Final minutes Open Session TMIV2011

Biocides Technical Meeting
12 - 16 December 2011

INTRODUCTION

The meeting was chaired by E. van de Plassche and for specific items on the agenda by A. Payá Pérez, J. Janossy, C. Pecorini, P. Piscoi, V. Rodriguez Unamuno, S. Pakalin, B. Raffael and L. van der Wal from DG JRC and J. Bernsel from DG ENV. E. van de Plassche welcomed the participants to TM IV 2011. Representatives from the MS, NO and CH were present at the TM. For specific items of the agenda, the interested companies were invited to attend.

1. Approval of the agenda

COM informed agenda item 6c of the TOX Session was withdrawn. The agenda was adopted without any further changes.

2. Adoption of the minutes

SE and NO distributed comments on version 2 of the minutes. It was agreed to take these comments into account.

3. Action List TM

COM apologised for not updating the action list for this TM.

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

-

5. Next Technical Meetings

2012

TM I 26 -30 March

TM II 18 – 22 June

TM III	1 – 5 October
TM IV	26 – 30 November
CA I	28 February – 3 March
CA II	22 – 26 May
CA III	3 – 7 July
CA IV	18 – 22 September
CA V	11 – 15 December

TOXICOLOGY SESSION

1. SUBSTANCES in PT 02

1a. Evaluation of disinfectant by-products

At TMIII-2011 the RMSs of sodium and ammonium bromide were asked to prepare a position paper on the evaluation of DBPs formed as a result of disinfectant use. **COM** stated that it was mere coincidence that the discussion originates from the evaluation of the two substances. The evaluation of DBPs relates to all disinfectants, not only to one class of disinfectants. **COM** urged to have the discussion on a general level without referring to substance specific confidential information. **NL** introduced two documents; the first describes the present management practices of DBPs by other regulatory frameworks, the second gives an initial overview of issues that is expected to be encountered while drafting the guidance on how to handle DBPs in the context of the biocidal products evaluation. In the second document **NL** proposed an approach based on using marker compounds and existing European and if necessary WHO drinking water limit values to go forward with the evaluation of DBPs. It was discussed whether the evaluation of the active substance be put on hold or proceed with a remark that the DBP issue should be considered at product authorization (PA). **DE** and **UK** were not in favour of postponing the hazard assessment of DBPs to PA arguing that a harmonised approach has to be established before AnnexI inclusion. **SE** preferred not to halt the evaluation of the active substances. **COM** proposed to discuss whether the evaluation of the DBPs based on the available information and the approach proposed by NL was possible. The **TM** approved the basic methodology of the NL**.** The selection of limit values was discussed. **NL** explained that some MSs do not agree to use WHO limit values in the absence of EU limit values, as for mutagenic carcinogens, they are set based on a life time cancer risk of 10^{-5}. **DE** asked what the consequences are when national limits are more stringent than the EU ones. In some cases, **DE** has lower values for swimming pool water than for drinking water; **DE** disputed that higher oral exposure compared to dermal is considered by the WHO report. For trihalomethanes, with high first-pass metabolism, higher blood level concentrations were measured after swimming compared to taking in *via* drinking water. **NL** proposed to use the most stringent values; for this a policy decision is needed. **COM** asked if the drinking water limits are only applicable for PT2. **NL** responded that for other PTs, like PT11 and 12 environmental limit values maybe more applicable. **COM** asked whether limit values exists for all relevant DBPs, or occasionally such limit value will need to be derived. **NL** believed that sufficient information is available on the formation of DBPs during use of disinfectants and limit values exists for the relevant DBPs. **DE** replied that not for all toxicological relevant DBPs limit values were derived referringto a conference on DBPs in ballast water management askedto have a similar meeting. **DE** said that the presentations of the meeting if possible will be circulated. **UK** will also consult experts from other UK Agencies who were present at the meeting.
MSs were requested to send their **national** drinking water **standards** and/or swimming pool limits for disinfection byproducts to NL by **mid January**. It was decided that **NL will prepare a position paper for the next CA meeting** to obtain policy consensus on the derivation and use of limit values. The document will reflect the concerns of mutagenic carcinogens. In parallel with the CA document **NL** will try to **prepare a DBP evaluation proposal** for the two substances for TMI-2012. If the proposals will be accepted the substances can proceed to AnnexI inclusion.

1b. BCDMH (RMS: NL)

-

1c. Copper sulphate (RMS: FR)

-

1d. MMPP (RMS: PL)

-

2. SUBSTANCES in PT 03

2a. Benzoic acid (RMS: DE)

-

3. SUBSTANCES in PT 04

3a. Benzoic acid (RMS: DE)

-

3b. Bromoacetic acid (RMS: ES)

-

3c. Octanoic acid (RMS: AT)

-

3d. Decanoic acid (RMS: AT)

-

4. SUBSTANCES in PT 18

4a. S-metoprene (RMS: IE)

-

4b. Octanoic acid (RMS: AT)

-

4c. Decanoic acid (RMS: AT)

-

5. SUBSTANCES in PT 19

5a. Decanoic acid (RMS: AT)

-

6. AOB

6a. Update HEEG

6a.1. HEEG opinion on Assessment of Inhalation Exposure of Volatilised Biocide Active Substance

The paper has been produced by DE and UK in cooperation with HEEG.

UK presented the opinion by saying that in the past if a substance had a low vapour pressure it was considered that the risks from inhaling the vapour were negligible. The paper brought into discussion the fact that if no comparison was made between the exposure and a toxicological endpoint, a conclusion on a risk was not really possible. Therefore the paper was intended as a tool providing a Tier 1 screening assessment. The paper was concerned with the vapours volatilised froma treated surface. The approach was worst case, for an infant exposed for 24h/day.

NL and **AT** thanked for the preparation and supported the approach.

The paper was endorsed by the TM for the publication in MOTA.

6a.2. Revised HEEG Concept Paper on the Development of Human Exposure Scenario Documents (HESDs)

The concept paper was prepared by DE with the support of FR, UK and HEEG and was revised to reflect the written comments submitted by the MSs.

COM introduced the paper and said that the following points have been clarified:

1. The work concerning the development of HESDs would be best undertaken by the HEEG.

2. Drafting and decisions related to the HESDs will be best taken at HEEG level. As in the case of all guidance, TM will be presented with the draft documents for comments and eventual augmentation and for endorsement. The CA and COM will finally approve the documents.

3. All the matters related to the drafting of the documents will be best decided at HEEG level.

The work will start with the following PTs: **PT 14** – DE, FR, UK expressed interest; **PT 18** – CH expressed interest; **PT 1-5** – IT, NL expressed interest.

A harmonised approach was considered necessary therefore the work will start with the creation of a common template and eventually the working procedures.

The discussion will start in HEEG.

COM asked for the MSs to express their interest to participate at the groups mentioned, by mid January 2012.

6b. Update DRAWG

COM informed the TM that the "Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products" and the "Draft guideline on risk characterisation and assessment of maximum residue limits (MRLs) for biocides" was released for public consultation on the following sites http://ec.europa.eu/environment/biocides/consultation.htm and

http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp&jsenabled=true respectively. The deadline for comments is 30 June 2012. DRAWG is presently working on a guideline focusing on the carry-over of biocidal active substances into foods. In January the DRAWG will have a workshop to prepare the first draft of the document. Experts are welcome to join the working group.

6c. Consultation ES on OPP

-

6d. Review of local assessment

The guidance document on local risk assessment was adopted by the TM in 2010 with the provision that it should be revised in a year. Several problems surfaced leading to discussions at the TMs. As revision of the document became timely NO was asked to prepare a brief discussion starter. **NO** introduced the document, clarifying that the document was mainly focusing on local dermal effects, and summerized the main concerns related to the guideline:

- Performance of a quantitative risk assessment (RA) depends on the availability of suitable studies. Such studies are not always available leading to potential unequal treatment of actives.
- Guidance is needed on the use of exposure data. The degree of conservatism applied has a major impact on the outcome of the RA.
- Relevance of external reference values to products. Local effects depend significantly on product formulation and use.

AT agreed with the concerns of NO, supported the revision of the draft guidance, and added more detail and background to the arguements:

- The draft guidance differentiates between local effects i) derived from single dose studies leading to C&L; ii) minor, reversible irritant effects seen in acute studies and after repeated dosing not severe enough to warrant C&L and iii) other local effects, non minor effects that appear only after repeated dosing. The guidance deals with these other local skin irritations. In contrast REACH only deals with local effects leading to C&L.
- Quantitative results from repeated dose studies exist only for the active substances; extrapolation to biocidal products is questionable.
- Assessment factors are needed to set AEC. Agreed AFs for local effects are set pragmatically, without an underlying database leading to high uncertainties e.g. extrapolation for respiratory AECs from rats to humans where choosing the median of the NOAEC vs. the range may lead to huge differences, a factor of 100. High local variability for dermal effects is seen for humans e.g. 20% SDS causes skin irritation in 75% of people, whereas 0.25% still causes in 9% of exposed population. Seasonal variations may also be significant. Irritation is not an immunological inert process, which partially explains the high human variability.
- No reliable exposure models exist to compare exposure to AEC. Fluctuation in time and heterogeneous skin surface exposure (e.g. high dose at restricted areas vs. average)
- Problems with wording, when to carry out local and when systemic effects. The dominance of systemic or local effects depends on the use of the product (e.g. local effect dominant at high conc. combined with low dose; systemic effect may dominate for diluted products used at high dose).
- Defining what is an acceptable risks: will depend on the conservatism of the RA, on estimating AEC, the AFs etc., the uncertainties need to be considered. Distinctions can be made for irreversible corrosive effects (products not for general public), irreversible sensitizing effects (not covered by the present) guidance doc, only by REACH), and reversible effects – need to elaborate when they are unacceptable.

AT proposed to carry out qualitative local risk assessment by default: describe the effects and include the C&L of the product, elaborate the acute data in a qualitative way for skin and eye e.g. its for professionals or amateurs; describe a measure to reduce risks - use a device/package it in a way that it cannot end up in the eye; do not apply where children can be exposed as they may show irritation etc. Quantitative RA should only be carried out if suitable data is available for the product, when the product is only a dilution of the active, and even in this case AFs and other parameters should be determined cautiously. Instead of using a strict cut-off value provisions could be given in a qualitative way how to go further with the RA. **FI** added that a semi-quantitative, descriptive approach could also be followed. For example, compare the effects seen in animals at a certain exposure levels with the expected exposure levels in humans; and describe what is expected in humans at these exposure concentrations. This could be described without a clear cut-off value or an AEC and used in decision making. The TM supported the revision of the guidance document. **NO, AT, FI, UK, FR, DE** and **SE** confirmed to be willing to contribute to the revision. **AT** proposed to give headlines and start the first preliminary rearrangements of the guidance.

The **TM** agreed that until the guidance is revised a qualitative or descriptive local effect assessment should be carried out for all actives. Quantitative risk assessment could be done only in limited cases. The present draft guidance should be left as a reference. AEC values will not be included in the LoE as the way they are derived may be misleading. Reflections on deriving a dermal or respiratory AEC may be included in Doc IIA or Doc IIC. For respiratory effects the exposure assessment is less problematic but the extrapolation and assessment of hazards is still ambiguous. If the product is identical to the active, an AEC might be derived but interpretation (duration of study used for derivation, use of AFs for time duration etc) has to be done with caution. If AEC values are derived it should be kept in mind that these values are only preliminary and indicative.

Conclusion: a working group will be formed to revise the guidance document. Until than qualitative or semi-quantitative assessments need to be carried out. MSs are kindly asked to notify the COM if they are willing to contribute to the revision of the document.

GENERAL SESSION

1. Reporting on the last CA meeting

COM informed about the last CA meeting.

2. Tracking System: Progress reports

-

3. SUBSTANCES in PT 02

3a. BCDMH (RMS: NL)

-

3b. Copper sulphate (RMS: FR)

-

3c. MMPP (RMS: PL)

4. SUBSTANCES in PT 03

4a. Benzoic acid (RMS: DE)

-

5. SUBSTANCES in PT 04

5a. Benzoic acid (RMS: DE)

-

5b. Bromoacetic acid (RMS: ES)

-

5c. Octanoic acid (RMS: AT)

-

5d. Decanoic acid (RMS: AT)

6. SUBSTANCES in PT 18

6a. S-methoprene (RMS: IE)

-

6b. Octanoic acid (RMS: AT)

-

6c. Decanoic acid (RMS: AT)

-

7. SUBSTANCES in PT 19

7a. Decanoic acid (RMS: AT)

-

8. AOB

8a. Efficacy of PT 21

The European Council of producers and importers of paints, printing inks and artists' colours – CEPE has put forward to the attention of the MSs two documents:

I TNsG Annex on Efficacy for PT 21
CEPE had previously suggested changes to the document and the revised document was circulated by the Commission to the Member States. The document is not a CEPE owned document – CEPE suggested changes to bring the old document up to date in relation to present day technologies.

II Efficacy Evaluation of Antifouling products: Conduct and reporting of static raft tests for antifouling efficacy
This CEPE document is a revision of the previous CEPE methodology document circulated to Member States. Comments were received during June/July from NL, FR and DE and incorporated into the document.

The comments received from FR, NL and DE were summarised in a response to comments table. As CEPE has not accepted all MSs requests for modification, some of these points were discussed within the TM. As the time did not allowed for the finalisation of the discussion it has been decided to organise a parallel session to deal with these documents in a dedicated working group. The target was to have this session during the TM I 2012.

Comments discussed:

Comment 3: 2.4 application method /dose rate – NL, FR (TNsG)
The commenting MSs considered that since the total dry film thickness will vary depending on several factors, the label should also include a description for what circumstances which dry film thickness should be used.
IND explained that the thickness of the paint is greatly variable, depend on conditions of use and is decided mainly by the painter. Since the thickness is not a determining factor for the efficacy IND considered that the information should not be on the label.

Conclusion: the film thickness is not relevant for the efficacy. CEPE will include in the document the necessary explanation on the reasons.

Comment 5: 3. Evaluation of efficacy – NL (TNsG)

Why should only the general efficacy of a product under typical fouling conditions be demonstrated? Normally the worst case is assessed.
IND explained that raft testing is a worst case.
NL agreed but asked that this is written as such in the document.
NO asked if in the case of non self polishing paints the raft testing would still be considered as a worst case. **IND** confirmed that the test still represented a worst case. As the slime layer builds up, the leaching would be lower.

Conclusion: raft test is a considered as a worst case scenario.

Information on how to use the paint in different circumstances should be available. To this end the label should contain a range for the dose rate that can be used and tests should be done with the highest and the lowest dose rate.
IND responded that it was the ship's operating characteristics, such as idle times and travelling speeds that will govern the DFT and not the biocidal activity of the product.
The 'dose rate' for a product is already given, i.e. the amount of paint applied per square meter of surface to be painted which will enable the owner to apply the correct amount of paint required for a given DFT defined by the supplier.
NL accepted the explanation.

Comment 6: 4 Available data – NL and FR (TNsG)

The commenting MSs asked for a list of that organisms can be used as model for the different groups (aquatic plants, animals). How should slime be tested?
IND considered the laboratory tests as not being relevant and are limited to only early screening. Such tests provide limited information for actual antifouling products when compared to field trials. Organisms that have been used for this purpose are *Balanus amphitrite* and *Amphora coffeaformis*.
The efficacy of antifouling products is proven by field tests.
FR asked how the spectrum of activity would be defined.
IND said that the whole spectrum of the organisms present at the site would be tested.
NL clarified that the point originated in the fact that laboratory tests were mentioned and therefore the testing organisms should be listed. If the laboratory test were not relevant, than this should have been explained or eventually deleted. **IND** said that for the products the lab tests are not relevant and they are applicable more for active substances. **NO** asked for the list of organisms. **COM** clarified that such a list will come with the dossiers for active substances.

Conclusion: the clarification will be introduced in the test.

Comment 9, 20, 21, 25: 4 Available data Simulated field tests – NL, FR (TNsG)

The commenting MSs asked that a remark that tests should be done in replicates is introduced.

After a lengthy discussion that covered the number of panels, the size of the panel and possible orientation as a partial conclusion it was agreed that more than on panel seem to be necessary. **IND** did not agreed with this.

Given the time constrains it was agreed that the point will be followed up during a workshop.

Overall conclusion: the discussion will continue at a dedicated workshop having as a target TM I 2012.

8b. Update regarding drafting of guidance on efficacy evaluation of products in PT 02 and 08

NL, the leader of the drafting party, informed the TM that the group had four workshops until now and is in the process to finalise the draft guidance. The intention is to present it in TM I 2012 and to gather input from the MSs. A document describing the stage of development was uploaded in CIRCA.

COM informed that the guidance on the efficacy of PT18/19 was at the moment revised to take into account the comments received in the public consultation. The target would be to have it published at the end of January 2012.

FR informed that the guidance on the efficacy of PT08 has been revised during the workshop that took place in November. A new version is expected before the summer of 2012.

8c. OECD Biocides Task Force

COM presented a short communication and a room document "TMIV2011-GEN_item8b_OECD TFB_ information.doc" to inform the TM (Technical Meetings) on the progress in the implementation of the TFB programme of work. The note "TMIV2011-GEN_item8b_OECD TFB_ information.doc" and the draft minutes of the 9th Meeting of the Task Force on Biocides are uploaded in CIRCA under OECD Biocides Task Force/ OECD TFB Meetings http://circa.europa.eu/Members/irc/env/ber/library?l=/oecd_biocides_force/oecd_tfb_meetings&vm=detailed&sb=Title

Issues of interest to the TM are the following:

- Generation of Efficacy Data
  - the OECD work on treated articles
  - Development of Guidance Documents for the generation of efficacy data for biocides used against insects and mites
- Antifoulants
  - A document describing a Possible Approach for Developing Data to Estimate Leaching Rates of Biocidal Active Substances from Antifouling Coating Films was endorsed with minor changes. The document was developed based on the need to address leaching rate of biocide from antifouling products, which is one of the most important parameters to estimate the emission of antifoulants in an environmental risk assessment. Therefore, the purpose of this document is to outline various approaches used to estimate leaching rates of antifouling products. It is to be considered as a living document, likely to be revised when new data become available.
- Harmonising Physical/Chemical Test Methods: N. 3 new guidelines on phys-chem properties pH, density and viscosity have been endorsed by the Task force.
- Risk Assessment of Combined Exposures to Multiple Chemicals: Report of the WHO OECD ISI/HESI Int. Workshop on Risk Assessment of Combined Exposure to Multiple Chemicals will be made available in the CIRCA site/TM-Biocides.

- Emission Scenarios Documents: JRC reported on the finalisation of the revision of the Emission Scenario Document for Wood Preservatives (PT 08). Comments can be submitted to OECD secretariat until 23rd January 2012, and after revision the ESD for PT 8-wood preservatives will be published by the OECD.
- Next OECD Task Force on Biocides will take place in Venice (Italy) on 27-28th September 2012.

ENVIRONMENT SESSION

1. SUBSTANCES in PT 02

1a. Evaluation of disinfectant by-products

Background
This agenda item concerns the discussion on a harmonized approach for disinfection by-products. **NL** presented the paper on the DBP which was prepared in collaboration with SE.

The NL/SE document presents the following conclusions: there is insufficient data available in the dossiers to assess DBP following environmental exposure where,

- NL proposes that data on identity and occurrence for DBP should be collected and reviewed; marker by products and active substance (a.s.) should be identified for its environmental exposure and limit values should be established.
- a whole effluents programme is carried out for (DBP) raw sewage, and it should take into account the effluent emissions to surface waters.
- Of the DBP the potential for ozone depletion, PBT and ED potential should be characterised.

COM: informed on at the outcome of the TOX session where TM would like to see the question on DBP addressed at Annex I inclusion stage. COM reminded that the discussion is about the formation of DBP in general and not on individual substances, with special attendtion to halogenated by-products. On the risk assessment report of hypochlorite made under the ESR (Existing Substances Regulation Programme 793/93/EC) a whole effluent testing program was carried considering the use in bulk and paper bleaching of hypochlorite and in swimming pools. **COM** asked if the conclusions of this assessment cannot be extrapolated to brominated DBP. **COM** proposed to focus on risk mitigation measures and potential measures that are already in place before embarking on a research programme of whole effluent testing in relation to brominated DBP or the identification of brominated DBP formed. **DK, DE, FR** asked to include a qualititative identification of the DBP in the CAR for Annex I inclusion stage and not to postpone the evaluation to the PA stage. IND raised the problem of the need for harmonised guidance and to consider that the formation of DBP depends on local conditions. IND can provide some national limits for AOX (halogenated organic compounds), while for brominated by-products there is information provided in the PT12 dossier. **DE** informed about a Workshop on Ballast Water Treatment and by-products which can provide information useful on DBP. **NL** informed on IMO papers on the identification of by-products following ballast water treatment. This information will be also included in a revised version of the NL/SE paper.

Conclusion: The TM agrees to find a harmonised approach to all halogenated disinfectants at Annex I inclusion stage and not to postpone it to the Product Authorisation. TM agrees that possibly an identification of the DBP formed and a qualitative assessment of the DBP in the CARs shall be included and that the same approach for chlorinated and brominated DBP shall be followed with respect to the assessment of environmental effects. The discussion papers from the workshop on Ballast Waters Treatment will be included in the revised version of the NL/SE document with the input from OMS and IND. The revised document is expected to be ready for the discussion at TM I 2012.

Action: OMS will send their comments to NL by 16th January 2012; NL will prepare a revised paper which will be discussed at the TM I 2012.

1b. BCDMH (RMS: NL)

-

1c. Copper sulphate (RMS: FR)

-

1d. MMPP (RMS: PL)

-

2. SUBSTANCES in PT 03

2a. Benzoic acid (RMS: DE)

-

3. SUBSTANCES in PT 04

3a. Benzoic acid (RMS: DE)

-

3b. Bromoacetic acid (RMS: ES)

-

3c. Octanoic acid (RMS: AT)

-

3d. Decanoic acid (RMS: AT)

-

4. SUBSTANCES in PT 18

4a. S-metoprene (RMS: IE)

-

4b. Octanoic acid (RMS: AT)

-

4c. Decanoic acid (RMS: AT)

-

5. SUBSTANCES in PT 19

5a. Decanoic acid (RMS: AT)

-

6. SUBSTANCES in PT 21

6a. General dicussion

NL informed the meeting that they are preparing a paper on the assessment for freshwater environments with respect to the application of the wider environment scenario and issues which need to be considered at product authorisation.

The paper from **NO** "Open issues regarding PT21 questions" was used as the basis for the discussion. The following issues were consequently discussed:

Exposure assessment for STP
IND referred to information from CESA that commercial ship facilities are not connected to municipal sewage treatment plants and usually have specific on-site treatment. **COM** concluded that there is no need to calculate the PEC_{STP} for new building and maintenance and repair for commercial ships.

Fa.i. old paint
Based on information provided by **IND** it was argued that in order to maintain the mass balance of 100% following the principles of the CEPE calculation method (where 90% leaches out during service life), the Fa.i. old paint needs to be increased to 0.9 rather than decrease to 0.1. CEPE will provide a document explaining this issue for the next TM. In the meantime **UK** agreed to incorporate this in the evaluation for tralopyril. **NO** suggested that as a consequence for the combined risk assessment now two scenarios need to be assessed: i) application and in-service, and ii) removal and in-service. **NO** proposed to calculate both scenarios as application and removal are carried out often at different facilities and risk mitigation measures may be different. The TM agreed.

MAMPEC
UK explained the reason for using 3 cm for the sediment depth. The previous proposal for 6 cm was based on a review paper and refers to a global average. UK and SE proposed to use 3 cm representative for the Northsea, where DK proposed 1 cm representative for the Baltic Sea. The latter may be too worst-case so overall UK proposed 3 cm. **COM** stated that the sediment depth may not be that relevant as the assessment will be based on suspended matter. **NO** stated this may still be relevant for persistent substances like copper. **FR** stated that suspended matter is always the worst-case. **COM** concluded that 3 cm will be used for the sediment depth when a higher tier risk assessment will be needed with MAMPEC.

Calculation of PECs for metabolites

- Use of anaerobic degradation study to estimate the percentage of metabolite(s) formed: UK explained the reasons for using this study in the evaluation of tralopyril. Their reasoning was accepted, where it was agreed that in principle the aerobic degradation study will be used. On a case-by-case basis a RMS may deviate from this.
- Use of QSARs for estimating intrinsic properties of metabolites: QSARs can be used to estimate these properties. In case no reliable QSARs are available a scenario can be performed by setting the vapour pressure to zero and use a low and high Koc value and investigate the consequences for the concentration in suspended matter. In case the Koc

value doesn't influence this concentration the assessment can be performed and no further data are required.

- How to apply MAMPEC for situations where in a water-sediment study the metabolite is formed in the sediment, but not in the water phase? **NO** stated they use the percentage formed in the sediment as an input in MAMPEC for the percentage formed for the daily loading of the water phase. **UK** agreed to this approach as MAMPEC will then distribute the amount formed between the water phase and suspended matter. The latter concentration can then be used for the risk assessment. **UK** stated that in the tralopyril assessment the sum of the maximum amounts formed in the water and sediment phase were used to estimate the daily loading of the water phase in MAMPEC. Correction needs to be done for molecular weight. The approach was agreed by the TM.

Risk mitigation for commercial harbours
It was agreed to postpone this to the discussion on tralopyril

Market share for marinas
It was already agreed at an earlier TM that in justified cases the market share for commercial ships can be changed. The question is if this can also be done for pleasure crafts. It was agreed to postpone this discussion to a later stage.

Risk mitigation for marinas
IND informed they are preparing a document on risk mitigation for marinas for the pleasure crafts market. It was decided to await that document.

All decisions will be inserted into MOTA.

6b. Tralopyril (RMS: UK)

-

7. AOB

DE informed about several projects ongoing in DE on (1) cumulative assessment, (2) revision of ESD PT6 which will include a questionnaire to be send out to industry and MS, and (3) proposal for standard scenarios and parameter settings of the FOCUS groundwater scenarios which will be discussed with the MS in beginning 2012 . DE also informedabout an upcoming workshop organised by UBA on environmental mixture toxicity assessment for biocidal products (update: will take place in Leipzig on 24. and 25. of April). **NL** informed about the development of guidance on the assessment of risks to bees following a recent discussion at the CA meeting.