Final Minutes TMI2012.doc

Biocides Technical Meeting
19th-23rd March 2012

INTRODUCTION

The meeting was chaired by E. van de Plassche and for specific items on the agenda by A. Payá Pérez, J. Janossy, P. Piscoi, V. Rodriguez Unamuno, S. Pakalin, B. Raffael, R. Letrich, C. Pecorini. E. van de Plassche welcomed the participants to TM I 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 from TM II 2012 the meeting will be chaired by A. Payá Pérez as E. van de Plassche will move to ECHA. B. Raffael will assist in the coordination of the peer review process for the Review Program and new active substances. DG JRC will inform the members of the TM in more detail.

COM informed that all documents now uploaded on CIRCA under the interest group "Biocides TM" will be migrated to a new system entitled CIRCA BC. Once the migration is completed, **COM** will inform the TM.

For the agenda **COM** added item 7f of the TOX Session entitled "Information on training on CONSEXPO and BEAT". On request of AT item 7e of the GEN Session was added entitled "Participation of pre-accession countries of the EU in the TM". The agenda was adopted without further changes.

2. Adoption of the minutes

No comments were made on the draft minutes version 2 distributed by COM. The minutes were consequently adopted without any changes to be made to this version.

3. Action List TM

1. *Development of refinement marina scenario for PT21 to be used in product authorisation*

   The document was received: see agenda item 5h of the ENV Session. Action can be removed.

2. *Comments on document PL on "Harmonisation of environmental risk assessment for PT 06".*

   PL will revise and finalise the guidance document and forward to the CA meeting. However, **COM** did not receive the document yet.

3. *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.

4. *Draft guidance document on field studies and distribute to COM and involved MS.*

   The document was received: see agenda item 5d of the ENV Session. Action can be removed.

5. *Finalise Document on emission estimation for insecticides for households and professional uses: targeted applications for discussion at CA meeting.*

   COM is waiting for the outcome of consultation between **UK** and **SE** on a document prepared by SE (this action item was discussed as agenda item 5f of the ENV Session (TM II 2011)). However, the method is laid down in MOTA so it can already be applied.

6. *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.*

   COM has no news on the progress on this action item.

7. *Send reactions to DE on environmental risk assessment for PT 22.*

   COM received the document from **DE**. This information was made available on the web-site of JRC-IHCP on the web-page of the ESD for PT 22. Action can be removed.

8. *Consultation on document of DK related to several ESDs.*

   COM will consult with **DK** on the status of the document.

9. *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.

10. *Groundwater assessment and Annex I inclusion: information on the number of FOCUS scenarios requested at national level to COM.*

    COM informed a document was prepared for the last CA meeting. The document will be discussed again at the next CA meeting, as first written comments were asked for. Action can be removed.

11. *Preparation of a document with the basis for a TM discussion on requirements and validation of confirmatory methods for residues.*

    COM prepared a document: see agenda item 7a of the GEN Session. Action can be removed.

12. *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).*

    COM informed that **NO** will prepare a questionnaire to be sent out after this TM.

13. *To organise workshop on the evaluation of efficacy tests of PT 21.*

    COM stated the workshop is organised on March 22 during this TM. Action can be removed.

14. *Send comments to NL on document on the evaluation of disinfection by products (DBP).*

    COM stated that several MS send comments to NL: see agenda item 1a of the TOX Session. Action can be removed.

15. *To distribute EFSA Guidance (2011) on the use of scientific literature data for the approval of PPP active substances.*

    COM stated that this document was uploaded on CIRCA. Action can be removed.

16. *Finalise guidance documents on environmental risk assessment for PT 21.*

    COM stated that this document will be finalised by the UK for the next TM.

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

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5. Next Technical Meetings

2012

TM II	18 – 22 June
TM III	1 – 5 October
TM IV	26 – 30 November

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 01 – PT 05

1a. Evaluation of disinfectant by-products

COM emphasized that the evaluation of DBPs relates to all disinfectants, not only to one class of disinfectants. Therefore, the discussion of DBPs is considered general and as earlier, an open session was considered appropriate. It was decided at the previous TM that the risk assessment of DBPs has to be dealt with before Annex I inclusion. The **NL** has prepared a paper for the CA meeting and an example risk assessment on two substances to be discussed at the TM. Due to insufficient time for commenting the discussion was postponed to TMII-2012. **NL** proposed to include all comments and to organise a telephone conference in the middle of May. **FR, DE, PT, AT** and **IND** indicated that they will send their comments.

Conclusion
MSs and **IND** were asked to send their comments by April 20, 2012 to the **NL** and the **COM**. The revised version of the document including the results of the consultations will be discussed at TMII-2012.

First discussion for the following substances

1b. Sodium hypochlorite (RMS: IT) for PT 01 – 05
1c. Calcium hypochlorite (RMS: IT) for PT 02 – 05
1d. Active chlorine (RMS: SK) for PT 01 – 05

2. SUBSTANCES in PT 02

Second discussion for the following substances

2a. BCDMH (RMS: NL)

3. SUBSTANCES in PT 06

First discussion for the following substances

3a. DMDMH (RMS: PL)

3b. Formaldehyde core dossier (RMS: DE)

4. SUBSTANCES in PT 13

First discussion for the following substances

4a. DMDMH (RMS: PL)

5. SUBSTANCES in PT 18

Second discussion for the following substances

5a. Diflubenzuron (RMS: SE)

6. SUBSTANCES in PT 21

Second discussion for the following substances

6a. Copper pyrithione (RMS: SE)

First discussion for the following substances

6b. Zineb (RMS: IE)

7. AOB

Announcement of the training on ConsExpo and BEAT

A training course on the use of IT tools, namely ConsExpo and BEAT, to assess human exposure to biocides will be organised by the Institute for Health and Consumer Protection – Chemical Assessment and Testing Unit and will be delivered by the UK's Health and Safety Laboratory.
The aim of the course is to improve capacity, understanding and harmonisation in biocide exposure assessment. The possibility of running a 3 day course, including a 2 day basic course and an additional day of advanced training, is being explored.
The training is open to Competent Authorities on Chemicals in all Member States and in the Countries from the Enlargement and Integration Action, as well as to Delegates from Industry. If not enough confirmations are received, the training course could postponed or cancelled.
The training will be held in Italy, and the provisional dates are from 20th to 22nd June 2012, in parallel with the General and Environmental sessions of the TM II 2012. The provisional deadline for registration is 30th April 2012.

7a. Update HEEG

7a.1 The HEEG Opinion is focused on the paper by Links et al. "Occupational exposure during application and removal of antifouling paints", published in 2007 in the *Annals of Occupational Hygiene*.

7a.2 The HEEG paper has been prepared by **UK**, after a pre-HEEG consultation involving some HEEG members and other Consultees out of HEEG. **COM** thanked **UK**, **DE**, **FR**, **NL**, **NO** and **SE** and the other HEEG members who contributed with their comments to the paper, for their excellent work.

7a.3 The opinion is organised in several points which **COM** summarised as follows:
(a) First, it has been agreed that the data reported in the Links' study are scientifically sound, due to the fact that the paper has been peer-reviewed in order to be published.
(b) Secondly, it was considered that the Links' data can be used only for professional application of paint by roller. The data cannot be used for exposure assessment for application by brush by either the professional or the non-professional user. **NO** commented that for the professional application of paint by brush **and** roller, combining the Links data on rolling with the TNsG data on brushing (consumer product painting model 4) might be a possibility if time duration could be specified for the two different tasks. Although the Links' data for professional application by roller are suitable for regulatory purposes, the choice of the geometric mean seems to be not sufficiently conservative. A HEEG-appointed group will be formed to determine exposure values used for assessment of professional application of antifouling by roller. **SE** offered to lead the group. If the paper of the HEEG-appointed group will not be ready by TM II 2012, the relevant

RMSs can proceed with their assessment and then amend their Dossiers when the HEEG-appointed paper is endorsed by the TM.
(c) The Links' paper also addresses professional application of antifouling paint by means of air-less spraying. The data on exposure generally give significantly lower values for dermal exposure compared to the peer-reviewed TNsG and User Guidance update. Therefore, in line with the decision to consider the worse case dataset, the TNsG data, updated by User Guidance, should be used for exposure assessment for spaymen.
(d) Then, the Links' paper deals with professional exposure of professional potman, responsible for mixing and loading of paint and for tendering tasks. The MOTA decision and the TM III decision support the view that the TNsG data, updated by User Guidance, should be used for review of antifoulings.
(e) Another scenario taken into account by the Links' study is professionals removing antifouling paint by means of sand blasting. In order to remain in line with the current environmental assessments, the OECD Emission Scenario Document (ESD) data should be used (as revised, cf. agenda item 7e) – until further notice – to assess human exposure to antifoulings during removal from a treated surface. **FR** confirmed that the OECD ESD data are relevant for humans as well. **NO** pointed out that OECD ESD data cannot be used alone, but together with exposure data (i.e. exposure data from the Links study (sand blasting) or from the TNsG 2002/User guidance (the spraying model 3)). As the only real exposure data for the process of paint removal can be found in the Links study, **NO** was in favour of given the Links data preference. A HEEG-appointed group will be formed to devise a human exposure model combining the OECD ESD data together with exposure data from Links and, if necessary the User Guidance Spraying model 3. In addition, environmental discussions on leaching rates will be taken into account, if necessary. **NO** offered to take the lead of this group.
(f) Finally, the Links' paper addresses exposure of professional grit-fillers, who are responsible for monitoring the grit and water supply to the kettle and air to the tower wagon. A HEEG-appointed group will be formed to assess the suitability of the data on exposure of grit-fillers and to evaluate what PPE is appropriate for these professionals. So far, nobody has offered to lead the group.
(g) The last point of the HEEG Opinion concerns the confirmation as to whether the paper by Hughson et al. "Determination of dermal exposures during mixing, spraying and wiping activities" (published in 2004 in the *Annals of Occupational Hygiene)* and the LLewellyn data ("Exposure during application of antifouling paints: copper and organotin compounds", *Internal Report. Health and Safety Executive, UK*) has been already included in the BEAT database.

7a.4 COM concluded the presentation on the HEEG Opinion on the Links' paper by mentioning that after endorsing the HEEG Opinion and addressing the abovementioned points, the Links' data will be forwarded to BEAT with the aim of considering their inclusion in the BEAT database. **NO** suggested to contact the ones responsible for updating the database as soon as possible to ascertain that the exposure data are included in the upcoming next version of BEAT (if considered suitable).

Overall conclusion
The HEEG Opinion on the Links' paper is considered as endorsed by the TM and will be published in MOTA as usual practice.

7b. Update DRAWG

DE updated the TM on the latest developments of DRAWG. A new draft guidance document on estimating transfer of biocidal active substances into foods is expected to be ready for commenting in May. **DE** asked the **COM** whether after finalizing the TGD there is a possibility that DRAWG could go on similarly to HEEG or in other format to give opinions on dietary risk assessment related issues. **COM** promised to consider the proposal.

7c. Classification of biocidal products for sensitisation

UK prepared a discussion paper on classifying biocidal products containing extreme skin sensitizers (with concentration limits below 0.1% w/w) with human data. The question was whether a negative formulation skin sensitizing study on animals can override the human data on the active and the application of the conventional calculation method according to the Dangerous Preparation Directive or the CLP. Written comments arrived from **SE**, **SI** and **IND**. The issue was briefly discussed. **FR** and other MSs were prepared to send their comments. **AT** proposed that the group involved in the revision of the local effect assessment guidance may discuss the problem and include it in the revised guidance. The UK asked that particular attention is paid to these situations and that negative formulation animal studies should not be readily accepted. It was agreed that generalised advice cannot be given and that a case-by-case approach should be taken (depending on whether the animal data support the human data on the active and the nature of the formulation).

Conclusion
MSs and **IND** were asked to send their comments by 20 April to the **COM**.

7d. Evaluation Manual for Product Autorisation

The TM was invited to send written comments to NL by April 23 on the document prepared.

7e. PT 21 AOB

NO presented the results of the trilateral discussions among **SE**, **NO** and **IND**. For details see "TMI2012-TOX-item 7e-Fai old paint and human health exposure assessment PT21" document uploaded to circa.

GENERAL SESSION

1. Reporting on the last CA meeting

COM reported on the outcome of the CA discussions.

2. Tracking System: Progress reports

The TM was invited to send written comments to **COM**.

3. SUBSTANCES in PT 01 – 05

3a. Active chlorine (RMS: SK) PT 01-05

4. SUBSTANCES in PT 06

First discussion for the following substances

4a. DMDMH (RMS: PL) PT 6 and 13

4b. Formaldehyde core dossier (RMS: DE)

4c. IPBC (RMS: DK)

5. SUBSTANCES in PT 13

First discussion for the following substances

5a. DMDMH (RMS: PL)

6. SUBSTANCES in PT 21

Second discussion for the following substances

6a. Copper pyrithione (RMS: SE)

6b. Cybutryne (RMS: NL)

First discussion for the following substances

6c. Zineb (RMS: IE)

7. AOB

7a. Confirmatory analytical methods for residues: requirements and validation

Background

Almost in all TM there are some discussions on the confirmatory methods for residues. **COM** prepared a paper with a proposal for the TM on the requirements for these analytical methods where some flexibility on the time of delivery can be granted.

Discussion

COM introduced the paper saying that after checking the available documentation, the proposal of reducing the requirements for validation of the confirmatory methods for residues seems not supportable by any legal background. Thus the document deals only with the timing for the delivery of such methods.
COM said that the proposal highlighted in the paper is that some flexibility on the timing for the delivery of such methods, when missing for relevant reasons, can be decided, based on a case by case approach. In some cases, under specific circumstances (e.g. when the submitted information fulfilled the data requirements that were valid at that time of submission of the dossier), the TM can agree to leave the applicant some more time for the development of the requested method and/or its validation, granting the permission to provide the information at product authorisation stage.
COM specified that this approach does not substitute the necessity of providing the required methods at Annex I stage. It only allows some flexibility in some specific cases, where additional information is required, and it has to be agreed upon by the TM.
It has in no way to be seen as derogation from the requirements that could be granted on a regular base to all dossiers.

UK agreed with the proposal to grant flexibility in some cases and proposes to ask for the confirmatory methods 6 months before product authorisation stage, so that the methods are sent to the RMS. This would avoid having many MSs to check the same methods.
UK also proposed to allow applicants not to submit confirmatory methods for residues in air when there are sufficiently validation data in soil and water, which are more complex matrices.

DE, IE, NL, FI and **FR** agreed with the proposal of **COM** on the flexibility in the delivery requirements for the confirmatory analytical methods for residues, with the timing proposed by **UK**. They also agreed on the additional proposal by **UK** on the confirmatory analytical methods in air.
IE asked if there is the possibility of granting flexibility on the requirements for the validation of the primary methods, bridging the PPP. COM replied that for the Biocides field the validation requirement of the primary methods are not under discussion and the primary methods have to be provided sufficiently validated for Annex I inclusion.
NL asked if the biocides TNsG will be updated following the PPP approach. COM said that revisions of the TNsG are not foreseen until the hand-over of the tasks to ECHA, who is starting to organise specific expert groups on the topic. So any proposal in this sense has to wait and be done directly to ECHA starting from 2014.
AT proposed to add to a future revision of the TNsG the definition of confirmatory analytical method, taken from the dioxins legislation. **AT** agreed with the proposal of COM on the flexibility in the delivery requirements for the confirmatory analytical methods for residues, with the timing proposed by **UK**.
No MS opposed to the two proposals, so they were both accepted.

Conclusion

The TM accepted to leave the applicants some more time for the development of confirmatory methods for residues and/or their validation, in some specific cases, accepts to provide the missing information on confirmatory methods to the RMS 6 months before the product authorisation stage.
The TM also accepted to allow applicants not to submit confirmatory methods for residues in air when there same methods are sufficiently validated in soil and water.

However, any revision of the TNsG is not foreseen until the hand-over of the tasks to ECHA, starting from 2014.
Point closed.

7b. Evaluation Manual for Product Authorisation

NL introduced the document. The document is related to the revision of the Evaluation Manual for Product Authorisation which will be revised once a year. **NL** has gone through the minutes of the TM for 2011 and extracted those issues which will need to be addressed according to them in the revision. The following issues were discussed:

- Develop guidance on how to extrapolate to different types of packaging for shelf life studies. **UK** will prepare a draft guidance document.
- GLP requirements for physico-chemical properties and other safety data. **UK** referred to Annex II and III of the new Biocidal Products Regulation where it is stated that " international standards", where according to **UK** it is unclear what is meant by "other international standards" as to their understanding GLP is the only one. **COM** referred to a discussion in the PA & MR FG on GLP requirements for these types of data. It was decided that **COM** will forward the relevant document from the PA & MR FG to **NL**.
- Develop guidance on storage stability studies. **NL** stated that it was at an earlier TM decided that guidance needs to be developed and that **NL** will develop guidance for PT 06 and 21, the latter in consultation with industry. **DK** recommended organising a workshop on this aspect where for example the acceptability of the accelerated storage stability test versus a 2 year test has to be addressed.
- Consideration of new guidance from DG SANCO on the residue definition.

TM was invited to send additional issues on physico-chemical properties and safety related data or on efficacy to **NL**.

COM clarified on request of **IND** that the Evaluation Manual for Product Authorisation will be revised once a year. **NL** has now collected issues which will need to be taken up in the revised version. The TM is the forum to discuss the revised manual, where on a case by case basis it will be decided if a dedicated meeting is required for a certain issue.

7c. Inventory concerning the development of resistance in mice and rats

NL introduced the document. The purpose of the questionnaire is harmonisation of resistance management approaches in MS. **COM** stated this topic is more in the remit of the PA & MR FG, where currently product authorisations of rodenticides are discussed. **DE**, **IND** and **DK** stated they will forward information to **NL**. **(FR** already answered before the **TM)** Other MS were invited to send their reactions within 2 months after the TM.

7d. Guidance on evaluation of efficacy for PT 02

COM introduced the point by describing the general history of the document and the proceedings. Given the high number of the comments and their late submission, the TM was presented with a number of points of a general nature leaving the rest for a written round.

NL, the leader of the project, introduced the document.

7d.1 Use of disinfectants for soft furnishing – NL, BE, CH

MSs expressed their concern on this type of use, mainly due to possible induction of antimicrobial resistance (used in homes, hospitals).
Conclusion: additional comments will be presented in the written round.

7d.2 Use of a biocide for bacteriostatic effect – DE

The TM was asked if the use only for the bacteriostatic effect would be acceptable. **DE** was concerned by the possible induction of antimicrobial resistance. However, **DE** was aware that such products are on the market, mainly for the households, and considered that it is relevant to have a specific chapter covering the matter. However, DE is of the opinion that due to the risk of antimicrobial resistance development a highly proper assessment of this kind of products is necessary. **COM** informed that a SCENIHR opinion is being developed on the matter and that a targeted project - BIOHYPO is being financed under the FP7 – http://sites.google.com/site/biohypo . **NL** asked on the impact of the new PT 2 description under the BPR. The group will discuss the matter; a follow up at CA level may be necessary.
Conclusion: DE will send a proposal in the written round. A decision will be taken on keeping or deleting the chapter and respective products.

7d.3 Pass criteria, norms to be used – DE

Sometimes draft norms are mentioned as norms to be used. Is this acceptable? The comment refers to room disinfection. **NL** clarified that as long as a code number is available for a test, then it can be mentioned.

Conclusion
A reference to the draft document "Methods of airborne disinfection of surfaces" (referring to CEN/TC 216 resolution 77/2011) will be included in the guidance.

7d.4 Pass criteria – IT, SP

The guidance says at the moment that the pass criteria will be the one mentioned in the **EN** norm used. Sometimes standards that are not **EN** are recommended and some do not include pass criteria. The matter concerns the biofilm. As the matter was considered very technical, it was postponed for the written round.

Conclusion
Topic to be discussed under the written round or in a dedicated group and the decision to be taken by the CA-Meeting.

7d.5 Claims – IND, NL

The current text states that it would not be possible to claim a single species without having a group of organisms tested. **IND** opposed to the principle, especially for very specific industrial uses. **NL** proposed to leave in the general chapter a more broad definition and then specify under specific chapters if one species claims are allowed with testing involving only that species. **NL** was of the opinion that for private uses such a claim should not be allowed and asked the TM for an opinion. **DE** agreed with **NL** and considered that a standard test should be performed for all uses under PT2. A sentence concerning the claim will be sent to **NL**, covering the potential of such claims to mislead the consumers. **IND** said that tests for the claims are necessary. **IND** asked for flexibility in specific applications. Also **IND** pointed out that to request for general tests in all the cases may lead to a situation in which the concentration of the product has to be higher, that may lead to reformulation of the products that renders them unusable for specific uses. **IE**

supported the idea that enough flexibility in the document should be introduced so that specific uses may be accommodated.

Conclusion
Topic to be discussed under the written round or in a dedicated group.

7d.6 Testing for viruses

The current text states that Products against viruses must be effective against viruses with and without "envelope". **NL** asked for the opinion of the TM. **IND** explained why testing for certain types of very difficult to destroy viruses would not be necessary for certain types of products. Products that can easily deactivate influenza might not pass the criteria for Polio.

Conclusion
Topic to be discussed under the written round or in a dedicated group.

Overall conclusion
Due to the high number of comments and their technical complexity a written round of one month was proposed. Based on this round and in consultation with the members of the working group, the MSs and **COM** the leader may propose a dedicated workshop. The practical arrangements for such a workshop will be discussed with the **COM**.

7e. Residue definition

Background

After the issue of residue definition was raised several times in the past TMs, COM prepared a document to clarify the difference between residue definition under Directive 91/414/EEC on Plant Protection Products (PPP) and under the Directive 98/09/EC on Biocidal Products (BPD), and the requirements of the guidance documents for Biocides on the topic.
Based on such requirements, the approach to be followed by Competent Authorities (CAs) in deciding upon residue definition and for planning TM discussions on the topic will be clarified.

Discussion

COM introduced the paper and explained that in recent TMs, the issue of residue definition was raised several times. To avoid duplication of discussions, COM prepared the paper with the aim to clarify the approach to be followed by Competent Authorities (CAs) in deciding upon residue definition and for planning TM discussions on the topic.
COM said that according to the BPD and the TNsG, the CAs should establish which are the relevant metabolites and establish the LOQ values for the analytical methods in the different environmental and toxicological matrices, based on the risk assessment.
The analytical methods to analyse the metabolites in all the relevant matrices have thus to be present in the CAR. In case there is a disagreement with other MSs on the residue definition, or in particular cases where identifying the residues can be controversial and bilateral discussions with other MSs do not lead to any acceptable conclusion, the CAs can discuss the issues at the TM, in the environmental and/or in the toxicological sessions. The technical issues, concerning the feasibility, suitability and requirements fulfillment of the analytical methods to detect the residues in all the matrices, where any, have to be discussed in the general session of the TM.

DE proposed to have a specific guidance document prepared on how to define the residue definition or to have a revision of the existing guidance. They would like to have a table added to the List of Endpoints in Doc I. The residue definition used in PPP and in veterinary products

should be harmonized. It should be as simple as possible: if the active is a good marked, the inclusion of other metabolites should be avoided as it would increase the costs for validation and for routine analyses. Only metabolites of ecotoxicological and toxicological relevance and/or metabolites present in relevant quantities should be added. A chapter on the relevant residue definitions in food is currently included in a draft Guidance in preparation by the DRAWG.
COM said that any change to the TNsG will be done by ECHA in the future. At the moment there is no different between the two residues ion the Biocides TNsG, but in the document under preparation by DRAWG this separation is expressed. COM proposed to rely on the document that will be presented possibly within 2012 by DRAWG.
IE agreed with **DE** and added that a distinction between residue definition for risk assessment and residue definition for monitoring is needed to avoid having the need of analytical methods also for substances that do not need to be monitored. It is important that ENV and TOX experts agree on which are the relevant metabolites that need to be analysed, to avoid having too many substances to analyse which would lead to an increase in costs for the control laboratories. The same issue on residue definition was extensively discussed in PPP and the differentiation of definitions was decided.
UK agreed with **DE** and **IE** and added that there is not enough info on how to determine the residue definition, thus for the CAs this can be very difficult.
NL agreed with **DE** and **IE**.
IE agreed with **UK**, and added that it is very important to define what is really relevant and how to determine it.
COM proposed to wait for the DRAWG document to be ready and then eventually to expand it if there are further needs.
DE said that the DRAWG document will be ready in a few weeks and then it will be circulated to all MSs. **DE** asked the MSs that commented this topic to send their inputs so that they can be included or discussed further.

Conclusion
TM agreed to wait for the document prepared by DRAWG to be ready and then in case expand it to respond to the necessity to have a clear residue definition and the means to determine it.
Point closed.

7f Participation of pre-accession countries of the EU in the TM
AT supported that acceding countries (Croatia) and candidate countries (Iceland, The former Yugoslov Republic of Macedonia, Montenegro, Serbia and Turkey are invited to participate in the Biocides TM. Significant investments are done by the EU by Twinning Projects and similar activities to foster the transitions. Inviting representatives from these countries to the TM could be very helpful to maintain and improve the results of these projects in terms of contacts and competencies.

WORKSHOP EFFICACY PT 21

After extensive talks, the team decided that the guidance document needs restructuration to follow the new approach used in the case of PT 02, 14, 18. **UK** will provide the new structure to the drafting group. **IND** will use the current text to fill in the proposed structure. Where needed, with the participation of the drafting team, new text will be produced.
The conclusions of the discussion, structured as editorial notes, will be used to prepare the draft guidance taking into account future comments.

ENVIRONMENT SESSION

1. SUBSTANCES in PT 01 – PT 05

1a. Evaluation of disinfectant by-products

Background

NL presented the paper on the DBP as follow-up discussion from TM I-2012. The document was not circulated for e-consultation and only **DE** and **SE** have sent comments.

Discussion

DK: Support the PEC/PNEC approach.
FR: Need more time to comment
SE informed on their long experience with Whole Effluent Testing doing characterization of industrial discharges, containing i.a DBP and using toxicological testing in test batteries, having different tiers. The system can be proposed and commented further in the paper. As regards brominated by-products **SE** has asked **IND** to address the DBP in the effluent testing and expects to find some solutions to propose for the general paper.

Conclusion
Several MS asked to have more time to comment the **NL** paper on DBP. From **COM** point of view there is a need to have a solution for Annex I inclusion.
NL will launch an e-consultation on DBP and at next TM in June **NL** will present the information gathered during this e-consultation to which **IND** is also invited to contribute.

Action: OMS to send comments to NL by end of April 2012; NL will revise the paper to be discussed at the TMII-2012 (June).

First discussion for the following substances

1b. Active chlorine (RMS: SK)

2. SUBSTANCES in PT 06

First discussion for the following substances

2a. DMDMH (RMS: PL)

2b. Formaldehyde core dossier (RMS: DE)

2c. IPBC (RMS: DK)

3. SUBSTANCES in PT 13

First discussion for the following substances

3a. DMDMH (RMS: PL)

4. SUBSTANCES in PT 21

Second discussion for the following substances

4a. Copper pyrithione (RMS: SE)

4b. Cybutryne (RMS: NL)

First discussion for the following substances

4c. Zineb (RMS: IE)

5. AOB

5a. Guidance document on derivation of Koc

It was discussed prior to PT 21 substance discussions.

Summary of the proposal: When the environmental concentration of interest is lower than the reference concentration in the OECD test (1.0 mg/l), it is proposed that the results at the lowest tested concentration in the adsorption/desorption study should be used as a surrogate for behaviour at lower concentrations.
In order to do this, go to the OECD 106 study report, and look at the Tier 3 isotherm plots or data tables and calculate Kd from CSolids/CWater for the lowest concentration batch tested. Then divide Kd by the organic carbon fraction of the solids, and you have the KOC (at this lowest concentration). Where replicate samples have been tested in the batch equilibrium study it would be appropriate to use the arithmetic mean of the two Kd values in further calculations.
It is additionally proposed that n in the range 0.96–1.04 is to be accepted as sufficiently close to 1

The following issues were discussed.

- Use of the regression equation. As proposed by **NL** and supported by other MS, a regression line will be used to derive the value of the Kd at the lowest concentration. This will allow taking all the isotherm information into account.
- Use of a reference value adequate for all PT21. The reference value 1 mg/L as used in the OECD 106 guideline doesn't seem to be environmentally relevant for PT21. Therefore, it was proposed to look for a new value.
- Regarding the concentration dependency of Koc it may happen that for different PTs, different Koc values should be used; however, for the time being it was agreed by the TM to start first with antifoulings. Then in a later stage the possibility of extending the discussion on Koc to other PTs will be considered, as it might also be relevant.

COM proposed to collect all available information on antifouling a.s. concerning the concentration ranges tested in the OECD 106 studies present in the dossier. This would aim to determine whether there is a common lowest concentration level which could be used as reference concentration for antifoulings.
SE and **UK** will be contacted in order to further develop this guidance taking into account the results of the discussion.

5b. Evaluation Manual for Product Authorisation

The TM was invited to send written comments to **NL** by April 23 on the document prepared.

5c. Update development of an opinion paper with the methodology of the risk assessment to bees

COM informed **NL** is preparing a paper following the discussions at the CA meeting on the inclusion of thiamethoxam for PT 18. **NL** has informed **COM** they want to await the current developments in EFSA. A document will be prepared for TM II 2012.

5d. Biocides higher tier guidance

IND introduced the document. The document aimed to provide further guidance on the use of higher tier studies. The document is also intended to help developing tailor made strategies for biocides. **IND** highlighted that this guideline should be considered as an extension of the already existing guidance and not a substitute. The following issues were discussed.

- The SSD approach as outlined in the document. On this regard, **DE** and **NL** were concerned about the new proposal and would proposed not to change the TGD.
- The mesocosm studies. The discussions held at the TM were not covered by the document as indicated by **DK**, **DE** and **FI**.
- Weight of evidence approach. **NL** could agree that this point needs further consideration since this is not explained in depth in the TGD.

Due to the importance of the document, MSs asked for a commenting round to provide comments. The TM was invited to send their comments within two months after the TM to CEFIC. **COM** will discuss with CEFIC how to progress with the guidance.

5e. Project DE cumulative environmental assessment

A study commissioned by **DE** was presented by the contractor. Feed-back was requested with a dead-line of 2 months after TM I 2012 to be send to einvernehmensstelle.biozidg@uba.de.

5f. PT21 AOB

COM informed that the document on the Fai old paint prepared by **NO**, lays down the decisions taken at the last TM. Consequently, the document will not be discussed but is presented as a background document. The correct value for Fa.i old paint will be included in MOTA.

COM informed that the document prepared by CEPE on the PT21 evaluations, which was also distributed for the TOX Session, shall be used as a background documents to the PT21 discussions.

5g. Risk mitigation PT 21 for pleasure crafts

This agenda item was postponed to TM II 2012.

5h. Study CEPE regional marina scenario

This agenda item was postponed to TM II 2012.

TMI2012-item1-Draft-Agenda-version4.doc

02/03/2012

Draft AGENDA

Biocides Technical Meeting

Place of meeting
Hotel Concorde, Arona, Italy

19 - 23 March 2012

START: 19 March 2012 at 09:00 hrs
FINISH: 23 March 2012 at 16:00 hrs

INTRODUCTION

START: 19 March 2012 at 09:00 hrs
FINISH: 19 March 2012 at 09:30 hrs

1. Approval of the agenda
(TMI2012-item1-Draft-Agenda-version1)

2. Adoption of the minutes
(TMI2012-item1-Draft minutes TMIV 2011_version1.doc)
(TMI2012_Comments applicant OPP draft minutes TMIV2011.doc)

3. Action List TM
(TMI2012-item3-Action List TM.doc)

4. Members of the Technical Meeting
(TMI2012-item4-tm-members.doc)

5. Next Technical Meetings and CA meetings

2012

TM II	18 – 22 June
TM III	1 – 5 October
TM IV	26 – 30 November

CA II	22 – 26 May
CA III	3 – 7 July
CA IV	18 – 22 September
CA V	11 – 15 December

TOXICOLOGY SESSION

START: 19 March 2012 at 09:30 hrs
FINISH: 20 March 2011 at 17:00 hrs

1. SUBSTANCES in PT 01 – PT 05
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

1a. Evaluation of disinfectant by-products
(Document to be prepared by NL)

First discussion for the following substances

1b. Sodium hypochlorite (RMS: IT) for PT 01 – 05
(Only the effects part in DOC II A and III A will be discussed. Two documents are prepared by the RMS: a summary of the physcio-chemical properties uploaded in the folder of the First Draft CAR of Product Type 01 at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_programme/q-t/hypochlorite_7681-52-9/product_type_01/first_draft_car&vm=detailed&sb=Title and the consolidated RCOM for the effects uploaded in the folder of the First Draft CAR of Product Type 01 under the folder Comments at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_programme/q-t/hypochlorite_7681-52-9/product_type_01/first_draft_car/comments&vm=detailed&sb=Title)

1c. Calcium hypochlorite (RMS: IT) for PT 02 – 05
(Only the effects part in DOC II A and III A willl be discussed. The documents prepared by the RMS for sodium hypochlorite also cover calcium hypochlorite.)

1c. Active chlorine (RMS: SK) for PT 01 - 05
(Note that active chlorine in PT 01 is a new active substance uploaded on CIRCA at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_substances/a-d/active_chlorine&vm=detailed&sb=Title, while active chlorine in PT 02 – 05 is in the Review Program and uploaded on CIRCA at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_programme/a-d/active_chlorine&vm=detailed&sb=Title)

2. SUBSTANCES in PT 02
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

Second discussion for the following substances

2a. BCDMH (RMS: NL)
(A document is prepared by NL and uploaded on CIRCA in a dedicated folder under the First Draft CAR entitled "Documents for TM I 2012")

3. SUBSTANCES in PT 06
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

First discussion for the following substances

3a. DMDMH (RMS: PL)

3b. Formaldehyde core dossier (RMS: DE)
(The formaldehyde core dossier was uploaded on CIRCA under the folder of the First Draft CAR for DMDMH for PT 06 at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_programme/a-d/hydantoin_6440-58-0/product_type_06/first_draft_car&vm=detailed&sb=Title. The consolidated RCOM is not yet available.)

4. SUBSTANCES in PT 13
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

First discussion for the following substances

4a. DMDMH (RMS: PL)

5. SUBSTANCES in PT 18
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

Second discussion for the following substances

5a. Diflubenzuron (RMS: SE; applicant Chemtura)
(Two documents prepared by the RMS are uploaded in a dedicated folder entitled "Documents for TM I 2011"at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_programme/a-d/diflubenzuron_35367-38-5/product_type_18/applicant_chemtura/documents_tm_2011&vm=detailed&sb=Title)

6. SUBSTANCES in PT 21
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

Second discussion for the following substances

6a. Copper pyrithione (RMS: SE)
(Documents are prepared by the applicant and uploaded on CIRCA in a dedicated folder under the First Draft CAR entitled "Documents for TM I 2012")

First discussion for the following substances

6b. Zineb (RMS: IE)

7. AOB

7a. Update HEEG

7b. Update DRAWG

7c. Classification of biocidal products for sensitisation
(TM-2012-I_Tox_item7c_Extreme skin sensitisers with human data.doc)
(TMI2012-TOX-item 7c-IND comments on skin sensitizers with human data.pdf)
(TMI2012_Tox_item 7c_SE comments on specific skin sensitisation issues.doc)

7d. Evaluation Manual for Product Authorisation
(document to be prepared by NL)
(TMI2012-Encoded_standard_instruction_phrases_compiled_DE.doc)

7e. PT 21 AOB
(TMI2012-TOX-item 7e-Fai old paint and human health exposure assessment PT21.pdf)
(TMI2012-TOX and ENV Session-Comments CEPE PT21 Evaluations.pdf)

GENERAL SESSION

START: 21 March 2012 at 09:00 hrs
FINISH: 21 March 2012 at 18:00 hrs

1. Reporting on the last CA meeting
(COM to inform)

2. Tracking System: Progress reports
(TMI2012-GEN-item2-Progess Report Existing Active Substances.pdf)
(TMI2012-GEN-item2-Progess report for substances under evaluation (article 11).pdf)

3. SUBSTANCES in PT 01 – 05

3a. Active chlorine (RMS: SK)
(Note that active chlorine in PT 01 is a new active substance uploaded on CIRCA at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_substances/a-d/active_chlorine&vm=detailed&sb=Title, while active chlorine in PT 02 – 05 is in the Review Program and uploaded on CIRCA at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_programme/a-d/active_chlorine&vm=detailed&sb=Title)

4. SUBSTANCES in PT 06
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

First discussion for the following substances

4a. DMDMH (RMS: PL)

4b. Formaldehyde core dossier (RMS: DE)
(The formaldehyde core dossier was uploaded on CIRCA under the folder of the First Draft CAR for DMDMH for PT 06 at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_programme/a-d/hydantoin_6440-58-0/product_type_06/first_draft_car&vm=detailed&sb=Title. The consolidated RCOM is not yet available.)

4c. IPBC (RMS: DK)

5. SUBSTANCES in PT 13
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

First discussion for the following substances

5a. DMDMH (RMS: PL)

6. SUBSTANCES in PT 21
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

Second discussion for the following substances

6a. Copper pyrithione (RMS: SE)

6b. Cybutryne (RMS: NL)
(Documents are prepared by NL and uploaded on CIRCA in a dedicated folder under the First Draft CAR entitled "Documents for TM I 2012")

First discussion for the following substances

6c. Zineb (RMS: IE)

7. AOB

7a. Confirmatory analytical methods for residues: requirements and validation
This agenda item will be discussed after agenda item 2.
(TMI2012-GEN-item 7a-COM paper on method requirements.doc)

7b. Evaluation Manual for Product Authorisation
(document to be prepared by NL)

7c. Inventory concerning the development of resistance in mice and rats
(TMI2012-GEN-item 7c-Inventory resistance_NL.doc)

7d. Guidance on evaluation of efficacy for PT 02
(TMI2012-GEN-item7 d-Cover Note PT2 Draft Guidance.doc)
(TMI2012-GEN-item 7d-Commenting Table PT2 Draft Guidance_NL.doc)
(TMI2012-GEN-item 7d-Draft Guidance Efficacy Disinfectants PT2_NL.doc)
(TMI2012-GEN-item 7d-Appendix 2 claims matrix_NL.xls)

7e. Residue definition
This agenda item will be discussed after agenda item 2.
(TMI2012-GEN-item 7e_COM paper on residue definition.doc)

WORKSHOP EFFICACY PT 21

START: 22 March 2012 at 10:00 hrs
FINISH: 22 March 2012 at 17:00 hrs

At TM IV-2011 it was agreed to organise a session at TM I 2012 on the evaluation of efficacy tests for PT 21. This workshop will be organised in parallel to the first day of the Envirionment Session.

Relevant documents from TM IV 2011:
(TMIV2011-GEN-item 8a_Introduction documents submitted by CEPE.doc)
(TMIV2011-GEN-item 8a_Revision TNsG Efficacy Annex 7 PT 21- CEPE Proposal.doc)
(TMIV2011-GEN-item 8a_CEPE Efficacy Methodology for BPR - Revised version.doc)
(TMIV2011-GEN-item 8a_Efficacy Reply to FR NL DE - Commenting table.doc)

Documents and an agenda are uploaded on CIRCA in a dedicated folder under the folder of TM I 2012.

ENVIRONMENT SESSION

START: 22 March 2012 at 09:00 hrs
FINISH: 23 March 2012 at 16:00 hrs

1. SUBSTANCES in PT 01 – PT 05
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

1a. Evaluation of disinfectant by-products
(TMI2012-ENV-item 1a-Assessment of disinfectant by-products_NL.doc)

First discussion for the following substances

1b. Active chlorine (RMS: SK)
(Note that active chlorine in PT 01 is a new active substance uploaded on CIRCA at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_substances/a-d/active_chlorine&vm=detailed&sb=Title, while active chlorine in PT 02 – 05 is in the Review Program and uploaded on CIRCA at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_programme/a-d/active_chlorine&vm=detailed&sb=Title)

2. SUBSTANCES in PT 06
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

First discussion for the following substances

2a. DMDMH (RMS: PL)

2b. Formaldehyde core dossier (RMS: DE)
(The formaldehyde core dossier was uploaded on CIRCA under the folder of the First Draft CAR for DMDMH for PT 06 at http://circa.europa.eu/Members/irc/env/ber/library?l=/ca-reports/ca-reports_programme/a-d/hydantoin_6440-58-0/product_type_06/first_draft_car&vm=detailed&sb=Title. The consolidated RCOM is not yet available.)

2c. IPBC (RMS: DK)

3. SUBSTANCES in PT 13
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

First discussion for the following substances

3a. DMDMH (RMS: PL)

4. SUBSTANCES in PT 21
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

Second discussion for the following substances

4a. Copper pyrithione (RMS: SE)
(Documents are prepared by SE and the applicant and uploaded on CIRCA in a dedicated folder under the First Draft CAR entitled "Documents for TM I 2012")

4b. Cybutryne (RMS: NL)
(A document is prepared by NL and uploaded on CIRCA in a dedicated folder under the First Draft CAR entitled "Documents for TM I 2012")

First discussion for the following substances

4c. Zineb (RMS: IE)

5. AOB

5a. Guidance document on derivation of Koc
(TMI2012-ENV-item 5a-Sorption_guidance_note_proposal.pdf)

5b. Evaluation Manual for Product Authorisation
(document to be prepared by NL)
(TMI2012-Encoded_standard_instruction_phrases_compiled_DE.doc)

5c. Update development of an opinion paper with the methodology of the risk assessment to bees.
(NL to inform)

5d. Biocides higher tier guidance
Following an action agreed at an earlier TM industry has prepared a draft guidance document on the use of higher tier studies.
(TMI2012-ENV-item5d-Biocides higher tier guidance_IND.doc)

5e. Project DE cumulative environmental assessment
(TMI2012-ENV-item 5e-Cumulative environmental risk assessment_DE.doc)
(TMI2012-ENV-item 5e-Summary feasibility study_DE.doc)

5f. PT21 AOB
(TMI2012-ENV-item 5e-Fai old paint and human health exposure assessment PT21_ info for ENV Session.pdf)
(TMI2012-TOX and ENV Session-Comments CEPE PT21 Evaluations.pdf)

5g. Risk mitigation PT 21 for pleasure crafts
(TMI2012-ENV-item 5g-CEPE ICOMIA paper introduction.pdf)
(TMI2012-ENV-item 5g-ICOMIA - Paint control measures for recreational boats.doc)

5h. Study CEPE regional marina scenario
(TMI2012-ENV-item 5h-Regional Marina Scenario Study.pdf)