and they agreed on including the user category in the guidance document. Further it was also agreed on the information to be presented on the label regarding the non-professional users and additional comments on this aspect were submitted by DE during the workshop. It was proposed to remove use class 3 and 4 and replace them with 'indoor/outdoor' on the label claim. The document will be revised according to the comments received.

Conclusion
The document will be revised by FR and the new version will be uploaded on CIRCABC.

4h. Guidance on Efficacy of PT 22

COM reported that FR submitted a proposal of the draft guidance document for the efficacy of PT 22 (embalming products). A proposed guidance document is used in France for the evaluation of PT 22. It was translated into English and mentioned at the occasion of iodine's discussion at TMII 2012. Some MSs had expressed their interests in that document and therefore it was uploaded on CIRCABC and it was presented at that meeting. The intention of putting it on the agenda of TMI was to gather the opinion of other MSs to see whether it can be developed further and to be used in all MSs. It was also underlined that the aim was to have it endorsed at TMII in June 2013. The comments were received from NL and UK before this meeting.

FR presented the document and explained that if there is an agreement on its content during the commenting period, then FR will delete the non relevant parts and harmonise the document. However, if a common agreement cannot be reach during the commenting round, then FR expects to have a working group on that guidance document in ECHA in the future.

DE reported that they have some editorial comments that they did not manage to send before the meeting and they will forward them to FR in writing after the meeting.

Conclusion
It was agreed to set up a written commenting round until 15/04/2013 and send comments to FR. Based on the comments it will be decided whether the development of the guidance document will be started or not.

SPECIAL SESSION

START: 14th March 2013 at 09:00 hrs
FINISH: 14th March 2013 at 13.00 hrs

WORKSHOP ON EFFICACY OF PT 21

Discussions took place on proposals for the revision of the draft guidance on the PT 21 efficacy testing, mainly on the types of tests available, types of fouling organisms in fresh and seawater, acceptance criteria of the efficacy tests and positive controls.
Drafting responsibilities were allocated between MSs and IND.
When the guidance will be revised, it could be tabled as a TM agenda point at the General session, aiming for the TM in June or September. The guidance could be revised at a later stage considering the experience of IND and MSs, but it is important to have a first draft endorsed at the TM as soon as possible.
When ECHA will take over the efficacy guidance work, they would have a good starting point.
More detailed summary of the discussion will be circulated among participants.
The final minutes have been revised and uploaded to the dedicated workshop folder under TM I 2013.

ENVIRONMENT SESSION

START: 14th March 2013 at 09:00 hrs
FINISH: 15th March 2013 at 16.00 hrs

1. GENERAL ISSUES

1a. Preparations for the hand-over of the activities under the Review Review Programme from the Directive (BPD) to the Regulation (BPR). (For information)

Information reported in the section TOX and GEN above.

1b. Evaluation of disinfectant by-products

Information reported in the section TOX above.

3c. BIP 6.1 – Guidance for Information Requirements

The comments received during the commenting period were discussed.
ECHA will provide a revised RCOM table with the conclusions of the TM for each comment and will revise the document accordingly.
Further discussion will take place as a written commenting procedure on metabolite trigger values for water/sediment studies, the use of the die-away test in STP studies, degradation vs. dissipation half-lives in field studies and the relevance of bound residues in the evaluation of fate studies.
ECHA informed that upon completion of the revision, the document will undergo editorial check and will then be sent for public consultation to stakeholders and CAs.
Any question or request of further information should be addressed to ECHA.

3d. BIP 6.7 – Cumulative and synergic effects

DE presented the revised version of the document and the changes made following comments received.
The TM was asked to send written comments to DE by April 05.
ECHA informed that upon completion of the revision, the document will be sent for consultation to the CA meeting.
Any question or request of further information should be addressed to ECHA.

3.l BIP 6.8 –Giuidance on microorganisms

The item was only for information; SE informed the TM for an upcoming workshop in June 2013 in Stockholm and invited interested MS to participate.

3. AOB

3a. MOTA Version 5

COM presented the revised version of MoTA; two documents available on CIRCABC (1_ revised version of MoTA and 2_ list of new issues inserted into MOTA).
Comments were received by **FR**, **NO**, **NL**, **SE**, **DE, UK.**

The following points were agreed by the TM.

3a.1 MoTA Chapter 5.2.2. on degradation
The sentence introduced by **NO** *"Normalisation has to be done for biological degradation DT50s, not for abiotic DT50s"* should be deleted. Normalisation of abiotic DT_{50} such as hydrolysis to 12°C would be performed since is temperature dependent and follow the Arrhenius equation.

Q2: Do DT_{50} values have to be converted to a standard temperature?
A2: (TM IV 07)
As stated in the TGD, Part II, §2.3.6.1 and Table 5 "Definition of the standard environmental characteristics", DT50 values shall be normalised to 12°C for all compartments, except for the marine water compartment, where normalisation should be performed for a standard temperature of 9°C. ~~Normalisation has to be done for biological degradation DT50s, not for abiotic DT50s.~~

3a.2 Details reported for city-scenario Q1 Chapter 5.2.5 on PT 10
COM suggested to leave the text how is presented, since the discussion on the city-scenario (developed by **NL**) will be discussed at the next TM in June. **DK** had already some reservations on the text, on which **NL** was asking **DK** for proposals. Modification to the text will be re-discussed and included within the next MoTA revision.

Q1: Which input values should be used to calculate emissions reaching the STP for the city-scenario in PT10?
A1: (TMIII 10, TM IV 2012)

- Consider that 100% of the houses are of the specific type (brickwork, wood, etc.) so they would need treatment with PT10 product.
- Include market share if documented by applicant with tonnage data.
- As a worst case, consider 4000 houses in the city catchment area or 300 commercial buildings together with 2500 standard houses (will result in 4000 standard houses).
- In the Emission scenario document for biocides used as masonry preservatives PT10 (Mignè 2002) a suggestion for treated roof area in a city is proposed.
- Two methodologies proposed for the city scenario: a) Normal case approach, were leaching data is available and b) Worst-case approach, were leaching data is lacking.

For the proposed city scenario
Normal case approach, were leaching data is available. Following defaults are advised:
a service life of:

- years for paints (which is also proposed in the revised ESD for wood preservatives) and sealants around windows and doors outside;
- 10 years for indoor fillers (sealants);
- 25 years for outdoor joint fillers and outdoor plasters;

- products holding the specific preservative is applied on all houses in a city (fhouse = 1.0).

These values may be reduced when sufficiently substantiated with tonnage data; the surface of:

- a standard house is 125 m² (default for wood preservatives);
- joint fillers applied between bricks per house of 125 m² is 35 m² (see appendix);
- exterior windows frames and doors is 3.5 m² per house ;sealants around windows and doors on a standard house is 2 m²;
- joint fillers between tiles in the wet area of bathrooms is 0.24 m².

b) Worst-case approach: 100%leaching is assumed during the product's service life. The following defaults values are advised:
- The value for application rate (DE suggested 4 kg/m3).
- The value for surface area of silicone caulks (DE suggested 0.12m2).
- Number of houses treated daily depends on service life of the product.
- The default value for fhouse and approaches to lower this factor (1 with the use or tonnage or market share data, or number of treated houses, as possible approaches for refinement).
- Fraction of product lost during application (default for non-professionals of 0.05).

3a.3 Chapter 5.2.10 on PT21
The Q10 was deleted since **SE** remarked that national scenario could be and are currently used. The question in the update document from UK on PT21 was already deleted.

Q10: Should any additional scenarios from those used in MAMPEC v.2.5 be used?
A10: (*TM III 2011*)
No, national scenarios are not necessary.

3a.4 Chapter 5.2.10 on PT21 (Q11)
The question is correct but incomplete. **SE** highlighted that parameters for the *"wider environment"* should be checked and verified, a proper assessment should be performed (currently default values are accepted as they are proposed in MAMPEC). This issue should be taken into account in the UK document on the PT21 Technical Agreements. Modification to the text will be included within the next MoTA revision.

Q11: Which default values should be used for "the wider environment" scenario?
A11: (TM III 2011)
For Annex I inclusion, the dimensions as defined in MAMPEC v.2.5 should be used.

3a.5 Chapter 5.2.2. on degradation (Q2bis)
Discussion on whether TM needs some additional Guidance on PBT assessment for Biocides took place. PBT working group in ECHA will define properly the issue. Q2 bis on the use of field data in the PBT risk assessment was deleted.

Q2 bis: Should DT50 be normalised to a temperature of 12°C in the PBT-assessment and are field studies taken into account?
A2 bis: (TM II 2009)
In the PBT-assessment normalisation of degradation half-lives to a temperature of 12°C is necessary. Results of field studies are not taken into account in the PBT-assessment.

3a.6 Chapter 5.2.4. on PT08 (Q7)

On the applicability of the new water pond volume the Q7 was modified. Since the new pond volume was already use for IPBC (RMS: DK) CAs should be consistent and proceed using the new pond volume value of 1000 m^3. The document should be endorsed by the OECD Task Force on Exposure Assessment at the next meeting in 2013.

Q7: Should the bridge over pond scenario for UC3 be included in the CAR even if this is not proposed as an intended use by the applicant?

A7: (TM V 07)

The bridge over pond scenario is not used to evaluate the application phase but the use phase, in order to describe the emission pathway into open water bodies, and should therefore be included in the CAR.

However, it should be kept in mind that the current bridge over pond scenario represents a worst case scenario. A new scenario covering the risk from in-situ application (e.g. brushing) as well as the leaching from treated timber near or above static water bodies was developed for the revised PT08 ESD as "Draft revised emissions scenario document for wood preservatives" was endorsed by the Task Force on Biocides (TFB) and it has been submitted for endorsement by the Task Force on Exposure Assessment (TFEA). This revised scenario is proposed to be used for the bridge over pond calculations in connection to the Annex I inclusion of a.s. (e.g. for a.s. IPBC RMS: DK) as well as at the product authorisation.

3a.7 Chapter 5.2.10 on PT21, Q12

According to the suggestion made by FI on Q12 by adding the reference to "metabolite" since CAs use MAMPEC for active substances. **UK** suggested that the point is related to the discussion on loses via application and removal loads, so a differentiation for metabolite and active substances could not be performed. **SE** indicated that clarification is needed, that the point is regarding applications and not service life. UK reported that they always use MAMPEC for service life. **UK** will take on board this issue in the revised document on PT21 Technical Agreements.

Instead the availability of MAMPEC version 3.0 with updated parameters, TM agreed that CAs will continue to use MAMPEC 2.5. In the document on PT21 Technical Agreements a reference to this point should be done. Modification to the text will be re-discussed and included within the next MoTA revision.

Q12: Which approach should be used for the calculation of PEClocal, dissolved for marine environments?

A12: (TM III 2011)

In order to harmonize calculations for all PT 21 a.s, as first tier the TGD equation will be used. MAMPEC calculations will be used for the second tier.

3a.8 Chapter 5.4. on groundwater concentration limit (Q1)

SE reported the decision on PPP risk assessment for the rodenticide Bromadiolone (RMS: SE), where the GW limit should be lowered to the 0.016 µg/L. TM agreed that the limit of 0.1 µg/l should be applied for single biocidial a.s., unless a lower concentration limit is been set based on its toxicological properties . NL suggests following the legal text on the Drinking Water Directive 98/83 for an appropriate formulation in the revised MoTA.

Reference to the Drinking Water Directive 98/83 will be added to MOTA: "the limit of 0.1 µg/l should be applied for single biocidial a.s., unless a lower concentration limit is been set based on its toxicological properties ".

3a.9 Chapter 5.4. on groundwater concentration limit (Q1)

DK and **DE** had some reservation on the following text *"For metabolites shown to be non-relevant according to the tiered SANCO guidance, a final drinking water risk assessment may be required to demonstrate the acceptability of non-relevant metabolite concentrations above the 0.1 µg/L"*. The text was proposed by **UK** in reference to the SANCO guidance SANCO/221/2000 rev.10 (2003), were a final drinking water risk assessment for the non-relevant metabolites with concentrations above 0.1 µg/L should be performed in order to confirm their acceptability.

Q1: What groundwater concentration limits should be applied to single biocide active substance, metabolites and mixtures (e.g. when the active substance is defined as a mixture block)?

A1: (TMIV 2011, TM IV 2012)

For single biocidal active substances the limit of 0.1 µg/l[a] should always be applied in groundwater. This is an absolute trigger, and no risk assessment or relevance assessment of active substance concentrations above this limit is ever possible. The 0.1 µg/l should also be applied to all metabolites in a tiered assessment scheme. Any metabolites predicted to occur above the 0.1 µg/l should be assessed with regards to their relevance according to the existing PPP SANCO/221/200-rev.10 (2003). Where a metabolite is determined to be relevant according to this guidance, the 0.1 µg/l must be strictly applied just as it is for a biocide active substance (i.e. no risk assessment of a relevant metabolite above 0.1 µg/l is ever possible). For metabolites shown to be non-relevant according to the tiered SANCO guidance, a final drinking water risk assessment may be required to demonstrate the acceptability of non-relevant metabolite concentrations above the 0.1 µg/l.

The 0.1 µg/l limit should also apply to all individual fractions of a biocidal active substance mixture or mixture block, when these individual fractions are separately quantified with regard to groundwater contamination potential. Additionally for a mixture or block group of biocide active substances, the higher 0.5 µg/l limit should apply to the total mixture concentration predicted in groundwater. For mixtures of metabolites formed from active substance mixture or mixture blocks, the same approach as applied to individual metabolites should apply. The 0.1 µg/l limit (for individual metabolites) and the 0.5 µg/l (for total metabolite mixture concentrations) should both be applied at the first tier. Where either of these limits is exceeded, the PPP SANCO guidance on relevance of metabolites should be applied.

[a]*Note that for some substances a lower limit than 0.1µg/l may be set on the basis of, for example, toxicological data. In these situations the 0.1µg/l limit should be replaced with the lower toxicological limit when applying the guidance above.*

3a.10 Guidance Document on PT13

IND is developing a Guidance Document on PT13, a reference and modification to the text will be re-discussed and included within the next MoTA revision.

3b. Evaluation Manual for Product Authorisation

Evaluation manual version 1 was revised by NL including the comments received during the public consultation. This revised version (version 1.1.) was tabled at the last

PA&MRFG meeting and CA meeting in December 2012, and was presented for the first time at TM I 2013.
At TM IV 2012, on the evaluation manual agenda point there were no issues raised. After the meeting **CEFIC** sent written comments, and these were uploaded to CIRCABC as an RCOM table where **NL** provided written comments. The RCOM table was uploaded as one document for all the TM sessions. There were no issues raised at the meeting.

Conclusion
Evaluation manual was endorsed at the TM Environment session, and also in the previous days in the General and Toxicology session. Therefore the version 1.1 of the evaluation manual will be sent further to the next CA for endorsement.

3.e Study CEPE regional marina scenario

Background
This was the second discussion at the TM on this document. The discussion at TM IV 2012 focused on the Baltic input parameters (vessel occupation, DOC value and salinity), layout of the marina, representatively of the marina, defining the protection goal of marinas and the inclusion of the Black Sea marinas in the study. MSs were invited to send further comments by the end of January. **UK**, **SE** and **FI** sent comments which were uploaded in CIRCABC. In response to these comments, **CEPE** sent a document to **COM** and the commenting MSs in the first day of the TM. As the deadline to upload TM documents have passed and the TM started, it was not possible to upload this to CIRCABC for TM I meeting. Therefore, **COM** asked **CEPE** to orally present the ideas of the document as not all the TM participants had received this document, and MSs that received the document by email might not had time to consider the submitted information.

Discussion
SE presented the main comments in their paper. In response to the **SE** comment that 5 of the marinas were actually located in the fresh water, **CEPE** agreed to modify this. **SE** presented to the TM a PowerPoint slide with the Baltic borders and the areas of the transition, and the variations of the salinity in various regions. In respect to the Baltic salinity, **SE** thought that an appropriate average salinity would be 6 PSU. For the value of the DOC, **SE** proposed 3.8-4 mg/L, as a lower value would provide more protection.
CEPE reminded that the scope of the document was to define the regional scenarios, and not specific national scenarios. In respect to the Kattegat marinas, **CEPE** noted that the analyses showed that these marinas can be grouped to the Baltic marinas. **SE** responded that the Kattegat should not be considered as a part of the Baltic Sea. The Kattegat is part of a transition area between the Baltic Sea and the North Sea. The Kattegat does not share the special characteristics of the Baltic Sea (i.e. low species diversity, an enclosed area with slow water turnover rate, heavily polluted) and including the Kattegat in the Baltic Sea would be contrary to the work with assessing and handling the sensitivity of the Baltic Sea.
CEPE asked the MSs with the border to the Baltic Sea to comment on this. **CEPE** asked that before criticising the model, to consider whether the model provides realistic PEC values to be compared with the monitoring data.

FI shared the **SE** concern about the exclusion of the Kattegat from the Baltic region analysis**. FI** presented their written comments**,** asking for detailed information about the marina, and not only the links in the Appendix 5. Marinas chosen for Finland were not the most representative ones. **FI** sent information on national antifouling scenario, where it

was highlighted that the Finnish marinas were shallower, the volume per boat is lower, this influencing the PECs.
CEPE referred to the representative marinas, and the protection goals. **CEPE** asked not to concentrate on the national marina scenarios, but for the regional marina scenario. **FI** and **SE** wanted to continue the discussion on which marina to include in the document, highlighting that some of the marinas included in the study are situated so far north that AF use is not needed and some of them are so small that they do not fulfil demands of marinas.. It was also discussed to exclude the Gulf of Bothnia from the scenario, since neither **FI** nor **SE** have any antifouling products approved for this region. **CEPE** accepted to add the marinas that MSs considered important to the model, and agreed to provide more information in the Annex 5.

UK submitted proposals on how to take the document further. **UK** appreciated the high number of marinas analysed (150 marinas). **UK** encouraged the use of probability distribution model. As this presents the disadvantage of higher time and costs involved to do the work, **UK** asked MSs to check how to help in this. **CEPE** suggested avoiding probabilistic model as the first step, referring to the information that have submitted recently (that were not uploaded in CIRCABC for TM I).

DK did not comment in the second round but also did not receive responses to their previous comments. **CEPE** responded to **DK** in a late submitted document that was not uploaded on CIRCABC. **COM** asked **DK** and **CEPE** to continue this consultation bilaterally.

At the request of **CEPE** it was agreed that **SE**, **FI**, **DK** will send input to define the Baltic area. **UK** noted that the other MSs that have shoreline to the Baltic to be also included in the consultation. **SE** had a seminar on the sensitivity of the Baltic Sea, and with this occasion they have some contact points from other countries around the Baltic Sea. **SE** offered to ask these contact points the feedback for this discussion.

AT asked if there is something foreseen for the fresh water scenarios, how to deal with mutual recognition on fresh water. **CEPE** pointed out as a reference OECD ESD on antifouling.
COM reminded to respect the deadlines for sending documents to be uploaded on CIRCABC.

Conclusion
MSs were invited to continue the bilateral consultation and send further comment to the document by the 15th April. Other MSs around the Baltic Sea, but also for the Mediterranean, Atlantic and Black Sea were invited to send their input before the next revision is performed by CEPE.
Point to come back to the TM once the revision is performed, taking into consideration the comments received from MSs and the agreement of the TM discussions.

NOTE: After the TM, MSs indicated that they would want to send further comments after the established deadline. The document sent by CEPE via email on the 11th March will be uploaded on CIRCABC for the discussions in TM II
(TMII2013_Env_Regional_Marina_Scenario_CEPE_responses_March13)

3.f Substances of Concern

COM reminded that at TM IV 2013 2 proposals from UK and DK on how to assess substances of concern were discussed. As no agreement was reached at the last meeting, the TM requested further input from the working group (WG) on substances of concern that met on the 10th December 2012. The WG decided to make a side-by side comparison of examples from various PTs under both DK and UK proposals (ex: wood preservatives and disinfectants). It was understood that this huge exercise would take time, so the point comes back to the TM as information point and not for the discussion.
DK and **UK** informed that the work on the examples using both approaches is still on-going.
COM asked also other MSs to support DK and UK in this exercise.

3.i Outcome of "Evaluation of Simple Treat" project and further approach

DE informed that a report has been finalized and MS have already received it. DE asked MS to send comments by **30th April 2013.**

3.k. Biocides higher tier guidance.

Background
COM introduced this agenda point. In TM III 2012 IND was asked to redraft their proposal focusing on mesocosm studies and WFD EQS approach. COM requested the development of the guidance in 2009 for the use of mesocosm studies dataset in the framework of biocides risk assessment. **IND** presented at TM I 2012 the outline of the guidance. **IND** received comments from **DE**, **SE**, and **NL**. **FR** will report comments after TM. A workshop was planned to finalise the guidance document (GD).

Discussion
DK reported different uncertainties issues as the GD AF proposal, since for PPP in the Northern zone and Baltic countries an agreement has been made not to use so low AF. They added that recovery time agreed for PPP in the Northern zone is 4 week as a consequence of the shorter growing season. **DK** decided to have an AF of 5 for one available valid mesocosm study. Difference between PPP and Biocides in the exposure pattern is not well reported; additionally most of these studies will be conducted with formulated PPP. **SE** agreed with **DK** on recovery and always oppose to the use of the AF 1. When evaluation on this mesocosm study is performed recovery should not be used in Biocides. Several TM discussions concluded that recovery is not appropriate even with intermittent exposure. **DK** agreed with **SE** that recovery has so far been rejected for Biocides. **UK** agreed with **DK** that a good understanding of the pattern of environmental exposure for biocidal use is a requisite, even if some reference is present in the GD for intermittent or continuous release. In the workshop the exposure pattern should be covered in details; **IND** and **NL** agreed. **NL** asked IND to prepare a RCOM table similar to the one used for commenting on other dossiers. IND agreed to do so.
IND highlighted that a clear commitment should be defined since MSs on one side wait for the finalisation of the EFSA GD ("Guidance Document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters") and on the other side they contest the exposure pattern in the proposed GD. The GD focuses on the intermittent and continuous exposure that is comparable to PPP scenario, the point is when and how to use these studies (e.g. reduced AF or just in case of intermittent releases). Since the EU has countries with different approach, the ideal is to have a baseline valid for all the MS, this does not exclude national deviation from the EU framework. **NL** and **SE** remarked that the EFSA Guidance is important for the future

improvements of the Biocide GD. **DK** reported that at TM III 2012 it was decided to not only consider the EFSA GD but to look more in the EQS from WFD. **NL** remarked that EQS, EFSA GD and Dutch Document are core documents, adding that GD should report the fact that the draft was only prepared by IND, (without the contribution of NL as suggested in the current version). **NL** asked for the involvement of ECHA in developing this GD. **COM** will consult with the ECHA colleagues about the future directions and argued on whether having 3 workshops at the TMII in June will be feasible, (PT08 leaching, Substances of Concern and Higher tier GD). **COM** reported that Substance of Concern will be dedicated for the Toxicological Session. **COM COM** confirmed that for this work they created a dedicated folder, under Environment Related Issues in CIRCABC "Guidance for higher tier approaches in aquatic effect assessment". **IND** and the following MSs will to attend workshop: **BE**, **DK**, **DE**, **SE**, **NL**, **FR**, **UK**, **FI**, **CH**. **COM** will discuss with NL and IND on the feasibility of the workshop for the next TM.
NL remarked that the GD should report that the GD is draft by IND, and that NL only commented the Draft.

Conclusion
IND will provide a RCOM table with comments received (DE, SE, and NL).
The exposure pattern should be covered in details in the workshop. The following MSs willing to attend the workshop: BE, DK, DE, SE, NL, FR, UK, FI, CH.
NL will check availability to contribute to organisation of workshop.
COM will have a bilateral discussion with IND and NL on the feasibility to organise a workshop at the next TM.
COM will check on the possible involvement of ECHA in following the development of this GD.

3.m Consolidated PT 21 technical agreements

Background
COM introduced the document prepared by **UK**, which should be considered as a first start of a document which would replace the existing chapter about PT21 in MOTA. **UK** presented their proposal. **UK** explained that they had taken out the agreements on PT21 from the existing version of MOTA and had revised the minutes from previous TM where there had been generic or substance-specific discussions on PT21 in order to include in this document the agreements that had found a common ground.
UK reported there were comments from **IND** in three points where **IND** disagreed and highlighted that the current version only includes the environment agreements and in a single final version the human health agreements could be included.
UK also informed that they were not aware of the existing document produced by CEPE with agreed consolidated list. **COM** informed that this was a document for information and was not discussed at the TM level.

Discussion

3m.1 Comments on agreement 1.12
UK reported that this point made reference that the market share data could be used for commercial shipping, as they are associated with long service lives and stable markets. This market share data was not agreed for pleasure crafts in marinas where historical or average market share is not necessarily a good indicator of future market share. **UK** also indicated that many MS have a very small number of active substances available for the amateur craft market across the EU, so EU average data on market share would not really be relevant at a local scale.

This was considered by **UK** an agreement taken at TMIII 2011 and **UK** highlighted that this was a case where at the following TM (TMIV 2011) it was agreed for commercial ships, but the question whether this could be done for pleasure crafts was postponed by the TM to a later stage. **NO** stated that it was agreed on using market share data for the commercial market, but for the pleasure crafts it was agreed not to use it as this is a more dynamic market. **FI** reported that they had also interpreted that the market share data could only be used for commercial ships, but not for pleasure crafts. **IND** would not like to rule out the possibility to present more data in the future, since if a particular biocide provides robust data to suggest an effective and realistic market share, it could be incorporated to a future risk assessment.
UK proposed to reword the last part of the agreement in order to leave it more open and to reflect the minutes of the TMIV 2011, where it was stated that the TM would postpone the decision to a later stage. **UK** also asked other MS and IND for opinions and to decide if they are happy with the new wording at next TM.
COM agreed with **UK** proposal to reword the sentence in order to reflect better the agreements of TMIV 2011.

3m.2 Comments on agreement 2.2
UK indicated that this agreement states that when using the total system degradation rate from water sediment, it should be taken care not to double count abiotic processes by also including a hydrolysis rate constant. The comment by CEPE was that this was not fully recorded in the minutes of TMIII 2011. **UK** stated remembering the agreement on that TM, although it might have not been properly recorded in the minutes. **UK** asked MS if they were happy with the wording of point 2.2.
COM suggested that the sentence might be reworded in order to reflect better what the discussion was about. **COM** will also come back to the minutes to check and compare the wording.
UK stated that what might be incorrect was not the wording of the agreement but the source, since the minutes of the TM did not cover that point, so **UK** proposed to change the source of the agreement. **COM** asked **UK** to reword so that other MS could see the reflection of the discussion and agree on the final proposal. **NO** also confirmed that in TMIII 2011 this point was agreed and asked **UK** if this was part of a guidance document on how to perform the ED50 evaluation which was agreed on TMIII 2011. **SE** also reported that they agree with **NO**.

3m.3 Comments on agreement 5.1
UK informed that these comments were related to sediment. The agreement stated in the proposal was that "A risk assessment for sediment dwellers is always required irrespective of the levels of active substance or metabolite formed in the sediment phase of a water sediment study. This is to address risks posed by leaching from intact paint particles that may be deposited on the sediment layer". At TMIII 2011, the proposal of using 10% trigger in sediment to perform the risk assessment was discussed. **UK** had in their recollection that **SE** made the comment that using the occurrence in a water sediment study would not reflect the fate and behaviour of intact paint that was lost on removal and maintain activities, where a loss of intact paint that would be deposited on the sediment layer might exist. **UK** considered that the view of **SE** was that this 10% trigger should not be used in the water sediment study, but conservatively the risk to the sediment should always be assessed for the a.s. and metabolites because the leaching from intact paint would be deposited on the sediment layer. **UK** stated that this discussion was not fully recorded in the minutes which reflect that the 10% trigger for parent and metabolites should be used. The **UK** recollection was that **UK** and **SE** would require the information. **UK** asked to reopen the discussion if other MS have a view either on sticking on the 10% trigger or not.

NO agreed with **UK** that the wording in the document was not in line with the conclusions reflected in the minutes from TMIII 2011. **NO** reported, although the 10% trigger value should not be used for the a.s., it should be used for metabolites (TM I 2012 conclusion) and this is what they commented in the **UK** document.
IND stated that they have not been involved in all the discussions and asked if the risk of paint particles would be evaluated by taking the **SE** approach to do the tier I sediment evaluation on the basis of suspended particles given the emission of paint particles from application and removal processes which lead to a particular release into the water column. **IND** stated that perhaps they should await the accurate record of the minutes and previous discussions, rejecting the 10% metabolite concern guidance which has been followed at the TM.
FI stated remembering the discussion regarding tolylfluanid as this substance was not detected in the sediment phase of thethe water sediment study. **FI** reported that it was agreed that the risk assessment for sediment was not needed for tolylfluanid.
COM outlined that the trigger value of 10% would be checked.

3m.4 Temperature
UK reported about the confirmation of the temperature which should be used in MAMPEC, since in the original CAR UK had used a range of temperatures, the TGD 9°C for marina environment and the OECD ESD temperature of 15°-20°C. **UK** asked to confirm if there was an agreement to use the TGD temperature and that they would include this as an extra agreement.

3m.5 Fish net scenario
NO sent a proposal for rewording on agreement 1.10, concerning the fish net scenario. This scenario was developed as part of the evaluation of an active substance dossier. **NO** reported that the TM had not yet decided using this fish net scenario generally, since the decision at that time at TM was to launch an e-consultation. **NO** informed that the consultation would be re-launched by them after the summer holidays. **COM** also confirmed that **NO** will re-launch the e-consultation regarding the fish net scenario after summer. **SE** informed that this e-consultation was already going on for some time and a lot of information already existed. This information and related questions had been submitted to **NO** as a start of the e-consultation. **NO** asked **SE** to provide all the new and latest questions and information before summer holidays in order to **NO** to organize how to proceed with the e-consultation. **SE** affirmed that there had been a discussion with **NO** and **COM**, and since **NO** has a considerable experience with fish cultivation and has many guidance documents, **SE** preferred **NO** to continue with this topic. This was agreed.

3m.6 Sediment
FI would like to come back to the point of sediment (agreement 5.1). In the minutes of TMIII 2011, it was written that "**FI** gave an example of a substance where they have not done risk assessment for sediment because the active substance was rapidly degraded and no partition to the sediment was observed. However, for the risk assessment of the metabolites, in which partition to the sediment was performed, **FI** wondered if this approach would be considered acceptable. **COM** confirmed that this approach was acceptable." **FI** confirmed that, at least for tolylfluanid, it was accepted that the sediment risk assessment was not needed.

3m.7 Inclusion of human health
CEPE expressed that it was beneficial that **UK** had prepared a separated document isolated from the CEPE document, and indicated that they were close. The CEPE document included the human health agreements, since there had some discussion on that field (mass balance between in-service-release vs application, removal exposure). **CEPE**

asked if it would be beneficial to include the human health agreements into a single document as the MOTA. **COM** replied that this issue could be taken to the human health part and considered for the next MOTA version.

3m.8 Risk mitigation

NL expressed some remarks to the document. In agreement 1.8 about risk mitigation it is stated that the level of risk mitigation measure should be quantified using the data from the CEPE and CESA surveys. However, NL did not know these documents. **CEPE** stated that the documents had already been circulated but since MS did not have them, these documents would be recirculated. **FI** asked if the risk mitigation measurements were also proposed for pleasure crafts since for **FI** understanding RMM had not been discussed for pleasure crafts. **CEPE** reported there had been a discussion on pleasure crafts where the rough documents that came out from the industrial emission directive were introduced. Maintenance and repair of the crafts are within the scope of the industrial emission directive, which will be regulated through local authorities. Also the best practice document gives examples of risk mitigation that could be applied at the local level. The CEPE understanding was that the MS would discuss this, however since BPD does not intend to double regulate, this aspect is already covered by the industrial mission directive, taking the scope of prevention and control regulation. **UK** confirmed that in the minutes there was an old action by **COM** to speak to colleagues who were covering the industrial emission directive to see their view on that point. **UK** said this would be a good idea. **COM** stated they would check that point in order to complete the information.

NO wanted to come back to the risk mitigation factors which were agreed only for the commercial ships in TM IV 2011. For pleasure crafts, **NO** expressed that TM had not made any agreement. It was agreed that TM could not use any figure on the risk mitigation for the do-it-yourself products, so there was not conclusion on this topic, although for the commercial marked an agreement was reached.

3m.9 Shipping lane scenario

NL pointed out another remark on point 2.3. This agreement stated that when assessing risks in the shipping lane scenario, a correction factor of 3 to correct for biodegradation in remote areas has been agreed. **NL** asked to include a clarification in the text that this factor is to be multiplied as the degradation is slower. **NO** clarified that the reference is to the TGD.

3m.10 Photolysis

NL stated they had some problems with the use of module in MAMPEC, since this part requires validation, which has not been done, which included that there might already be photolysis in other degradation coefficients. Furthermore, in the marine it was agreed not to use photolysis since there is no certainty the photolysis is happening there. **NL** considered there were still some problems with this proposal. **NL** suggested putting effort to show that under realistic conditions this occurs in the marinas. **CEPE** replied that the issue of the photolysis module validation was raised for copper and zinc pyrithione discussion, where photolysis is critical. CEPE also commented about photolysis in marinas that CEPE would not understand whether the evidence to suggest that was a reasonable position.

NO agreed not to use photolysis in the marinas, since the light would not penetrate in the water. However, the new wording "in a higher tier for all scenarios provided that quantum yield data can be used in this new MAMPEC version" would take into account the water conditions also in the marina, since the water is not so clean in the marina as in the open sea. **NO** stated that in a first tier there was an agreement not to use photolysis.

CEPE proposed to go case-by-case basis in the cases of photolysis. The quantum yield data are needed to work effectively in the photolysis module, which was explicitly agreed

on the minutes. **CEPE** also agreed that in the same way that hydrolysis should not be double-counted if a total system degradation study is used, photolysis should not be double-counted. **CEPE** considered it should be a case-by-case basis. In a case where the applicant has performed a total system degradation study in the dark and a separate photolysis degradation study, it would be reasonable to define a photolysis rate in the MAMPEC module if the quantum yield data are available. **CEPE** stated that if the advanced photolysis module was not applied, a more simplistic approach to figure out how degradation occurred, and also took into account stability of the water. **CEPE** reported that there were assumptions in the modules and the ESD which would attenuate the intensity of the light as going down on the depth. **CEPE** considered that the concern of marinas filtering out light, and photolysis not being available, were reasonably handled in MAMPEC and could be considered as a reasonable position to take. **CEPE** reported that there is height in marinas to allow plant growing on the bottom and there were sufficient evidence that light penetrates to the depth at around four meters in marine waters.
NL commented that the discussion was more sophisticated since the wavelength at which molecules absorb light has to be considered. **CEPE** replied that they had been involved in this topic at a local level, with the **NL** directly, and they agreed with the **NL** that a particular wavelength within a spectrum is important for the degradation. **CEPE** agreed that this is a justifiable position that should be taken on a case-by-case basis. According to **CEPE**, saying that there is no light penetration in a marina scenario would be incorrect.
NL replied that comparing modules with each other is very hard to validate. **NL** agreed that if photolysis is used, there should not be double-counting. **NL** stated that more information from representative studies was required for photolysis before adding it to the MAMPEC.
NO reminded the meeting that the **UK** document is a recollection of all the decisions which already were taken at the TM, at that this decision was taken at TMIII 2011. **NO** asked if it made sense to re-open the discussion points.
UK clarified that the agreement 2.4 came on the discussion of UK CAR for tralopyril and it reflected the agreement taken on TMIII 2011. **UK** also indicated that for that particular substance, although UK performed the higher tier photolysis routines of MAMPEC with the quantum yield data, they did not have a great effect on tralopyril. **UK** reminded that **SE** had provided them a lot of information that **SE** had included in one of their CARs, where **SE** had shown that the advanced photolytic routines of MAMPEC matched measured data. **UK** considered that the validation was not only that MAMPEC uses EXAMS, but also that there was a substance where it was accurately reflected degradation in real water. **UK** also informed that for tralopyril, as it was a new substance, there was not much information.
NL agreed with the **UK** approach on when to take into account photolysis. **NL** considered that for some substances this is a major issue and asked for good evidence, not just a photolysis study.
CEPE reported that looking at point 2.4 it looked clear that photolysis should be excluded from MAMPEC calculations at the first tier as it is a refinement option in a higher tier in a case-by-case basis. **CEPE** asked for the implementation of EXAMS in MAMPEC, where there is not a validation of a model with another model. EXAMS, as a calculation module, is a set of calculations and algorithms, though the same calculations and algorithms have been built into MAMPEC. Therefore, for all terms and purposes EXAMS is pushed into MAMPEC. According to **CEPE**, the effectively validated photolysis module in MAMPEC is EXAMS.

Conclusion

COM summarised that **UK** will revise the recollection of agreement and a further update will take place at next TM. Meanwhile, if any other MS has additional comments, please send them to **UK** and **COM** by 15th April.

COM asked **UK** if for next TM it would be possible to discuss the guidance on PT21 and **UK** confirmed it would be possible.

3.n EFSA 2nd public consultation on bees

Links to the EFSA public consultation:
http://www.efsa.europa.eu/en/consultationsclosed/call/130215.htm

3.o 2nd EU Leaching Workshop on wood preservatives PT 08.

DE and **ECHA** are preparing a workshop which will take place at TM II 2013 and will be open also to IND. **COM** will circulate this information.
MSs are requested to send comments to DE-UBA and ECHA by 15th April 2013.

3.p EFSA report on pesticides residues in food

EFSA report on pesticides residues in food is available from March 2013.
Link to the EFSA website:
http://www.efsa.europa.eu/en/press/news/130312.htm?utm_source=homepage&utm_medium=infocus&utm_campaign=pesticideresidues

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1/03/2013

Draft AGENDA

Biocides Technical Meeting I 2013

Place of meeting: Palace Grand Hotel, Varese, Italy

Date: 11th – 15th March 2013

START: 11th March 2013 at 14:00 hrs
FINISH: 15th March 2013 at 16:00 hrs

PLEASE NOTE that the schedure within the days is only indicative and discussion topics might be shifted, due to the length of the other discussions.

INTRODUCTION

START: 11th March 2013 at 14:00 hrs
FINISH: 11th March 2013 at 14:30 hrs

1. Approval of the agenda

2. Adoption of the minutes

3. Action List TM

4. Members of the Technical Meeting

5. Next Technical Meetings and CA meetings

TM II	10-14 June 2013
TM III	16-20 September 2013
TM IV	25-29 November 2013

CA I	27 February – 1 March 2013
CA II	15 -17 May 2013
CA III	10 - 12 July 2013
CA IV	25 - 27 September 2013
CA V	11 - 13 December 2013

TOXICOLOGY SESSION

START: 11th March 2013 at 14:30 hrs
FINISH: 12th March 2013 at 18:00 hrs

1. GENERAL ISSUES

1a. Preparations for the hand-over of the activities under the Review Review Programme from the Directive (BPD) to the Regulation (BPR). (For information)

1b. Evaluation of disinfectant by-products – For info
(Outocme of CA discussion)

2. SUBSTANCES
(The documents for this agenda item are distributed via the confidential CIRCABC site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

2.1 First discussion for the following substances

2.1a alpha-Cypermethrin PT 18 (RMS: BE)

2.1b Cyproconazole PT 8 (RMS: IE)

3. AOB

3a. Update HEEG – For info

3b. Update DRAWG – For info

3c. Evaluation Manual for Product Authorisation – For discussion

3.d Substances of Concern – For info

3e. BIP, 6.1 –Guidance for Information Requirements– For discussion (Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products)

3.f. BIP 6.4 HH- Block I (Hazard, effect-, exposure, and risk assessment) – For discussion
(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products)

3g. BIP 6.7 –Cumulative and synergic effects – **Mixture toxicity** - For discussion
(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products)

3.l BIP 6.8 –Giuidance on microorganisms – For info

(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products)
(E-consultation launch, by SE and NL)

3.h EFSA Guidance on Dermal Absorption to Biocidal products – For discussion and endorsement

3.i. MOTA Version 5 – For endorsement

3.j Reference values in ground water for rodenticides – For discussion
(Discussion requested by FR)

SPECIAL SESSION

START: 12th March 2013 at 09:00 hrs
FINISH: 12th March 2013 at 18.00 hrs

WORKSHOP ON PHYSICAL AND CHEMICAL PROPERTIES AND STORAGE STABILITY

A more detailed agenda will be circulated among participants.

1. Aims of the workshop
2. The use of accelerated storage data to support a 'provisional authorisation'
3. Specifying limits for the active content at the point of manufacture
4. Acceptable limit for the decrease/increase in the active content during storage
5. Major and minor formulation changes, the extrapolation of physical and chemical data and supporting frame formulations/ biocidal product families
6. Data required to support longer term shelf lives 2-5+ years.
7. Assessing substances of concern/relevant impurities in the formulation
8. Packaging extrapolations and flexible packs
9. Sampling of heterogeneous products
10. The stability of aversive agents and the retention of palatability
11. Variants of actives
12. Presenting batch analysis data and technical concentrates

GENERAL SESSION

START: 13th March 2013 at 09:00 hrs
FINISH: 13th March 2013 at 18.00 hrs

1. GENERAL ISSUES

1a. Reporting on the 49th and 50th CA meeting – For information

1b. Preparations for the hand-over of the activities under the Review Review Programme from the Directive (BPD) to the Regulation (BPR) (For information)

1c. ECHA presentation on preparatory activities for BPR – For info (Presented by ECHA)

2. Tracking System: Progress reports – For information

3. SUBSTANCES
(The documents for this agenda item are distributed via the confidential CIRCABC site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

3.1 First discussion for the following substances

3.1b alpha-Cypermethrin PT 18 (RMS: BE)

3.1c Cyproconazole PT 8 (RMS: IE)

4. AOB

4a. MOTA Version 5 – For endorsement

4b. Evaluation Manual for Product Authorisation – For discussion

4c. BIP, 6.1 –Guidance for Information Requirements – For discussion
(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products- COM)

4d. BIP, 6.3 –Technical equivalence – For discussion
(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products- COM)

4.g BIP 6.8 –Giuidance on microorganisms – For info
(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products)
(E-consultation launch, by SE and NL)

4f. Guidance on Efficacy of PT 8 - For discussion
(Document prepared by FR)

4h. Guidance on Efficacy of PT 22 - For info
(Document prepared by FR)

SPECIAL SESSION

START: 14th March 2013 at 09:00 hrs
FINISH: 14th March 2013 at 13.00 hrs

WORKSHOP ON EFFICACY OF PT 21

More detailed agenda to be circulated among participants.

1. Overview of the past TM discussions

2. Comments received from MSs at TM IV 2012 and responses from CEPE

3. Acceptance criteria for PT 21 testing – pass/fail

4. Future work planning

ENVIRONMENT SESSION

START: 14th March 2013 at 09:00 hrs
FINISH: 15th March 2013 at 16.00 hrs

1. GENERAL ISSUES

1a. Preparations for the hand-over of the activities under the Review Review Programme from the Directive (BPD) to the Regulation (BPR). (For information)

1b. Evaluation of disinfectant by-products – For info (Outcome of CA discussion)

3c. BIP 6.1 – Guidance for Information Requirements – For discussion (Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products)

3d. BIP 6.7 – Cumulative and synergic effects – For discussion
(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products)

3.l BIP 6.8 –Giuidance on microorganisms – For info
(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products)
(E-consultation launch, by SE and NL)

2. SUBSTANCES
(The documents for this agenda item are distributed via the confidential CIRCABC site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

2.1 First discussion for the following substances

2.1a alpha-Cypermethrin PT 18 (RMS: BE)

2.1b Cyproconazole PT 8 (RMS: IE)

3. AOB

3a. MOTA Version 5 – For endorsement

3b. Evaluation Manual for Product Authorisation – For discussion

3.e Study CEPE regional marina scenario – For discussion

3.f Substances of Concern – For info

3.g NOEC - PNEC setting for aquatic environment - For discussion
(Discussion requested by SI, in the frame of MIT)

3.h Use of OECD guidance for PT13 - For discussion
(Discussion requested by SI, in the frame of MIT)

3.i Outcome of "Evaluation of Simple Treat" project and further approach - For information (DE to inform TM)

3.j. Launch of the e-consultation on Silver Zinc Zeolite fish test. – For Information
(SE to inform)

3.k. Biocides higher tier guidance. For discussion
(Document prepared by IND and NL)

3.m Consolidated PT 21 technical agreements – For info
(UK to present)