



Minutes of Biocides Technical Meeting II 2012 18th-22rd June 2012

INTRODUCTION

The meeting was chaired by A. Payá Pérez and for specific items on the agenda by C. Pecorini, J. Janossy, S. Pakalin, Ana Paya-Perez, Tobias Posbring, B. Raffael, V. Rodriguez Unamuno. A. Payá Pérez welcomed the participants to TM II 2012. Representatives from the MS, NO, CH, and Industry were present at the TM. For specific items of the agenda, the interested companies were invited to attend.

1. Approval of the agenda

COM informed that the migration of all documents from CIRCA to CIRCABC is completed and that all documents now are uploaded on CIRCABC under the interest group "Biocides TM". For the agenda **COM** informed on the distribution of version 4 with a new item 3n of the ENV Session entitled "Outcome of E-consultation on Koc" requested by SE. The agenda was adopted without further changes.

2. Adoption of the minutes

NL asked to verify if their comments have been inserted and **NO** asked to insert a comment on the ENV session on Cybutryne which had been submitted to **COM**, but apparently had not been included in the draft minutes version 2 distributed by **COM**. The minutes were consequently adopted.

COM will revise the draft minutes accordingly.

3. Action List TM

1. *Comments on document PL on "Harmonisation of environmental risk assessment for PT 06".*
PL with the collaboration of **DE** will revise and finalise the guidance document and forward to **COM** for discussion by the CA meeting.
2. *Distribute list with tasks MS in EUSES training validation exercise and prepare the exercise.*
COM informed that the 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.
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.*



IND/CEFIC will coordinate with applicants of PT13 to provide some progress on this action item for next TM III 2012.

4. *Consultation on document of DK related to several ESDs (PT6, 9, 10).*

At TM II (2012) DK informed COM on the bilateral discussions with DE and OMS and TM agreed to proceed with the inclusion of the decision in MOTA. DK will provide the text to include in MOTA by 31st August 2012.

5. *Development of "swimming scenario" for PT 19 environmental risk assessment.*

Comments on the draft scenario were sent to **DE**, who will now prepare a revised draft.

6. *Preparation of a questionnaire and collection of data on leaching with/without a topcoat (input to draft guidance on the use of topcoat for PT 08 products).*

NO informed that they will send the questionnaire immediately after TM II 2012. Action Completed.

7. *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 could have the document ready for the TM IV 2012.

8. *Extreme sensitizers with human data.* Action on-going

9. *Review of local risk assessment guidance. 1st discussion in TM II 2012, and Workshop to be organised at TM III 2012.* On-going

10. *Guidance on the transfer of biocides to food.* DRAWG on-going

11. *Proposal of ESD for PT10 (number of painted houses) NL.* Doc distributed to TM II 2012. Action completed.

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

COM invites TM participants to communicate their contact details to Barbara Raffael by E-mail and which e-mail we should use to communicate the TM issues.

5. Next Technical Meetings

2012

TM III	1 – 5 October
TM IV	26 – 30 November
CA IV	18 – 22 September
CA V	11 – 15 December



TOXICOLOGY SESSION

1. GENERAL DISCUSSION

1a. Evaluation of disinfectant by-products

COM emphasised that the general discussion relates to the principles of evaluating disinfectant by-products (DBPs) formed in swimming pools *via* disinfectant use. **COM** stressed that the issue relates to all active substances used for swimming pool disinfection, and thereby does not contain any confidential, active substance specific information. **COM** noted that at the end of the discussion the opinion of the **TM** will be asked on the relevance of other **PTs** for the evaluation of DBPs. **COM** thanked the **NL** for leading the development of guidance on the DBPs **PT2** scenario. **COM** asked **NL** to introduce the result of the pre-meeting.

NL informed the **TM** of the pre-meeting, attended by eight **MSs**, on the general principles of evaluating DBPs. **NL** proposed to use the following approach:

- Compare DBP concentrations in swimming water to existing national swimming water limits.
- If the concentrations of DBPs exceed the swimming water limits the usage conditions need to be adjusted to lower the concentration of the DBP to guarantee safe use.
- In the absence of swimming water limits, as surrogates, drinking water limits may be used to screen for potential health effects. Since the drinking water limits are based on a different exposure scenario compared to exposure during swimming, the evaluation may be refined by comparing realistic worst case exposure to a toxicological reference value, such as the **TDI**.
- Inhalation exposure assessment primarily should focus on volatile compounds; measured air concentrations may be compared to existing air limit values.
- **NL** will evaluate the relevance of exposure to aerosols.
- For setting the minimum requirements – how many pools, concentration measurements, selection of sample taking places and periods - **MSs** and **IND** were requested to send their inputs on existing monitoring practices and data. **NL** will provide a pragmatic proposal on the subject. **IND** supported a thorough preliminary screen of the existing data to exclude DBPs of low concern.

The **TM** has supported the use of swimming water limits, as a primary option. However, **MSs** with swimming water limits were requested to send information on the derivation of the limits, especially whether they were based on toxicological data. Based on the available and received information, **NL** proposed to compile a list of reference values of individual DBPs including their sources and derivation. **COM** added that the list shall include the drinking as well as the swimming water limits and their derivation.

The **TM** also supported to use the drinking water limits, followed by the tiered assessment if necessary. **COM** said that at the **CA** meeting the use of **WHO** limits was agreed; however, when a lower national limit value exists compared to the **WHO** value the lower value is to be used. **UK** asked how often national limits are lower than the **WHO** limits. **NL** believed that it is generally the case. **IND** acknowledged that using water limits is a pragmatic approach for screening; adding



that when these limits are exceeded the understanding of the scientific basis of national limits are important, as they may be based on local conditions. **PT** added that the same approach, i.e. comparing the worst case exposure to a hazard value can be used for the evaluation of DBPs in other PTs.

IND asked **NL** whether other disinfectants, not chlorine based are also considered. **NL** responded the proposed methodology can be used for any pool disinfectant; specific, non-chlorinated DBPs will be selected case-by-case based on the literature, depending on their expected formation.

NL questioned the usefulness of applying the TTC approach and Cramer classes proposed by **IND**. Several genotoxic compounds are known among DBPs, argued **NL**, and the TTC for such compounds are very low, thus even at concentrations of micrograms per litre, the exposure will likely exceed the TTC. **IND** acknowledged the complexity of the evaluation and asked whether grouping, forming categories, and read-across was considered. **IND** proposed to make a pre-screen, group e.g. according to potentially genotoxic or not, followed by a specific assessment for each group and finally develop an approach in order to estimate exposure and risk. **NL** emphasized that only very few DBPs have a known toxicological profile making grouping difficult. Nonetheless, **NL** will consider the applicability of the TTC concept.

IND questioned the discussion of the PT2 pool scenario, implying other PTs may be more of a concern and suggested to evaluate them at the same time as pools. **COM** responded that the issue emerged first in relation with this scenario and its importance is also reflected by the international attention it attracts (e.g. WHO guideline). **COM** reminded that when the issue was first raised by **DE**, the **TM** decided that the issue needed further considerations at EU level. **COM** added that the issue for other relevant PTs will also be discussed as soon as the respective active substances will be discussed. The discussion of the present evaluation is independent from data requirements related to other PTs and therefore the **TM** will continue with the evaluations PT by PT.

IND expressed its intention to be more involved in the discussions, not only at the **TM** discussions, but also in between. **IND** undertook to share their knowledge and provide technical input to the proposal. Moreover, **IND** added that it will comply with the data requirements, but called for equal treatment; the application to all substances in that scenario and that data requirements need to be enforced at the same time for each sector, for each PT. **COM** assured **IND** that the approach will be compulsory for all a.s. having such a usage. Regarding other PTs, **COM** reiterated that the data requirement for DBPs is PT specific. The PT2 swimming pool scenario is currently discussed and the development of the method to evaluate the PT2 scenario should not wait for the evaluation of other PTs. Where relevant, the issue will be addressed appropriately. **UK** reassured **IND** that the **TM** peer-reviews all the CARs and ensuring that all RMS include a full evaluation of the a.s. according to the requirements.

With reference to **IND**'s participation, **COM** pointed out that **IND** has been repeatedly requested to be involved in the process. Moreover, the Applicant of the a.s. where the issue was first raised was specifically requested to assist **NL** and the other MSs in the guidance development. **COM** encouraged once more the active participation of **IND** and pointed out that comments have already been received and considered from **IND**. **IND** requested the contribution of all MSs to the guidance development. **COM** indicated that participation is open for all MSs and **IND**; however,



even if a MS or an applicant cannot contribute to the methodology development the resulting guidance will apply to all relevant substances.

The scheme on the evaluation prepared by the NL will be distributed.

For private pools it was agreed that if safe use is considered for a public pool, then usage in private pools will also be considered safe. In addition, clear label instructions will be required. **IND** added that public swimming pools are worst case relative to private pools as organic matter load is higher, which correlates with the DBPs formation.

With respect to the characterization of DBPs in other PTs PT 3, 4 and 5 was considered relevant for the human health. For PT2 only the swimming pool scenario was considered relevant. Exposures in other PTs to DBPs were not considered to pose significant concerns.

Conclusion: The approach proposed by NL was supported by the TM. NL will compile a list of reference values including information on the derivation of the specific value for the next TM. MSs and IND were requested to send all available information on national water limit values and on monitoring data and practices (results, monitoring plans, monitoring data requirements and their basis etc.).

3. AOB

3a. Update HEEG

The HEEG Opinion on an approach to identification of worst-case human exposure scenario for PT6 was prepared by **CZ** and **UK** in cooperation with HEEG. **COM** thanked for their work both the initiators and the HEEG members who participated in the consultation and discussion on the Opinion.

CZ presented the HEEG Opinion. **CZ** and **UK** were asked to prepare a concept paper to help in determining the worst-case scenario for PT6 scenario which would cover all other uses. The document was first presented at the HEEG workshop in Paris in May 2011. The document was implemented by several comments received from **FR**, **NL**, **SI**, **PT** and **DE**. The HEEG opinion consisted of two parts related to primary exposure and secondary exposure. The primary exposure was based on the use of RISKOFDERM calculator, which was used for evaluating primary dermal exposure of professional users. This calculator could be used in some cases also for non professional exposure, but suitable justification should be provided. Secondary exposure was based on a dossier evaluated by **FR**. The algorithm was defined in the Opinion. For both primary and secondary exposure, a hierarchical approach for identifying worst-case scenarios was detailed in the document.

COM reported some comments on the HEEG opinion provided by **UK**. The HEEG Opinion on an approach to identification of worst-case human exposure scenario for PT6 should be considered as a screening tool to identify the worst-case PT6 scenario for both primary and secondary exposure. The exercises reported in the Opinion should be considered as example cases. Besides RISKOFDERM, the exposure and risks associated with these worst-case products/uses could be addressed in detail using accepted models, e.g. those in the TNsG/User Guidance on Human Exposure to Biocidal Products, BEAT, ConsExpo.



With reference to the interpretation of the HEEG Opinion, some issues should be taken into account. The concentration of a.s. in the product as well as other properties of the product/in-use product and their use - as proposed by the Applicant - would determine which uses were foreseen as acceptable. Therefore, for the Annex I listing it would be necessary to provide enough detail to inform which product concentrate/in-use product or a.s. concentrations/uses were acceptable and which were unacceptable. This detail could allow leaving out the unacceptable products/uses at an early stage. Therefore, after Annex I listing, submission by the Applicants of another use not assessed at Annex I listing stage would imply that this other use would need to be assessed separately.

COM encouraged the use of the HEEG Opinion in future assessment in a view of implementing the document.

FR agreed with the **UK**'s comments.

CZ added that the detailed calculation **FR** would provide on secondary exposure should be verified and checked and the document would be anonymous.

IND commented that it was possible to define which uses could be excluded at the Annex I level on the basis of the representative product in the dossier.

CZ added that no use could be excluded at this stage, but the approach could make it possible to foresee which products would be difficult to be authorised.

IND was satisfied with this explanation.

CEFIC asked more clarification why the information provided by one Applicant was used and transposed to all dossiers.

FR commented that the majority of the scenarios presented were rebuilt and recalculated by **FR**. The range of efficacy doses was the unique information obtained from the specific Applicant. In addition, classical models, such as the TNsG and ConsExpo, were taken into account in the calculation. The calculation would be added to the HEEG Opinion after a commenting period of the HEEG and the MSs on the approach presented, because the calculation was provided by **FR** but had not been checked. **FR** suggested considering the release of a confidential version of the HEEG Opinion with the full calculation proposed and another document without the calculation.

COM proposed to endorse the HEEG Opinion and to have an additional commenting period (deadline 31st July).

CEFIC suggested including **IND** in the commenting period. **CEFIC** also asked how to manage situations in which an Applicant had only a limited range of uses for PT6.

FR commented that in case of limited uses they should be fully assessed according to the usual practice. In case of many applications with different field of uses, identifying a worst-case scenario could be useful in order to cover all the other uses.

COM proposed the deadline of 31st July to send comments on the Opinion. **IND** was invited to take part in the commenting. **COM** would send the document to **CEFIC**. The HEEG Opinion was not endorsed at the TM.

Conclusion: The Opinion was not endorsed at the TM, but an additional commenting period would be considered to take into account inputs provided from MSs and **IND**.

3b. Update DRAWG

DE introduced the draft guidance. MSs were invited to send their comments to DRAWG and DRAWG will respond to comments bilaterally and if required at the next TM discussion. **COM**



thanked DRAWG for the draft proposal. **COM** informed the TM that there are ongoing discussions to establish the framework for setting MRLs for biocides. **COM** is considering enlarging the scope of Regulation 396/2005 by amending the definition of residues of pesticides as well as some of its dispositions. **COM** prepared a room document with comments on the draft proposal (also uploaded to CIRCABC).

3b.1 Scope of the draft DRAWG proposal (TGD) for professional scenarios

According to **COM** the scope of the draft TGD covers the estimation of residue transfer to food and identification if further evaluation is needed. The proposed DRAWG TGD should only initiate dietary risk assessment (DRA), yet the assessment should be carried out according to a second guidance to be developed under the umbrella of EFSA.

FR agreed that the purpose of the draft TGD is the estimation of residue transfer to food, DRA is only used as a screening tool to determine whether MRLs setting is required. **NL** will send written comments.

EFSA explained that a method to determine the residue in a given food (mg/kg food) needs to be established for estimating residue transfer to food. In contrast, exposure assessments for DRA requires more elaborate considerations, taking into account acute and chronic exposures, children and adult food consumption data, the appropriateness of consumption data and finally develops a model for all groups and scenarios. EFSA asked whether including such data is essential, and whether DRAWG has the mandate to do it. If EFSA will do the dietary exposure assessment a different model than the current rough estimation included in the draft TGD will be used. EFSA added that if DRA is to be included more work has to be carried out.

IND commented that if only the exposure height of potential residues will be assessed the document needs to be revised thoroughly. Currently it contains elements addressing actual DRA. **IND** disagrees with the mandatory nature of residue studies. **IND** proposes to use other approaches than obligatory residue trials.

UK asked why to send comments before public consultation. **COM** explained that it is important to receive comments as early as possible to respond to concerns in an early stage. The TGD will need to be endorsed by the TM, followed by approval from the CA and finally will go through a 6 months public consultation.

Conclusion

COM asked the TM to send written comments by the end of July. The comments will be discussed within DRAWG, as well as at the next TM.

3b.2 Default toxicological reference value based limitation of the threshold level

COM introduced the comment that the same approach should be used as in the PPP framework (see comment 2.). **COM** disagrees to limit the threshold value based on a toxicological reference value by default, however, **COM** reserves the possibility of reducing the limit value for substances of concern. **EFSA** believed that limiting an assessment based on the ADI is a policy decision.



IND commented that the reasoning behind the limitation for substances with toxicology reference values below 0.01mg/kg bw/d needs to be more elaborated.

FR believed that the approaches for PPP and biocides are different as for PPP systematic DRA is applied. The aim of the DRAWG guidance is to have trigger values; the 0.01 LOQ is used to avoid residue measurements in food commodities. For pesticides a lower LOQ is sometimes used, because the 0.01 value was not considered safe. For biocides with an ADI above the LOQ of 0.01 is acceptable, but for other biocides with lower ADI an unacceptable risk may be present. **IND** disagreed with the example given by **FR** and believed the lower LOQ was the result of residue trials, where the residues could be detected at very low LOQ. The DRA showed that the ADI was not exceeded. **IND** asked to consider the TTC approach as it is more flexible and open to new compounds; it could be adapted to new metabolites without knowing their ADI. The TTC is applied by EMA and FDA. **COM** agreed that although compounds of concern, like metabolites, are covered by the guidance more consideration is needed to evaluate compounds with unknown ADI.

Conclusion

COM asked the **TM** to send written comments by the end of July. The comments will be discussed within DRAWG, as well as at the next **TM**.

3b.3 **COM** requested to send written comments on the use of existing limit values

3b.4 **COM** requested DRAWG to review the setting of maximum acceptable biocide residue concentration on the inner surface of machinery. The application of the limits may contradict present accepted residue estimation practices.

3b.5 Drinking water disinfection

FI quoted the draft TGD “The Drinking Water Directive covers biocides used to disinfect drinking water at all stages before it is drawn from the tap. Drinking water disinfectants that are used at any point after that are within the scope of the BPD.” **FI** asked whether disinfection of drinking water is in the scope of the BPD. **COM** said DRAWG will review the mentioned section and amend or rephrase the text to increase clarity.

Overall conclusion

COM asked the **TM** to send written comments by the end of July on the draft TGD and on the comments briefly discussed. The comments will be discussed within DRAWG, as well as at the next **TM**.

3c. Evaluation Manual for Product Authorisation

COM informed that the Evaluation Manual v.1 was endorsed during the 44th CA meeting in December 2011 and it was released for a 6 months public consultation period. Stakeholders can still send comment to ENV BIOCIDES mail box until 30th June 2012.

COM invited **NL** to present the proposal of three new items to be included in the revised version of the EM. **TM** agreed with the 3 new items and **NL** will draft the v.2 of the EM for Product



Authorisation to be submitted for endorsement by the CAs. **TM** agreed with the proposal that agreements in the MOTA will be incorporated in the EM.

UK commented that for dermal absorption there is no information in the LoEP on the concentrations that were tested, and MS have to use the default values. **COM** informed that a proposal on dermal absorption is under discussion. List B proposal (mixture toxicity, aggregate risk assessment, test with products) in the EM table was thus not discussed, waiting for **TM III** 2012 discussion on the special workshop on mixture toxicity.

Conclusion

TM agreed with the 3 new items listed in the Toxicology section and **NL** will draft the v.2 of the EM for Product Authorisation to be submitted for endorsement by the CAs.

TM endorsed **NL** proposal that all agreements in MOTA should be included in the EM. **NL** will add a phrase in the EM saying that agreements in MOTA will be included in the EM.

*After the **TM** **NL** informed **COM** on discussions with ECHA on future updates of the Evaluation Manual and on the agreement that from 2013 ECHA will include these subjects with their approaches and update of the EM (version 3).*

3e. Antimicrobial Exposure Assessment Task Force Presentation

Has Shah and Seth Goldberg, representing the American Chemistry Council's Antimicrobial Exposure Assessment Task Force, presented a summary of the Task Force work. Dr. Shah explained that the Task Force was formed in response to EPA concerns that existing exposure data are not adequate for risk assessments. The US EPA therefore decided to require registrants to generate actual exposure data. The Task Force is generating application-specific data that should apply across active antimicrobial substances. Dr. Shah then outlined the research program, describing the ethical and scientific reviews the protocols will be subject to and explaining the robustness of the new studies. He said the studies are being funded by antimicrobial registrants and the entire program will cost approximately US \$25 million. Dr. Shah explained that three studies have been completed: mop, wipe (trigger spray and wipe and ready-to-use wipe), and aerosol. He said that there will be an additional 14 studies of applicator exposure (high pressure spray, low pressure spray, pour liquid, pour solid, immerse/dip/soak, fogging, pump liquid, place solid, wood pressure treatment, metalworking fluids, brush/roller for painters, airless sprayer for painters, airless spray for marine antifoulants, and reactive/volatile chemistry). The Task Force also will perform two post-application exposure studies, focused on residues on hard surfaces and soft surfaces. One example was presented, comparing Task Force data to exposures under the TNsG (2002). This demonstrated very substantial reductions in exposure. This will allow more accurate and less conservative risk assessments. Dr. Shah explained that under the Task Force agreement these data are proprietary. They will be supported by the Task Force in the EU to support specific active substances or biocidal products at the request of a member company. Dr. Shah explained that the Task Force is composed of over 43 member companies, many of which are active in both the US and EU.

Discussion following the presentation addressed several member states' interest in the study and recognized that the data are proprietary to the Task Force members and will be submitted on behalf of those members.



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COM thanked for the presentation and mentioned that it is already uploaded to CIRCABC and it will also be circulated within HEEG. **DE** encouraged **IND** to buy AEATF data and submit them for product authorization to fulfill the data gaps. **CEFIC** noted that though there are initial results of the program, the finalization is expected in 2019. **CEFIC** asked how the US-EPA takes decisions on products where for certain scenarios refined data is not yet available. **AEATF** replied that the some data from the studies were already submitted to US-EPA and Canada. Where studies are not available yet, EPA provides a provisional registration pending the receipt of the data in the future. Final decisions will be taken when the data will be available for refinement. **COM** appreciated the possibility to take the **AEATF** inputs into account in the HEEG group, pending the agreement of the group.

3g. Workshop on the Mixture Assessment in Biocidal Products Authorisation

COM reminded that the current directive 98/8/EC requires that combination effects are accounted for. This requirement is even more strictly formulated in the upcoming new regulation 2009/0076(COD), where it is also stated that the European Chemicals Agency shall, in collaboration with the Commission, member states and other interested parties, develop "further guidance on the scientific definitions and assessment methodologies for cumulative and synergistic effects".

COM said that in this frame, a workshop was organised by the federal German Environment Agency (UBA) and the Helmholtz Centre for Environmental Research (UFZ). The aim of the workshop was to achieve a harmonised approach, which obviously also would form the basis for further work on guidance.

COM said that three topics in particular will require further consideration:

- How to account for synergistic effects and other uncertainties in the predicted toxicity
- Definition of the (relevant) substances in the product to include in the assessment
- The handling/consideration of unbalanced data situations at the stage of PEC/PNEC summation, where different ecotoxicological data are available for each of the single substances

COM added that there was an active contribution to the discussions from all the participants, and the motivation to work towards a final consented approach was high.

SPECIAL SESSION: Meeting of the working group on risk assessment for local effects

The summary of discussion of the special session will be circulated only within the dedicated working group.



GENERAL SESSION

START: 20th June 2012 at 09:00 hrs

FINISH: 20th June 2012 at 15.00 hrs

1. Reporting on the last CA meeting

COM said that Before the voting by the Standing Committee, the CA meeting had the final discussion for the non-inclusion of bifenthrin for PT 18 into Annex I, IA or IB to Directive 98/8/EC, and the final discussions for the inclusion of nonanoic acid for PT 2, of cis-tricos-9-ene for PT 19, of hydrogen cyanide for PTs 8, 14 and 18 into Annex I to Directive 98/8/EC and the final discussions on correcting the entry for disodium tetraborate in Annex I to Directive 98/8/EC and on amending the headings of Annex I to Directive 98/8/EC.

The standing Committee voted accordingly.

The CA meeting had the first discussions on the inclusion of chlorfenapyr for PT 8, of diflubenzuron for PT 18, of pyriproxyfen for PT 18, of DDAC for PT 8 and of ADBAC for PT 8 into Annex I to Directive 98/8/EC

Several other topics were discussed, on the revision of Directive 98/8/EC, where the progress of the revision work was reported and on the preparation of the implementation of BPR.

In particular, the following issues are of special interest for the Technical Meeting:

1) The use of focus scenarios for groundwater

Based on the comments received since last CA meeting the following 3 provisional conclusions were drawn and CAs were asked to comment.

a) The results of all 9 scenarios should be provided by the applicant and should be presented in the CAR. This does not represent an additional burden for the applicant as the FOCUS model already calculates all 9 scenarios. CAs agreed.

b) Only one scenario without risk is not enough. The proposal is to have 5 scenarios that show no risk for annex I inclusion, based on the fact that this number should allow covering for different environments and situations of use.

A discussion took place on the number of scenarios necessary, but no agreement was found. CAs are invited to send their preference by the 15th June and the final discussion will take place at the next CA meeting.

c) As the FOCUS groundwater model PEARL is applied also to other PT, the decision on the number of safe scenarios taken for PT 18 can be extended also to other PTs. CAs agreed.

3) Endorsement of the documents on guidance on in situ generated active substances,



With small amendments, the CA meeting endorsed the document, and COM will publish it on the public biocides space on CIRCABC.

4) Endorsement of the documents on disinfectant by-products and

NL presented their document and asked the CA to endorse the second last paragraph of the introductory paper.

The general decision was to take the WHO values, but if a MS has a lower national level, that level can be used for Annex I inclusion. This would avoid problems at mutual recognition stage.

CAs agreed.

With small amendments, CAs endorsed the proposal, so the TM can continue working on the topic. The room document was considered as accepted.

5) Endorsement of the documents on the use of open source data

With one amendment, the CA meeting endorsed the document, and COM will publish it on the public biocides space on CIRCABC.

6) Treated articles

COM and highlighted the importance of reaching a harmonised approach on the issue as early as possible in order to facilitate companies' compliance with BPR.

Discussion is still on-going.

7) A new item will need discussion by the TM: assessment of mutagenicity (SE request)

SE presented a room document on the assessment of mutagenicity, asking for a TM discussion on the topic. As a consequence, the topic might be inserted in the agenda of TM II 2012.

8) Borderline between cosmetics and biocides

COM presented the document that says that the product with double use should be registered under both regulations and pointed out that the issue is still being discussed between DG ENV and DG SANCO. Discussion is still on-going.

2. Tracking System: Progress reports

COM introduced the uploaded documents. No comment was raised by the TM.

4. AOB

4a. Evaluation Manual for Product Authorisation



NL introduced the items for discussion in Table B. of the EM. Paragraph Phys-chem

Item 1B: Self-life guidance and GIFAP

At TMI12 it was decided that **UK** would write a proposal for packaging requirements for inclusion in the evaluation manual. **NL** agrees with the approach of the **UK**, with only minor points to be discussed. **UK** prefers to discuss these points bilaterally, because the author of the proposal is not at **TM**. **DE** also would like to comment and will send their comments to **UK** and **NL** in writing. Conclusion: **DE** and **FR** comments will be discussed with **UK** and **NL**, a revised version will be incorporated in the manual. Comments can be submitted until the 30th of July.

DK According to GIFAP standards, degradation of active substances may be up to 10% during storage. Nevertheless often for some heterogenous products (such as rodenticides) it is noted that decrease up to 25% are reported in product authorisations. Could severe decrease >10% of the active substance during storage be described in the evaluation manual?

. **IND** asked a clarification on the 10% of the formulation. **IND** proposes not only GIFAP but also FAO for PT 18. **DK** and **NL** will look at other PT groups to see if the Guidance on storage stability used by **UK** for PA could also be used for active substances. **IND** proposes if this guidance can be used at EU level. **IND** will provide this guidance to **NL**.

Conclusion: **NL** agrees to draft a proposal. **DK**, **FR**, and **IND** will participate in the preparation of the proposal.

Item 2B. SANCO/825/00 Only **UK** has commented and they have reservations to use SANCO/825/00. rev. 8.1. **NL** agrees not to implement 8.1 version directly, but only applicable to new dossiers submitted but not applicable to the dossiers already submitted. **NL** would like to have the opinion of **OMS**. *The question to OMS is: Does TM adopt this document to be used under 98/8/EC and if so, when should this come into effect?*

Conclusion: **OMS** to provide comments to **NL** by July 30th 2012.

Item 3B. Efficacy section, **NL** may come back to next **TM** with a proposal for efficacy.

Conclusion: **OMS** to provide comments to **NL** by 30th July for discussion at the Next **TM**.

4b. **TM SOP update**

COM said that in this fourth version the text has been amended to incorporate the decision taken at the 42nd CA meeting regarding the "publication of draft CARs" and some editorials for the access to documents in CIRCABC and the JRC Website.

COM reminded the **TM** that CIRCA has been substituted by CIRCABC. The system is not as user friendly as the previous one and has still some problems. **COM** receives often complains from the **MSs** and requests for support, so reminded the **MSs** to address any technical difficulties to the CIRCABC support service and reminded the **MSs** that for new access to the Biocides **TM** group, the user has first to obtain a profile from ECAS authentication system and then apply to be accepted in the group.



Moreover, **COM** highlighted that on page 18, in paragraph 4.4, point 1 the responsibility for sending the relevant parts of the first draft of the TM minutes to the applicants passes to the RMS. This reflects the procedure for the sending of the relevant parts of the final TM minutes to the applicants, that is already responsibility of the RMS.

For the introduction of these amendments no endorsement procedure is foreseen via the meeting of representatives of Member States Competent Authorities.

COM also reminded the MSs to use the version of the commenting table that is provided with each First Draft CAR and not to use older versions. Moreover **COM** reminded the MSs that the RCOM table has to be filled using a progressive comments numbering system (not by documents or even worst by sections) to avoid confusions and misunderstandings. It is very important that the numbers of the comments are not in bullet point format, but just simple text.

SE proposed to send separate RCOM tables for each session (TOX, GEN, ENV). **COM** and the TM agreed, so RMSs who wish to do so can send 3 different RCOM tables.

UK proposed to send only the version with track changes of the Draft final CAR, which is the only one that is uploaded in CIRCABC, as it is an additional and meaningless effort to prepare a version without track changes that in any case will be changed to become the Final CAR. **COM** and TM agreed.

COM said that the two proposals from **SE** and **UK** will be incorporated in the new SOP version and this revised version will be uploaded on CIRCABC.

Conclusion: the revised version of SOP was accepted by the TM, with the two modifications by **SE** and **UK** on the possibility for the RMSs to send 3 different RCOM tables (1 per session) for the TM discussion, and on the possibility for the RMSs to send the JRC only the version with track changes of the Draft final CAR.

Action for COM: to update the revised version of the SOP with the possibility for the RMSs who wish to do so to send 3 different RCOM tables (1 per session) for the TM discussion, and with the possibility for the RMSs to send the JRC only the version with track changes of the Draft final CAR.

4c. Workshop on the Mixture Assessment in Biocidal Products Authorisation

DE informed on the workshop on Mixture Assessment in Biocidal Products Authorisation. (See also point 3g. of TOX session), that dealt with the environmental implications only.

Starting point was the documentation presented by **DE**, result of 2 research projects (also discussed at TM I 2011), and then the MSs presented their approaches and questions.

The idea was to start with a tiered approach for the assessment of mixtures. The first step would be the PEC/PNEC summation; next step would be the toxic units summation that would require much more data. The discussion focused on the intermediate step.

The need for a refinement of the assessment factors emerged, due to the fact that there are data gaps, mixed data and extrapolated data.

Another question raised was concerning the relevant substances to consider in the mixture assessment. An agreement was found on the substances of concern that should be considered as



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relevant substances and this topic will be further discussed by the dedicated working group that will work on the basis of the UK paper.

A third discussion topic was the scheme proposed to add the interaction factor as an additional factor for the assessment, accounting for unknown substances or synergistic effects, but no agreement was found on this topic.

As a conclusion six points were agreed upon and will be sent to all MSs by the end of July.

Further discussion is needed on the following topics:

- How to account for synergistic effects and other uncertainties in the predicted toxicity
- Definition of the (relevant) substances in the product to include in the assessment
- The handling/consideration of unbalanced data situations, for which a follow up workshop should be organised in collaboration with the COM in parallel to TM III 2012.

Results of the workshop will be circulated and they will be used as an input both for guidance development as well as for the BIP project and DE is willing to contribute.

COM confirmed that the topic will be discussed in a dedicated workshop in parallel to TM III 2012. **COM** also said that **FR** is preparing a paper on the **TOX** perspective of the same topic, so the workshop will hopefully cover both aspects.



ENVIRONMENT SESSION

1. GENERAL DISCUSSION

1a. Evaluation of disinfectant by-products

NL presented the document "Assessment of disinfection by-products (DBPs)".

SE is in favour of using the WET approach which is useful to identify unknown toxicity and mixture toxicity but probably not for Annex I inclusion. **ES** commented that the WET assessment is recommended in BRETH for big facilities and cooling system. **ES** informs that WET is applied in other pieces of legislation and proposed adding a phrase in the **NL** document to recommend **MS** to check the WET assessment from other legislations. **NL** informs that WET approach could be used as 2nd tier. **Chlorine-IND** also proposed to make WET assessment as a higher tier. **Chlorine-IND** supported **NL** document and commented on the use of most conservative PNEC as 1st tier and secondly it should be weighted according to actual concentrations of the relative species; in addition literature data is available on the further work that has been done on halogenated acetic acids which **Chlorine-IND** will provide to **NL**. **DK** asked how was going to be organised the monitoring program. **NL** replied that this programme is not feasible for the moment. **Chlorine IND** would like to assist with the technology and proportions that need to be assessed on case by case and on the monitoring data little has changed since the RAR were produced. For Annex I inclusion **CEFIC** proposed to list in the dossier the uses for which there is a need for further investigation at product authorisation and to list the DBP which will not raise concern at PA.

TM agreed with the approach to follow for Annex I inclusion:

- identification of the main groups of DBPs e.g trihalomethanes (THMs), halocarboxylic acids (HAAs), bromate, supported by monitoring data when available;
- evaluation the PEC/PNEC values for key compounds and specific groups of DBPs when possible;
- listing of uses for which at product authorization the assessment of DBPs will not be needed, depending on the PTs.

NL asked for more data in addition to the information provided by the RARs and asked **MS** and **Chlorine-IND** to provide the available monitoring data to **NL**. **COM** asked **CEFIC** to pass the message to other groups interested in the DBP (bromines, iodine, other task forces) .

TM agreed with the proposal presented by **NL**. With the outcome of **TM** discussions **NL** will revise the draft proposal and submit it for endorsement to next **TM**.

In addition, **TM** agreed with **NL** to create a working group on DBPs to work on specific issues such as:

- preparation of "factsheets" to calculate PNECs,
- examination of the adequacy of the REACH guidance on the requirements of monitoring;
- determination of a strategy on how to deal with the WET (whole effluent approach) for the biocides evaluations and other issues.

SE and **Chlorine IND** would like to join the working group. By end of July **NL** will send an e-mail to **MS** with the request to contribute to the WG on DBP.



Conclusion:

TM agreed with the proposal presented by NL and the way forward for Annex I inclusion. OMS and IND should send comments to NL **by July 31st** and NL will revise the paper for discussion at the next TM.

3. AOB

3a. Evaluation Manual for Product Authorisation

COM informed that the Evaluation Manual v.1 was endorsed during the 44th CA meeting on December 2011 and it was released for a 6 months public consultation period. Stakeholders can still send comment to ENV BIOCIDES mail box until 30th June 2012.

NL informed that DE has agreed to provide an updated document on mixture assessment, however the draft will not cover cumulative RA. OMS are invited to send other proposals for inclusion in the EM. If no further issues will be proposed, then NL can proceed with the revision of the EM. NL would like to have a text ready to paste into the EM.

COM informed on the agreements made in the TOX and General session (please read above).

Conclusion: The TM ENV agreed with the inclusion of MOTA agreements in the EM. COM asked OMS to provide issues to be included in the EM **by 31st July.**

After the TM NL informed COM on the outcome of the discussions with ECHA on future updates of the Evaluation Manual and specifically on the agreement that from 2013 ECHA will include these subjects with their approaches and update of the EM (version 3).

COM will inform to next TM.

3b. Risk mitigation PT 21 for pleasure crafts

ICOMIA submitted a discussion paper. A representative of the antifouling working group of CEPE was present to the meeting and presented an overview of the point. Last year, CEPE provided the TM a paper on the overview of risk mitigation measures (RMM) for application and removal of antifouling paints from the survey on the commercial shipyards. The TM December agreed on the adoption of these RMM measures for the professional use. The current paper from ICOMIA support earlier paper of CEPE and CESA, and representing the recreational boating industry on RMM that are in place for the application and removal of paints from pleasure crafts. A lot of these activities are carried out in boatyards and marinas, which are regulated by the IPPC rules. The code of practices and best practice are incorporated within the BREF (best available techniques reference) notes which are related to the IPPC regulation. A particular reference is the one which relates to solvent based surface treatment using organic solvents which has a special chapter on coatings of yachts and boats.

UK asked the TM whether the inclusion of recreational ship painting will be sufficient to implement the best practice in the commercial shipyards. UK questioned how enforceable can this be. IND responded that any commercial and pleasure boat operations in the marina will be bound to the same IPPC regulation as commercial harbours.

COM asked for input from MSs on the national situation on enforcing the code of practice in marinas. NL informed that this code of practice is endorsed at national level. NO mentioned a



report from 2011 showing high levels of pollution in marinas, as many of the maintenance and repair practices are not in place in marinas. **SE** noticed a similar situations to **NO**, and waits for a final report from June on a survey on national level before deciding on how to proceed for pleasure boats. **FI** have the same situation as in **NO**, plenty of marinas which do not have these measures in place.

COM asked if these RMM have already been proposed to be implemented for Annex I inclusion for bigger boats and pleasure jets. **IND** confirmed that these have been proposed by applicants for PT 21 Annex I inclusion.

At request of **COM**, **IND** agreed to update the paper by including more background information on IPPC rules and more examples of actual practices, then make it available to MSs.

3c. Study CEPE regional marina scenario

COM received a request from **CEPE** to propose an e-consultation as the representative could not attend the meeting.

MSs were requested to send written comments to **COM** by 30 August, then this point to come back to the next TM.

3d. Workshop on the Mixture Assessment in Biocidal Products Authorisation

DE reported from the workshop “Mixture Assessment in Biocidal Product Authorisation” (24./25.4.2012, Leipzig), organised by the Federal Environment Agency (UBA) and the Helmholtz Centre for Environmental Research (UFZ). The aim of the workshop was to achieve a consented, harmonised approach for the environment, which obviously also would form the basis for further work on the guidance. About 30 experts from competent authorities from EU Member States, industry, JRC, ECHA and research contractors were attending. There was broad agreement that mixture assessment can be regarded as doable based on reasonable default assumptions and that product or mixture testing is regarded as the ultimate golden reference in a tiered assessment scheme. Initially, a tiered approach was proposed by **DE** for the risk assessment of mixtures. Three topics were identified within the workshop for a more in-depth discussion: 1. Can we introduce a tier between a PEC/PNEC summation and the summation of toxic units for defined endpoint? 2. What are ‘relevant substances’? 3. What are Interaction factors (IF) for?

It was concluded that mixture risk assessment may be organised in a tiered fashion, consisting of the three major tiers PEC/PNEC summation, Toxic unit summation and Mixture testing. Intermediate steps should be considered, but will require further discussion. Since the quality of the assessment is ultimately dependent on the adequate identification of relevant components, the outcome of the ongoing discussions on Substances of Concern will be of high relevance.

The draft workshop documentation has been sent to the attendees for commenting, the final document will be available around end of July/early August and provided to the TM via CIRCA. **DE** and **COM** both agree that a follow-up workshop during the TMIII 2012 should be organised with the aim to develop intermediate steps for the agreed tiers in the assessment scheme for the environment, as well as to resolve remaining outstanding issues. The outcome of this workshop will form the basis for continued work on guidance development under BIP6.7.



Action for COM: To organise a follow-up workshop during the TMIII 2012 to develop intermediate steps for the agreed tiers in the assessment scheme for the environment, as well as to resolve remaining outstanding issues

3e. Update development of an opinion paper with the methodology of the risk assessment to bees

NL presented the point.

TM decided to wait for the EFSA guidelines to have a common ground before finalizing the draft to be submitted to the next TM. NL asked OMS having substances with systemic effects if they would like to receive the draft of the guidance document. ES welcomed the use of the EFSA guidelines but drew attention that not all the requirements for PPP might be used for Biocides. In NL data requirements are different, acute vs chronic, on both regulatory frameworks.

Conclusion: NL will distribute the draft paper to OMS involved in the evaluation of systemic insecticides. After receiving the EFSA paper NL will revise the document and will circulate it. NL will give a timeline of 6 weeks to OMS to comment it.

Actions for NL: to distribute the draft paper to OMS involved in the evaluation of systemic insecticides, to revise the document based on the EFSA paper and to circulate it.

3g. Outcome of the PT21 consultation on freshwater harbours

NL presented the discussion paper. The main objective was to harmonise the model or at least an ESD for fresh water marinas which is intended for product authorization and not for Annex I. NL proposed the development of a fresh water marina based on an OECD marina, adjusting the harbour and boat settings. After TM I, NL received input from UK, DK, FI and SE and thanked them for their contribution. The main outcome was that the Scandinavian countries do not allow antifouling paintings in fresh water pleasure crafts. FI and SE provided no further input on the scenario. UK and DK gave input on the main questions in the document. Because of the limited responses received, NL wants to address only few points of the document, like what ESD to take into account for the risk assessment, what type of marina do we want to protect (in river or inland lake), if this is enough for all fresh water environments or need additional models.

UK asked why we need specific fresh water scenario, and which were the protection goals of this new scenario. NL clarified that the salt water marina has a tidal influence that affects the refreshment rates, which is one of the main input that decides the PEC values. In consequence, NL does not consider the salt water marina protective enough for the fresh water marina. Also, the choice on where to measure the PEC inside/outside the marina is relevant to the discussion on where to assess the risk.

IND has not been part of the e-consultation, but would like to contribute to this consultation, NL agreed to this.

SE noted that in fresh water, the boat washing is a very good alternative to the protection with antifouling paint, and asked MSs to keep in mind that alternative methods do exist.

COM invited MSs to participate to the e-consultation and send comments to NL until 30 August, IND to be included in the consultation.



3i. Outcome of the Fish net e-consultation

This issue was discussed at TMIII 20111, and was followed by an extensive e-consultation lead by **SE**. **SE** proposed the e-consultation to be followed by a workshop, possible in connection to the November TM, suggesting this to the **COM**.

NO is looking forward to the workshop and would like to contribute further to the e-consultation. **COM** asked MSs to submit additional comments to **SE**. The workshop will be organised in agreement with **SE**.

3l. Calculation of groundwater concentrations for substances leaching from wood, masonry and films to soil using PEARL

NL presented the paper and asked TM for input in order to refine and finalize the work.

NL proposed a different methodology compared to what is used in the current guidance: *Groundwater exposure assessment for wood preservatives – Factors to consider*.

Regarding the PEC groundwater calculation **NL** suggested in the document a daily leaching value instead of 10 applications per year. **NL** specified that the active substance is not modelled in PEARL as "parent substance" but as metabolite. The "wall" where the active substance leaches from at a steady rate was set as parent substance.

DE suggested a different approach regarding the time frame of leaching rate to be taken into account in the calculation. **DE** will send written comments to **NL** with more details.

UK will also send more detailed documentation to **NL** for the groundwater calculation affected by leaching rate. **UK** mentioned the leaching calculation proposed by the PT 08 ESD (via PEARL) and reminded the TM to consider it for future comments.

DK and **SE** supported the opinion of **UK** and will consult their experts before sending future comments to **NL**.

NL agreed to take into account the PT 08 ESD and revise the assessment.

Conclusion

NL will collect all available information and additional comments by the 30th of August.

Point closed.

3m. Leaching from paints, plasters, and fillers applied in cities

NL introduced the paper and other general issues related to the guidance document methodologies for leaching scenarios, which are based on the current ESD PT 10 (city scenario).

The main issues discussed at TM were:

- Estimation of a potential "suburb scenario". **NL** suggested a worst case characterised by storm raining water not collected into a STP.
- Harmonization of the default values set for the different materials in the city scenario.

NL proposed (especially in support of PT 06) two different approaches:

- normal case approach: leaching data is available (supplied by applicants);
- worst-case approach: leaching data is lacking.



DK agree that several issues need to be discussed and common agreement to be found for several issues, especially for: possible direct exposure to surface water and product life-time contra leaching life-time. For a number of substances that **DK** is evaluating, the life-time is claimed to be very long, the life-time might in these cases be longer than the leaching life-time.

DK also asked **NL** to clarify the value of 100% leaching rate per year applied in the equations described in the paper. **DK** referred to earlier discussion at **TM** where it was decided to apply an f_{house} value of 1 instead of a value of 0.5.

NL provided a more in depth explanation on the methodologies used in the city scenario regarding the different time frame of leaching rate, supporting what has been done in the document.

IND supported the approach provided by **NL** regarding the leaching rate and proposed to clarify any questions by e-mail consultation.

DK agreed that the input data of one house treated per day might be too little; however the approach suggested by **NL** where 33 houses are treated on 30 days hardly makes no difference in the results. **DK** therefore suggest to keep the procedure proposed in the current ESD.

UK informed **TM** about their experience in this field and proposed to contribute to the paper refinement with more information regarding the "suburb scenarios". **UK** mentioned the approach currently used for PPP assessment (herbicides on pavements). **UK** also proposed to follow the PT 18 ESD which suggests two different methodologies regarding the leaching scenarios:

- 100% of storm raining water is considered to go directly to the surface water bypassing STP;
- 100% of storm raining water goes through STP to surface water.

CH added comments related to the storm raining water scenario and reminded the **TM** of new studies from Germany and Switzerland which indicate 40% of storm raining water usually bypassed STP.

Conclusion

COM asked **NL** to collect all available information and additional comments on leaching from paints, plasters, and fillers applied in cities by the 30th of August.

Point closed.

3n. Outcome E-consultation Koc for PT21

SE presented the point. As agreed at the last **TM**, **SE** made an overview of the derivation of **Koc** among the **PT21**, hiding the name of the active substances, and had an e-consultation on this. **SE** intended to find the lowest concentration, but it was not possible as it was on the borderline between the lowest and highest concentration. Considering the outcomes, **SE** proposed 2 ways forward:

- to follow the PPP approach, use the Freundlich default value of 0.9 for the extrapolation of the **Koc**.

- or, as suggested at the last **TM**, **IND** could be requested to submit new studies for all antifouling substances. One of the applicants already agreed to do that. **SE** is in favour of this approach.

UK asked for clarification regarding the further extrapolation to what was previous discussed. **UK** is not in favour of extrapolation to low concentrations of the order ng/L, although they are environmentally relevant, since the models do not allow to do this with enough certainty **UK**



discussed also about the size of extrapolation, that it should be reasonable and may be done over a few orders of magnitude.

DK noted that in EFSA, they decided to change the Freundlich default value to 0.8. (**DK** has afterwards discovered that this was a mistake and a Freundlich value of 0.9 should be used, however in cases where only measured K_d -values for a single soil solution concentration are available or estimated quantitative structure-activity relationship (QSAR) adsorption values are seen, it is necessary to set the corresponding $1/n$ -value to 1. **DK** was in favour of second way forward proposed by **SE** as it can be seen that a very narrow concentration range has been tested. In the OECD guideline it is stated that preferably two orders of magnitude should be covered and 5 test concentrations. **DK** is of the opinion that if possible new tests should be performed covering a larger concentration range, while **NL** was in favour of the first option. Regarding the second option, **COM** reminded MSs that some of the PT 21 substances are at the stage of final draft CAR, so requesting these applicants for further studies might not be feasible.

IND clarified that for a new study, it may be needed a period of 12 months before delivering the results. **IND** asked the TM to take into consideration their comments regarding the extrapolations.

IND and **SE** agreed to use the μg order of concentration and not ng.

COM proposed to investigate the use of this new default value of 0.8, and go forward from there.

COM pointed out that many documents arrived late and MSs did not have the time to read the document. **SE** agreed to continue this discussion via e-consultation.

Conclusion

The discussion will proceed via e-consultation.

Point closed.



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TMII2012-item1-Draft-Agenda- Version5.doc

15/06/2012

Draft AGENDA

Biocides Technical Meeting

**Place of meeting
Hotel Park Inn, Somma Lombardo, Italy**

18th-22nd June 2012

START: 18th June 2012 at 13:30 hrs
FINISH: 22nd June 2012 at 16:00 hrs



INTRODUCTION

START: 18th June 2012 at 13:30 hrs

FINISH: 18th June at 14:00 hrs

1. Approval of the agenda

(TMII2012-item1-Draft-Agenda-version5)

2. Adoption of the minutes

(TMII2012-item1-Draft minutes TMI 2012_version2.doc
TMII2012-Item 1-Draft Minutes TMI2012_version 1 comments AT
TMII2012-Item 1-Draft Minutes TMI2012_version 1_FIcom
TMII2012-Item 1-Draft Minutes TMI2012_version 1-DK comments
TMII2012-Item 1-Draft Minutes TMI2012_version 1-EuroChlor comments
TMII2012-Item 1-Draft Minutes TMI2012_version 1 PL comments
TMII2012-Item 1-Draft Minutes TMI2012_version 1_DE
TMII2012-Item 1-Draft Minutes TMI2012_version 1_NO comments
TMII2012-Item 1-Draft Minutes TMI2012_version 1_UK comments
TMII2012-Item 1-Draft Minutes TMI2012_version 1-FR
TMII2012-Item 1-Draft Minutes TMI 2012 Active chlorine TOX GEN_ENVapplicant response
TMII2012-Item1-Draft Minutes TMI2012_version 1_SEcomments)
TMII2012-Item1-Draft Minutes TMI2012_version 1_PL comments)

3. Action List TM

(TMII2012-item3-Action List TM.doc)

4. Members of the Technical Meeting

(TMII2012-item4-tm-members.doc)

5. Next Technical Meetings and CA meetings

2012

TM III 1 – 5 October
TM IV 26 – 30 November

CA III 3 – 7 July
CA IV 18 – 22 September
CA V 11 – 15 December

2013

TM I 11-15 March 2013
TM II 10-14 June 2013



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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



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TOXICOLOGY SESSION

START: 18th June 2012 at 14:00 hrs

FINISH: 19th June at 18:00 hrs

1. GENERAL DISCUSSION

1a. Evaluation of disinfectant by-products

TMII_2012_Tox_item 1a_ DBP_Points to be discussed at TM June 2012.pdf

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. Iodine (RMS: SE) for PT 01, 03 and 22

(TMII2012-tox2.1a, gen3.1a, env2.1a-Combined_RCOM table_Iodine _PT 01,03,22

TMII2012-tox2.1a, gen3.1a, env2.1a-Discussion_iodine PT 1,3,22_Applicant's comments to RCOM

TMII2012-tox-item 2.1a-Discussion_iodine PT 1,3,22)

2.1b. Cyromazine (RMS: EL) for PT 18

Response Commenting table_Cyromazine_PT18 (consolidated).doc

2.1c. Propiconazole (RMS: FI) for PT 09

(TMII2012-Tox-item2.1c,Gen-item3.1c-Propiconazole PT 9 Discussion paper Tox Gen)

TMII2012_TOX_GEN_Propiconazole PT 9_Discussion paper_LXS comments.docx

2.2 Second discussion for the following substances

2.2a. Trifluronon (RMS: IT) for PT 18

(TMII2012-Tox-item2.2b-Trifluronon second discussion)

3. AOB

3a. Update HEEG

(TMII2012-Tox-item3a-HEEG Opinion on an approach to identification of worst-case human exposure scenario for PT6)

3b. Update DRAWG

(Draft Guidance, to be prepared by DE)

(TMII2012-Tox-item3b-DRAWG DRAFT PROPOSAL_18 05 2012)

3c. Evaluation Manual for Product Authorisation



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(TMII2012-Tox-item3c-Encoded_standard_instruction_phrases_compiled_120507.doc;
TMII2012-Maintenance_evaluation_manual_Comments_DE)

3e. Antimicrobial Exposure Assessment Task Force Presentation

(presented by American Chemistry Company, US)

3f. Toxicity of Cinnamic Aldehyde (PT 2)

(follow up of e-consultation, presented by UK)

(TMII2012-Tox-item3f-Annex I - Cinnamic aldehyde - e-Consultation with OMS - Toxicology issues.doc;

TMII2012-Tox-item3f-Annex II - Cinnamic Aldehyde 2007 Submission IIIA6_8_2.doc;

TMII2012-Tox-item3f-Cinnamic Aldehyde PT 2 Tox way forward.doc)

3g. Workshop on the Mixture Assessment in Biocidal Products Authorisation

(COM to inform)

(TMII2012-Tox-ite3g, Gen-item 4c-Workshop on Mixture toxicity)

3h. TM opinion on the issues raised by CZ in relation to the mutual recognition procedures of four IPBC-containing products authorised by DK (request by the PA&MRFG meeting)

(TMII2012-tox-item 3h-Restricted notification_CZ, TMII2012-tox-item 3h-Restricted notification_CZ_applicant reply)

3i. Assessment of mutagenicity

(46th CA meeting follow up, to be prepared by SE)

(TMII2012-tox-item 3i-Assessment of mutagenicity CA 2012-05-04;

TMII2012-tox-item 3i-Assessment of Mutagenicity SE response after CA 2012-05-29)

SPECIAL SESSION (for those interested – to start after the TOX session):

Meeting of the working group on risk assessment for local effects



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GENERAL SESSION

START: 20th June 2012 at 09:00 hrs

FINISH: 20th June 2012 at 15.00 hrs

1. Reporting on the last CA meeting

(COM to inform)

2. Tracking System: Progress reports

(TMII2012-Gen-item2-Progress report existing.pdf

TMII2012-Gen-item2-Progress report new.pdf)

3. SUBSTANCES

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TMII2012-tox2.1a, gen3.1a, env2.1a-Discussion_iodine PT 1,3,22_Applicant's comments to RCOM

TMII2012-gen-item 3.1a-Discussion_iodine PT 1,3,22)

3.1b. Cyromazine (RMS: EL) for PT 18

Response commenting table_Cyromazine_PT18 (consolidated).doc

3.1c. Propiconazole (RMS: FI) for PT 09

(TMII2012-Tox-item2.1c, Gen-item3.1c-Propiconazole PT 9 Discussion paper Tox Gen)

4. AOB

4a. Evaluation Manual for Product Authorisation

(Document to be prepared by NL)

(TMII2012-Maintenance_evaluation_manual_Comments_DE)

4b. TM SOP update

(COM to inform)

(TMII2012-gen-item 4b-TM(BPD)_SOP v-4)

4c. Workshop on the Mixture Assessment in Biocidal Products Authorisation

(DE to inform)

(TMII2012-Tox-ite3g, Gen-item 4c-Workshop on Mixture toxicity)



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ENVIRONMENT SESSION

START: 21st June 2012 at 09:00 hrs

FINISH: 22nd June 2012 at 16:00 hrs

1. GENERAL DISCUSSION

1a. Evaluation of disinfectant by-products

TMII2012-ENV-item1a_Evaluation DBP NL proposal - adapted.doc

TMII2012-ENV-item1a_Evaluation DBP NL proposal - comments.doc

TMII2012_ENV_item1a_Assessment_of_disinfectant_by_products_NL-2_SK comments.doc

2. SUBSTANCES

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TMII2012-tox2.1a, gen3.1a, env2.1a-Discussion_iodine PT 1,3,22_Applicant's comments to RCOM

TMII2012-env-item 2.1a-Discussion_iodine PT 1,3,22)

TMII2012-TOX-Iodine PT3 food risk assessment for infants.doc

2.1b. Cyromazine (RMS: EL) for PT 18

Response commenting table_Cyromazine_PT18 (consolidated).doc

2.1c. Propiconazole (RMS: FI) for PT 09

2.1d. Sodium hypochlorite (RMS: IT) for PT 01-05

(Only the effect parts for the Environment will be discussed)

(TMII2012-Env-item2.1d_1-Doc IIIA_07_04_01_02_(03)

TMII2012-Env-item2.1d_2-Doc IIIA_07_04_01_02_(04)

TMII2012-Env-item2.1d_3-Doc IIIA_07_04_03_05_02_(01)

TMII2012-Env-item2.1d_4-ROOM DOCUMENT_rev)

2.1e. Calcium hypochlorite (RMS: IT) for PT 02-05

(Only the effect parts for the Environment will be discussed)

(TMII2012-Env-item2.1d_1-Doc IIIA_07_04_01_02_(03)

TMII2012-Env-item2.1d_2-Doc IIIA_07_04_01_02_(04)

TMII2012-Env-item2.1d_3-Doc IIIA_07_04_03_05_02_(01)

TMII2012-Env-item2.1d_4-ROOM DOCUMENT_rev)

2.2 Second discussion for the following substances



2.2a. Triflumuron (RMS: IT) for PT 18

(TMII2012-Env-item2.2a-Triflumuron-New studies.zip
TMII2012-Env-item2.2a-Triflumuron-Open points.doc)

2.2b. Copper pyrithion (RMS: SE) for PT 21

(TMII2012-ENV2b- Discussion_copper pyrithione.doc; TMII2012-ENV2b- RCOM for_TM II
2012_vs20120510)

3. AOB

3a. Evaluation Manual for Product Authorisation

(Document to be prepared by NL)
(TMII2012-Maintenance_evaluation_manual_Comments_DE)

3b. Risk mitigation PT 21 for pleasure crafts

(TMII 2012-env-item3b-from TMI2012-ENV-item 5g-CEPE ICOMIA paper introduction
TMII2012-env-item3b-from TMI2012-ENV-item 5g-ICOMIA - Paint control measures for
recreational boats)

3c. Study CEPE regional marina scenario

(TMII2012-env-item3c-from TMI2012-ENV-item 5h-Regional Marina Scenario Study)

3d. Workshop on the Mixture Assessment in Biocidal Products Authorisation

(DE to inform)

3e. Update development of an opinion paper with the methodology of the risk assessment to bees

(NL to inform)

3f. Evaluation of iodine released from IPBC for wood protection products

(Document prepared by DK, for discussion)
(TMII2012-Env-item3f-evaluation of iodine released from IPBC TMII2012-env-item3f-NL ENV
concerns on Induline mutual recognition)

3g. Outcome of the PT21 consultation on freshwater harbours

(presented by NL)

3i. Outcome of the Fish net e-consultation

(presented by SE)
(TMII2012-Env item3i-FishNetEconsultation_results _31May2012)

3l. Calculation of groundwater concentrations for substances leaching from wood, masonry and films to soil using PEARL

(presented by NL)



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(TMII2012-env-item3l-Groundwater concentrations for substances leaching from wood, masonry and films to soil using PEARL)

3m. Leaching from paints, plasters, and fillers applied in cities

(presented by NL)

(TMII2012-env-item3m-the city scenario)

3n. Outcome E-consultation Koc for PT21

TMII2012_ENV_item_3n-Koc_discussion (Follow up TM I2012 ENV session point 5a , Koc).pdf