EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Chemical Assessment and Testing Unit

Minutes of the open sessions of the Biocides Technical Meeting III 2012 1st-5th October 2012

INTRODUCTION

The meeting was chaired by A. Payá Pérez and for specific items on the agenda by C. Pecorini, J. Janossy, S. Pakalin, A. Paya-Perez, T. Posbring, B. Raffael, D. Blihoghe and J. Weber. A. Payá Pérez welcomed the participants to TM III 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

Agenda was approved by TM.

2. Adoption of the minutes

No more comments were added to the draft minutes version 2. Minutes were adopted by the TM.

3. Action List TM

1. Finalisation document "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.
At TMIII2012 DE informed on the on-going project which will be finalised in 2014.

2. Distribute list with tasks MS in EUSES training validation exercise and prepare the exercise: EUSES updated version, in which some bugs are repaired, is now available. Consequently, the validation exercise will now start. COM will distribute the documents to those MS that volunteered to participate.

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.
NL is collecting information from applicants which could be provided to a guidance for the TM including the non-confidential information.

4. Development of "swimming scenario" for PT 19 environmental risk assessment: comments on draft to DE: On-going. DE will prepare a revised draft.
At TM III2012 DE informed that a project started on 1st October 2012

5. Finalise guidance documents on environmental risk assessment for PT 21: COM informed that UK is preparing the document and waiting for the outcome of the discussions on the various e-consultations on PT21. UK could have the document ready for TM IV 2012.

6a. Extreme sensitizers with human data: On-going
6b. Review of local risk assessment guidance: Workshop to be organised by COM after TM III 2012 (scheduled on October 2012).
6c. Guidance on the transfer of biocides to food: On-going.

7. Proposal of ESD for PT 10 (number of painted houses): At TMIII NL informed that proposal will be available for TM IV2012.

8. Evaluation of Disinfectants by Products: NL to prepare a paper for the next CA meeting to ask for the CA opinion on:

- the timeframe;
- the scope of the assessment;
- the anticipated impacts on competent authorities, industry and the general public;
- how to proceed with particular DBPs not in the national legislation yet compliance to an agreed threshold maybe requested.

9. omissis

10. Can the TTC concept be used for the purpose of waiving nature-of-residue studies? COM to send a proposal for DRAWG opinion.

4. Members of the Technical Meeting

5. Next Technical Meetings and CA meetings

2012

TM IV	26 – 30 November
CA V	11 – 15 December

2013

TM I	11-15 March 2013
TM II	10-14 June 2013
TM III	16-20 September 2013
TM IV	25-29 November 2013
CA I	27 February – 1 March 2013

CA II	15 -17 May 2013
CA III	10 - 12 July 2013
CA IV	25 - 27 September 2013
CA V	11 - 13 December 2013

TOXICOLOGY SESSION

1. GENERAL DISCUSSION1a. Evaluation of disinfectant by-products

Background

NL presented the document uploaded on CIRCABC and proposed the way forward.
The evaluation of DBPs has been under discussion for a considerable period in several regulatory frameworks, including the biocidal regulatory framework.
The scientific knowledge of DBP is growing and new groups of DBPs have been identified even in recent years. Many factors influence the formation of DBPs, including water temperature, source water composition, and the degree to which organic and inorganic matter is introduced into the water during the disinfection process. This makes evaluation of DBPs even more complicated.
At the present stage there is no common approach on how to deal with DBPs.

The issue of DBPs arose for the first time for biocides in PT02, P11 and PT12 during TMIII 2010. **NL** agreed to make a proposal for the evaluation of DBPs for human toxicological aspects and for environmental aspects. A methodology was developed and discussed several times at the TM, while issues requiring policy decisions were forwarded to the CA meeting. With regards to the human toxicological assessment a simple risk assessment strategy was developed, and a similar approach was put forward for the environmental part.
In a meeting prior to TM II 2012, remaining questions regarding the human toxicological approach were discussed with several member states and subsequently put to the TM. Three main issues remained that needed to be resolved:

1. submission of (national) monitoring data;
2. identification of the toxicological basis of the chosen limit values;
3. specific proposal for data requirements as to concentration measurements.

Unfortunately no monitoring data and further information on limit values were supplied by MSs or IND. The available public literature provides only a very limited picture and does not allow differentiation concerning DBP levels present under different conditions.
Given this lack of information the proposal for further data requirements can at present only be made in general terms. So the specified marker DBPs should be measured under realistic worst case conditions, taking the environmental factors influencing the formation of these DBPs into consideration.
NL proposed that **IND** goes forward with this issue and submit concrete proposals for the data requirements, by way of submitting study protocols, relevant monitoring data and/or substantiated waiving of certain data requirements, where possible. The realistic worst case conditions and specific measuring requirements as proposed in the general approach need to be taken into account. When proposals have been developed they will be evaluated in a small committee before being followed through by **IND**.

The **Halohydantion Task Force** and **Eurochlor** sent their comments on the proposal placed on CIRCABC and expressed their intention to participate in the discussion of a possible testing scheme.
NL requested to discuss whether HEEG can develop a worst case exposure calculation.
NL believed that the approach proposed cannot be further refined.

Discussion
The following points were discussed:

Monitoring data
DE will send monitoring data for public indoor and outdoor pools in German to NL. **DE** anticipated sending the translated version of the report by the end of November. **AT** also intends to provide monitoring data.
Eurochlor cannot provide further monitoring data other than those available in the open literature.

Timeline
To speed-up the process delaying the evaluation of disinfectants **AT** proposed to separate exposure from the hazard issue, i.e. to define the threshold values for the most critical DBPs that need to be controlled and postpone the submission of exposure data. **AT** asked whether it is possible to estimate when the evaluations can continue. **NL** believed the decision on when to submit data is a policy issue. The **NL** cannot foresee the timeframe for finishing the assessment as it depends on a number of factors like whether the procedure allows IND to come up with a testing scheme within a short timeframe that can be evaluated by a dedicated group. **COM** supported to establish only the methodology of assessment for Annex I inclusion, the data requirements and the criteria for accepting supporting data, and to defer the submission of data substantiating exposure to product authorization (PA). However, **COM** reiterated that the TM agreement supported by the CA was to review the assessment of DBPs for the swimming pool scenario prior to Annex I inclusion and not to postpone the issue to PA without giving appropriate tools for the CAs to evaluate the safe use of the biocidal products.

Threshold values
NL proposed a set of threshold values with explanations of derivation and the conditions under which they need to be tested. **DE** will send a background document on the toxicological basis of the swimming water limits by the end of November. **NL** will include the explanations in the draft document. **SE** will send comments on the threshold limits.

AT requested clarification on the procedures for DBPs limit values that are not in the national legislation.

IND requested to review the threshold levels and provide more explanation on their derivation. As an example **IND** referred to THMs: there is a factor of 15 between the proposed threshold value and the one set by the WHO. The latter was based on liver

effects whereas the rationale still needs to be provided for the proposed limit based on a national value. **IND** also requested to provide additional explanations on the derivation of volatile/non-volatile limit (based on the Henry constant) and the detailed ConsExpo calculations in the appendix.

In light of the complexity of the issue **IND** proposed to focus on 2 or 3 markers only e.g. THMs and HAAs. **IND** also proposed to consider the TQ (esp. for THMs) and the TTC concept for Tier 1 assessment. Although the TTC approach for genotoxic substances proposes the limit value of 15µg/kg/day, for non-genotoxic compounds the limit values are much higher. **IND** will send the detailed comments to NL. Without additional monitoring data **NL** was unable to further narrow down the number of DBPs to be potentially assessed. **NL** commented that on the basis of the information currently available to them a further selection to only 2 or 3 marker compounds could be considered but would be a political decision not a scientific one.

Feasibility and CA support

IND asked whether feedback has been received from the Applicants on the feasibility of the proposal. **IND** believed the issue was becoming very complex and maybe only a few substances will be able to comply with all the strict requirements. **NL** responded that despite some critical remarks IND is not against the method as described, they are not dismissing the approach and expressed their willingness to discuss and join in a monitoring scheme. **NL** argued that first the risks need to be foreseen and then it will be up to the CA to weigh the risks and benefits and propose risk mitigation measures.

In light of the previous TM discussions and the present status of the draft proposal **COM** suggested that the TM and CA should decide how to proceed. How in-depth assessments are needed? Are further refinements to the TNsG on data requirements regarding DBPs needed for the assessment? Can a decision be taken based on the available information, taking into account the risks and benefits and available risk mitigation measures e.g. best available practices? Is it possible to focus on only a limited number of DBPs?

COM believed that the basic principles of the approach have been thoroughly discussed at several TMs and also at CA level. **COM** asked the **NL** to prepare a paper for the next CA meeting introducing the main issues for reaching a decision. The opinion of the CA is essential among others on the timeframe; on the scope of the assessment; on the anticipated impacts on competent authorities, industry and the general public; on how to proceed with particular DBPs not in the national legislation yet compliance to an agreed threshold maybe requested. The **NL** agreed to prepare the document. The TM was requested to send their comments and proposals to the NL and the COM by **16 October**. The proposal including the limit values will be discussed at TMIV 2012.

Other PTs

The assessment of DBPs in other PTs should be initiated and should not wait for an agreement to be reached for the PT2 swimming pool scenario. At TMII 2012 it was agreed that for the human health assessment PT3, 4 and 5 should be considered in

addition to the swimming pool scenario. The approach taken in other PTs is independent from the agreement on the PT2 scenario discussed above.

Conclusion

Comments on the paper proposed by the NL and available monitoring data are welcome. The deadline for commenting is 16 October. NL will prepare a concept paper for a CA discussion proposing the way forward.

ACTION for NL: *to prepare a paper for the next CA meeting to ask for the CA opinion on:*

- *the timeframe;*
- *the scope of the assessment;*
- *the anticipated impacts on competent authorities, industry and the general public;*
- *how to proceed with particular DBPs not in the national legislation yet compliance to an agreed threshold maybe requested.*

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**, **FR** and **UK** in cooperation with HEEG.
The Paper had already been discussed at the TM II 2012, but an additional commenting period including **IND** was proposed to finalise the Opinion.
The version of the HEEG Opinion presented at the TM III 2012 considered all the received comments and **COM** thanked the HEEG members, the **MSs** and **IND** for providing their inputs. In particular, **IND** asked more details about the models used, namely RISK OF DERM, and the expert from **CZ** provided a thorough review of the points raised by **IND**; therefore, **IND** should be satisfied with that.
Some additional comments were provided by **NO**, **FI** and **UK** after the end of the commenting period. However, these comments regarded only minor issues and they did not change the overall content and conclusions of the Opinion. They would be included in the final version of the Paper.
NL commented that the definition of primary and secondary exposure was very important in the paper, because for secondary exposure no RMM could be implied. This had an impact at product authorisation level. It was proposed to have a discussion on this item during the HEEG Workshop on 3-4 October 2012.
COM added that the "HEEG Opinion on an approach to identification of worst-case human exposure scenario for PT6" should be considered as a screening tool, based on a tiered strategy.
FR pointed that the CA meeting should deal with the issue raised by **NL**. The HEEG Opinion focused on how to assess the exposure, but management strategies were not considered.

NL concluded that the point was complex and could not be solved at the TM. **NL** was content with the HEEG document which provided more guidance on how to estimate the exposure to PT6.
CZ agreed with **FR** and added that the issue could be a matter for Authorities at national level as well.
Another relevant issue pointed by **COM** was the fact that the "HEEG Opinion on an approach to identification of worst-case human exposure scenario for PT6" would be made publicly available in its current form, including the calculations and examples provided for both primary and secondary exposure scenarios. As **FR** commented at the TM II 2012, the majority of the scenarios presented were rebuilt and recalculated. The range of efficacy doses was the only information obtained from the specific Applicant. Also, classical models, such as the TNsG and ConsExpo, were taken into account in the calculation. Finally, the calculations were checked and confirmed after a commenting period of the HEEG, the MSs and IND on the presented approach. Therefore, the current version of the HEEG Opinion would not display any confidential information.
IND did not see any objection in endorsing the HEEG Opinion and asked whether the document could be released directly for public consultation.
COM commented that the HEEG Opinions should be endorsed at the TM level only. They should be implemented during use by the assessors.
IND asked to have the possibility to check the final version of the HEEG Opinion including all the recent comments. **IND** also asked whether the document could have a living and development status, which could be updated and amended continuously.
COM commented that the HEEG Opinions were not legally binding documents and they were indeed living documents which could be amended at any time, if necessary.
COM added that the most recent comments to the "HEEG Opinion on an approach to identification of worst-case human exposure scenario for PT6" were not massive and did not change the overall conclusions of the paper. Therefore, **COM** suggested endorsing the HEEG Opinion after including these recent comments and putting it in MOTA, as usual practice. **COM** also invited the TM to start using the HEEG Opinion in the assessments and considering the possibility of implementing it, if necessary.
IND agreed with the proposed way forward and asked more details on the procedure to revise the HEEG Opinions included in MOTA, if amendments were needed.
COM explained that a concept paper should be drafted highlighting the issues to be implemented and a revision could be prepared after consultation within HEEG.
FR added that the calculations presented in the HEEG Opinion were only examples. If an update of the paper was needed, it would be preferably included in the relevant Human Exposure Scenario Documents, which were in an initial state of preparation.

Conclusion
The "HEEG Opinion on an approach to identification of worst-case human exposure scenario for PT6" is endorsed by the TM. The final comments will be included in the document. The HEEG Opinion will be put in MOTA as usual practice.
Point closed.

3b. Update DRAWG

The comments of COM, FR and IND on the draft proposal "*Estimating Transfer of Biocidal Active Substances into Foods*" were discussed. The following agreements were taken:

- The document will be split into two documents for professional and non-professional uses.
- The terminology will be checked and a glossary provided.
- The intention and scope of the guidance will be made clearer (i.e. for professional uses, to show that residues are below 0.01 mg/kg food, no recommendations for dietary risk characterisation for professional uses.)
- The exception from the trigger of 0.01 mg/kg food for particularly toxic substances is possible, but will not be tied to an explicit ADI value.
- It will be discussed whether the TTC concept can be used for the purpose of waiving nature-of-residue studies. **COM** will send a proposal for DRAWG consideration.

Conclusion
DRAWG will make the necessary revisions and provide the revised documents for TM discussion.
The TM should send further comments on the draft guidance by 16th October.

***ACTION for COM**: to send a proposal for DRAWG consideration on whether the TTC concept can be used for the purpose of waiving nature-of-residue studies*

3c. Evaluation Manual for Product Authorisation

EM Version 1 was endorsed at the 44th CA meeting in December 2011 and released for 6 months public consultation period, which ended on the 30th June 2012. **NL** will prepare the updated version 1 of the EM including the comments received from CEFIC, and it will be sent to CA meeting in December. Version 2 of EM will be prepared toward the end of 2012 including the agreed points in table 1, and will be brought back to the TM next year. MSs were asked to update the meeting on the status of different points presented in the table 2 for discussion uploaded on CIRCABC.

On the **DE** document "Encoded standard phrases for human health and environment", **NL** will send suggestions for few phrases that could be deleted from the list.

At the last meetings it was agreed that **NL** will incorporate the agreements from MOTA in the EM. **UK** asked how the agreements in MOTA will be incorporated in the EM, considering that MOTA is a living document. **COM** informed that is currently working on updating the MOTA version 2012.

On the questions from **IND** on the mixture toxicity, and how to deal with the SoC risk assessment in the BPD and BPR, **COM** pointed out the relevant agenda points for discussions these issues.

Conclusion

NL will prepare the revised version 1 of EM and send it to the CA in December. **NL** will send the comments on encoded standard phrases to **DE**. **OMS** to comment on issues from table 2 by 26th October. The next revisions of the EM will take into consideration the agreed points from the TM.

3d. BIP –Guidance for Information Requirements

3d.1 Presentation by COM on new ECHA guidance structure and on BIP6.1 progress

FI commented that references currently present insufficient guidance and make it difficult for the user to decide which one to use. **FI** proposed that COM/ECHA would name the ones that apply for biocides. **COM** agreed.

3d.2 Human health

The discussion was postponed to TM IV. **UK** comments were not considered due to time limitations. All comment were agreed upon; late comments (**UK**) will be considered and discussed at TMIV if needed. SE comments were missing on CIRCA and in the RCOM uploads for the meeting.
16-October 2012 was set as deadline for any additional written comments.

3d.3 Presentation on new ECHA guidance structure and on BIP6.1 progress

COM explained that the new structuring will be implemented after the current document has been finalised and all comments will be taken into consideration in the current drafting.
In order to better facilitate the discussion, **COM** agreed to upload only one RCOM table with the points to be discussed highlighted to CIRCABC for future discussions on the guidance.

3.e Substances of Concern

This agenda point was for information only. The relevant **UK** representative for this agenda point could not attend to the meeting; therefore JRC gave an overview of the documents.
As a result of numerous discussions at the PA&MRFG meeting on various issues regarding the substances of concern (SoC), in May 2012 COM invited MSs to participate to an *ad-hoc* working group (WG). The final aim of the WG is to draft a guidance to be addressed to both Applicants responsible to identify SoCs and to provide appropriate information/data and risk assessment, and MSCAs to perform the risk assessment of SoC in a harmonized way, to avoid different outcomes and problems in the MR process. The guidance document should help to provide a high level of protection, without missing any substance of concern, while maintaining a

pragmatic approach. It was also considered relevant to take into account the upcoming legal framework of Regulation 528/2012 (BPR).
On 2nd July 2012, 10 MSs participated to the first meeting of the non-technical WG, namely **DE**, **DK**, **ES**, **AT**, **NO**, **SE**, **FR**, **CH**, **NL** and **UK**. The WG decided, as a key step before drafting the guidance, to consult TM on a number of technical issues during the TOX and ENV session. All documents related to the WG meeting and follow-up actions are available on CIRCABC in the folder of PA&MRFG meeting (open session) at https://circabc.europa.eu/w/browse/7939038c-ab73-4dd1-84da-5576d22753a8 and https://circabc.europa.eu/w/browse/e2e8e813-3c95-4e1a-8a1f-f5bc7e6e08fd**UK** took the lead and prepared the TOX paper based on their previous proposal and the inputs received from other MSs. The revised paper with the latest comments from **SE** was uploaded on CIRCABC on the TM meetings documents and addresses 12 questions that need further consideration within the TM before starting to draft the guidance on SoC.
The question number 8 of the document is: "*Do you consider an initial screening step, prior to the SoC evaluation a useful tool*?". The WG considered necessary the creation of a checklist with clear screening criteria to identify potential SoC. The draft checklist was prepared by **SE** with contributions from **ES** and **FR**, and some of the comments from **DE** and **UK** are still visible in the text to be considered at TM. This second document is also uploaded on CIRCABC, and contains suggestions on the substances that should be considered as potential SoC (e.g. substances on the candidate list established with REACH Regulation), and an Annex with a non-exhaustive list of substances that might contain impurities with unacceptable characteristics (carcinogeniticity, mutagenicity, toxicity for reproduction or sensitising properties).

Conclusion
MSs are invited to send written comments to the two documents by 26th October. The full discussion of this agenda point will take place during the TM IV.
The TM discussions on both documents will be used as basis when drafting a future guidance on SoC/chapter in the Technical Guidance Document on data requirements under BPR.

3.h R26 classification
At TMI 2012 questions related to R26 classification were raised. To clarify the issue COM contacted ECHA and the replies are reported below, together with the relative questions:

Q1: "*Do you consider R26 classification necessary by default for corrosive products containing active substances classified with R26*?"
Answer: **no.**
Classification and labelling (C&L) refers to the intrinsic hazard of the substance or mixture irrespective of a subsequent risk related to the exposure. Skin corrosivity and R26 ("Very toxic by inhalation") are different hazard classes under CLP (and DSD) that must then be considered separately. If an acute inhalation toxicity study has been performed according to the test guidelines on the substance of concern (and maybe on

a mixture), the study results must be taken into consideration. Otherwise, there must be in principle no such hazard classes by default.

Q2: "*Should products containing corrosive active substances, having a particle size distribution that potentially allows exposure via the respiratory tract, be labelled as very toxic by inhalation (R26)*?"
Answer: **no.**
The CLP regulation stipulates in e.g. articles 5(1), 6(1), 8(6) and 9(5) that the physical state and the forms in which the substances or mixtures are tested & evaluated (for the purpose of C&L) should be the ones that are placed on the market and reasonably be expected to be used. Thus, if dust (or vapours or aerosols) may be created during any handling or use (also as used in mixtures), toxicity studies on dust (or vapours or aerosols) should be considered to be conducted. Further clarifications on the concept of "form or physical state" and "reasonably expected use" are provided in 1.2 in the CLP guidance. Again, no C&L is foreseen by default in absence of an acute toxicity study by inhalation. When a study is available, the test results will provide the answer as described in the § below. A further question to be considered is whether it can be excluded that dust (or aerosols or vapours) are created during any handling or use of the substance.
In EU a substance or mixture, which is classified for acute toxicity via inhalation (category 1 or 2; H330: fatal if inhaled) according to CLP and T+; R26 ("Very toxic by inhalation") according to DSD, shall also be labelled with a specific EU statement for health hazard "Corrosive to the respiratory tract" (EUH071) (see 1.2.6, Annex II, CLP). This is in case the data indicate that the mechanism of toxicity is corrosivity according to Note 1 to Table 3.1.3. Further criteria and a definition of corrosion of the respiratory tract are provided in section 3.1.2.3.3.

However, according to the criteria laid down in CLP regulation for applying EUH071, this statement for health hazard could also be used as follows: "For substances and mixtures in addition to classification for skin corrosivity, if no acute inhalation test data are available and which may be inhaled". As a consequence, the hazard statement EUH071 can be applied by default (please see also the CLP guidance (e.g. sections 3.1.2.3.2 and 3.2.4.2).

3.i Applicability of the default values of the EFSA Guidance on Dermal Absorption to Biocidal products

The applicability of the default values of the EFSA Guidance on Dermal Absorption to Biocidal products was discussed. The TM welcomed the use of the revised default values in general. However, **SE** noted that for some product types, like PT19, where products are formulated to remain on the skin, the default values may not be sufficient or at least may not have been included in the assessment made by EFSA. **DE, CZ** and **FI** supported **SE** and asked for caution when applying the default values for formulations that might not have been covered by the EFSA report. **SE** proposed to include a statement in MOTA that the EFSA dermal absorption default values can generally be used for simple formulations and for more complex formulations

together with an acceptable justification including considerations on its comparability to the database used to develop the EFSA default values.

UK, NL and **PT** were in favour of applying the revised default values. **NL** argued that the majority of biocidal products. do not defer from plant protection products; before setting the default values no correlation was found with any formulation type within the PPP. An exemption may be considered for a few products like PT21 and maybe PT19. **NL** pointed out that the present version of MOTA is referring to the EFSA guidance (Guidance Document on Dermal Absorption Sanco/222/2000 rev. 7) and proposed to reference the updated guidance document. NL proposes to integrate the whole EFSA approach with the precautionary considerations discussed earlier **COM** emphasised that the revised default values were based on extensive evaluations (EFSA Journal 2011;9(7):2294). **CZ** noted that raw data were not provided, however, expert judgement can be used.

Conclusion
The TM was invited to send comments by 26th October suggesting possible exceptions for which the default values may not apply. The examples shall be discussed at TMIV 2012.

3.l Mixture toxicity assessments

The draft proposal was prepared by **FR** and aimed at setting down principles and a tiered approach for mixtures' risk assessment.
COM thanked **FR** for preparing the document and the **MS**, namely **DE**, **UK**, **NO** and **NL**, who provided their comments on the paper.
FR briefly introduced and summarised the document with some slides.

3.l.1 Components to be included in the assessment

Background
It was suggested including in the assessment all components, especially all toxicologically relevant substances of a mixture, namely the active substance(s), Substances of Concern and other relevant individual components of the biocidal product. This approach would better reflect the interpretation of the legal text of the Biocidal Products Regulation (BPR), in particular Annex VI, recitals 3.3 and 55. The approach would also narrow down the assessment.

Discussion
FR agreed to apply the methodology to all toxicologically relevant substances in the mixture, namely the active substance, Substances of Concern and other relevant components. It was also stressed that only quantitative risk assessment for substances of Concern and other relevant compounds should be carried out. When only a qualitative risk assessment was available, mixtures' risk assessment could not be performed. This means that for these substances, sufficient data should be available to derive Toxicological Reference Values.

AT and **UK** agreed to the approach proposed by **FR**.
IND commented that three other scientific Committees, namely SCHER, SCCS and SCENIHR, established a document, the "Scientific committees opinion on toxicity and assessment of chemical mixtures", on the assessment of mixture toxicity. **IND** asked whether this document was taken into account in the proposal.
FR confirmed that the document had been taken into consideration, especially for the discussion on synergistic and additive effects.
COM suggested referring to this document in the proposal and **FR** agreed.
PT also agreed and suggested indicating the reference documents in the introduction.

Conclusion
The methodology should apply to all toxicologically relevant substances in the mixture and a quantitative risk assessment should be performed. The reference documents, including the "Scientific committees opinion on toxicity and assessment of chemical mixtures" (SCHER, SCCS, SCENIHR 2012), will be included in the draft proposal.
Point closed.

3.l.2 Additivity

Background
UK disagreed that at Tier 1, if no synergistic effects had been reported or suspected, the effects of the active substances would considered to be additive by default. Additivity was a conservative approach, but at the same time it was pragmatic strategy.

Discussion
UK commented that synergy or additivity should not be automatically assumed, but information or evidence to suspect this effect should be available. Potential additivity should be assumed at Tier 1 when the same target organs were affected by the chemicals.
NO agreed with **UK**.
PT also agreed with **UK** and reiterated that additivity should be based on the same mode of action.
CZ agreed with **UK** as well.
AT commented that if additivity was assumed by default and the risk was deemed unacceptable, it would be possible to go to the next step, in which it was investigated whether the chemicals had similar mode of action.
FI added that if additivity was not assumed at the beginning, the tiered approach should not be substantiated.
NL agreed with **AT** and **FR** that the approach was a step-wise strategy. If the risk index was below 1, no refinement was needed. In addition, the same tiered method was endorsed by other Authorities.
NO added that in line with the tiered approach, it was not scientifically justified to carry out mixture toxicity evaluation if there was not the same target organ.
FR commented that the rationale behind the proposal was to perform a first risk assessment based on a worst-case basis without identifying the target organs. **FR**

added that an impact study was performed on about 270 PPP using the proposed methodology and for 85% of them the process stopped at the Tier 1, thus saving a lot of time.
DE fully supported the tiered approach, but proposed a refinement (see below).
CZ agreed with **FR** position, because it could simplify the evaluation process.
NL added that if one wanted to look immediately at target organ toxicity, it would not be enough to look at the AEL, because at concentrations above the AELs it could be possible to have toxicity on the same organ. Therefore, in order to look at target organ toxicity at the first tier, a re-evaluation of all toxicity studies should be performed to detect whether the same toxicity was observed at doses above the AEL values. **NL** agreed with FR to assume additivity by default at Tier 1.
DK supported the approach.

Conclusion
At Tier 1 the effects of the active substances are considered to be additive by default.
Point closed.

3.l.3 Refinement by using PPE

Background
DE and **NL** raised the point concerning PPE.

Discussion
FR commented that one of the possible refinements was adding PPE to limit the exposure. In the impact study the refinement with PPE was tested in parallel with refinement with target organ AELs. Globally, it was found that most of the refinement by target organ AELs was unacceptable and PPE had to be added to make the risk acceptable. Even though the use of PPE could be limited, PPE were always added at the end of the assessment. Therefore, a pragmatic approach should be adding PPE before considering target organ AEL. However, for the assessment of biocidal products, **FR** proposed to run in parallel the assessment with PPE and target organ toxicity and identify the differences, if any, after one or two years of experience.
DE agreed with the proposal by **FR** and commented that RMM could be considered at any stage of the process.
NL added that PPE were used as the last resort in NL, but agreed with **FR** to evaluate in the near future the assessment in parallel with target organ toxicity.

Conclusion
The approach proposed by **FR** will be followed.
Point closed.

3.l.4 Synergistic effects

Background
With reference to Tier 2, **UK** commented on the paragraph on synergistic effects and proposed than rather than using these arbitrary values below 1 to judge the

acceptability of the risks, the actual data indicating synergism were used to make a judgement about the acceptability of risks.

Discussion
FR commented that for synergistic effects a value between 0.1 and 1 might be derived. This range of values was given as an example. **FR** suggested that the hazard index should be based on the available data. So far, only one example of synergistic effects was provided.
NL pointed that data on synergistic effects were very limited and they were dependent on the concentration ratio between two substances. A pragmatic factor of 10 might be a sufficient approach.
UK commented that if the hazard index was below 1, it was assumed that synergy was acting in the mixture. **UK** also asked what the way forward was in case the mixture acted in a synergistic way.
FR commented that the issue was not simple to clarify. The value of 10 was taken into account by default when scarce information on synergy was available, but no clear-cut strategy was available. Practical experience could be gained in the future on how to deal with this aspect.
COM asked whether the evaluation should be carried out substance-by-substance, if no common target organs of toxicity were identified. **FR** confirmed this point.
UK agreed with the difficulty related with the point and proposed to wait for further guidance.
PT asked whether the strategy could be considered as a case-by-case approach in case of synergistic effects. **FR** and **NL** agreed.

Conclusion
The tier 1 corresponds to an assessment substance by substance. If there is no common target organ, the tier 2 “assessment of mixture effects” (= additivity by default) is nonetheless realized. Tier 3 corresponds to the refinement by target organ (AEL by target organ). The Reference Risk Index should be derive on a case by case basis when synergy is identified based on the available data. If data is too limited a worst case pragmatic factor of 10 could be used.
Point closed.

3.l.5 Tier 3

Background
DE proposed a refinement of the tiered approach elaborated by **FR**.

Discussion
DE explained the refinement of the tiered approach. Due to the complexity of the item, **COM** suggested that a bilateral discussion would take place between **FR** and **DE** to define the refinement of Tier 3.
FR agreed to the **COM** proposal and suggested adding the outcomes of the discussion in the consolidated version of the document.

CEFIC asked how the discussion on the **FR** proposal was related with the parallel Workshop on "Guidance development for mixture toxicity assessments in biocidal products authorisations (Environment)".
COM explained that the Workshop on "Guidance development for mixture toxicity assessments in biocidal products authorisations (Environment)" was dealing with environmental related matters, whereas the discussion on **FR** proposal concerned human health issues. Some items were shared between the Workshop and the discussion on **FR** proposal, such as the components to be included in the assessment, on which a common conclusion was drawn.
CEFIC commented that the approach discussed in the Workshop was different from that proposed by **FR**, in which exposure assessment was taken into account as the first step and hazard assessment was evaluated on a later stage. **CEFIC** proposed to reflect this approach in the **FR** proposal.
COM commented that discrepancy between the toxicological and environmental discussions might exist on the topic and supported the proposal of **CEFIC** to mention the approach discussed at the Workshop in the **FR** document.
FR pointed that the approach described in their proposal took into account each use and each population and was based on risk assessment.
CEFIC proposed to deal with the two aspects separately and to send written comments for clarification.

Conclusion
A bilateral consultation between **FR** and **DE** will be set up to define the refinement of Tier 3. The outcome of the discussion will be reflected in the consolidated version of the proposal.
Point closed.

Overall conclusion
FR will prepare a consolidate version of the draft proposal taking into account the inputs from the TM. An additional commenting period, involving **IND**, is proposed to receive more comments on the issue. The deadline for sending comments is 16th October 2012. The consolidated version of the proposal should be finalised by **FR** for the TM IV 2012.

PARALLEL SESSION ON MIXTURE TOXICITY

During the mixture toxicity (ENV) workshop, key issues for a harmonised approach to biocidal products assessments were resolved. The German UBA will draft the final guidance proposal with additional support from several other member states, COM, and IND. The proposal will be discussed at TM I 2013, with the aim to publish the guidance in time for the application date of the biocides Regulation (EU) 528/2012

Full minutes of the special session will be circulated within the participants group.

GENERAL SESSION

1. Reporting on the last CA meeting

COM reported on the 47th CA meeting (4th-6th July 2012), on the 48th CA meeting (19th-21st September 2012) and on the OECD Task Force on Biocides 27-28 September 2012

2. Tracking System: Progress reports

No comments were raised by the TM.

4. AOB

4a. Evaluation Manual for Product Authorisation

Background
EM Version 1 was endorsed at the 44th CA meeting in December 2011 and released for 6 months public consultation period, which ended on the 30th June 2012. **NL** will prepare the updated version 1 of the EM including the comments received from CEFIC, and it will be sent to CA meeting in December. Version 2 of EM will be prepared toward the end of 2012 including the agreed points in table 1, and will be brought back to the TM next year. MSs were asked to update the meeting on the status of different points presented in the table 2 for discussion uploaded on CIRCABC.

Table 2, Item 1B Shelf life guidance
For the general discussion, **NL** informed that they would like to reach an agreement on the FAO tolerances before including it to the EM. **FR** will send written comments to on the use of FAO tolerance of shelf life. **DK** provided some comments to **NL** regarding the assessment of degradation values higher than 10 % for PT 14 and PT 8, and asked how to deal with these situations, as they are not covered by the existing guidance. In TM II 2012**, NL** agreed to draft a proposal and **DK**, **FR** and **IND** to participate to the preparation of the proposal. **NL** would like to provide this proposal for TM IV 2012. For PT21 shelf life **CEPE** prepared a draft: this is the agenda item 4b, and the discussion was done at that agenda point.
NL asked **MSs** for which PTs they want specific guidance, as PT 14 and 18 were mentioned. For PT 6 **NL** already agreed to draft guidance and bring it to next TM. **CEFIC** asked if the discussion will be opened for all PTs, or only for those mentioned, highlighting the necessity for specific guidance for disinfectants. **NL** clarified that the examples above were given according to the inputs received up to now regarding the current need for guidance for products authorisation and mutual recognition. **OMS** and **IND** can send further inputs to **NL** on this.

ITEM 2B SANCO/825/00 guidance ver. 8.1

At the last TM **UK** had reservations to use **SANCO/825/00 rev. 8.1.** and **NL** agreed not to implement version 8.1. directly, but only applicable to new dossiers, and not to dossiers already submitted.

OMS were asked to send comment on the question: **"***Does TM adopt this document to be used under BPD? If so, when this should come into effect, dossiers already submitted, or only new dossiers?***"**

NL said that they did not receive comments on the analytical methods.

NL reminded about previous TM decisions to use the biocides specific guidance when available (e.g. TNsG and analytical guidance), and only if the biocides guidance is not available for certain points to use other guidance such as PPP, REACH or other. **NL** also informed that in their opinion the version 7 of the SANCO guidance can be used for the analytical methods, as there are not huge variations in comparison to version 8.

COM also informed on a recent endorsed CA paper on the applicability of new guidance. **A**pplicants should not be asked to align data with new guidance if they already started collecting it based on old guidance, unless there are exceptional circumstances requiring it. If the new version is considered appropriate by the TM, it should be followed only for dossiers which start being prepared as from now.

At the request of **CEFIC** to circulate the documents to the TM, the relevant link for this document is from the DG ENV website, in the section guidance documents in force guidance, the document "Relevance of new guidance" discussed at the PA&MRFG and CA in July 2012:
https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp

Item 3B

UK provided a proposal for the packaging in TM II, for which **NL** had some suggestions regarding packaging for solids, and **FR** expressed the will to send written comments. Further comments to be send to **NL** and **UK**.

Item 1B Efficacy section

NL did not receive any comments on the efficacy since the last meeting, and asked OMS to update on the guidance listed in Appendix I, in particular for PT 5, 8 and 21.

DE informed that the next draft for PT 5 is expected to be ready within few weeks, (the guidance will be presumably presented in TM I 2013) and for PT 21 **CEPE** is working on the guidance. **FR** is working for the PT 8 guidance and anticipate to present the draft in TM I 2013.

Conclusion

NL will prepare the revised version 1 of EM and send it to the CA in December. Further comments regarding table 2 to be sent to **NL** by the 26th October. For packaging discussion, comments should be sent to **UK** as well.

The next revisions of the EM will take into consideration the agreed points from the TM.

4b. Evaluation of shelf life – PT 21

CEPE presented the document that discusses the shelf-life of antifouling (AF) products and proposes a strategy for storage stability testing and tolerance levels. Prior the meeting, comments by **DE** and **UK** were uploaded on CIRCABC, and **COM** and **CEPE** had the opinion of **NL** via email consultation.
The following points were discussed.

Determination of storage stability at low temperature
From the received comments, **DE** was of the opinion that the determination of storage stability at low temperature is required if a shelf life of 4-5 years is aspired.
UK and **NL** would accept that if the product will not be stored under low temperatures and appropriate label phrases are used (e.g. protect from frost) then data on cold temperature storage would not be required. **DE** agreed with this proposal providing appropriate label or alternatively to use a different wording allowing a case by case decision, and **CEPE** agreed to modify the text to reflect this.
NL informed that storage stability testing at low temperature is commonly required for liquids. In their experience, most of the authorised AF paints were solvent based, but they also had a water-based AF paints last year. **NL** was of the opinion that if you include appropriate label recommendation, you might be able to waive storage stability at low temperature not only for PT 21, but also for other PTs.

Affects of light on the storage stability
In agreement with **CEPE**, both **UK** and **NL** commented that if the products are stored in non-transparent containers, effects of light do not need to be investigated.
NL considered the discussion relevant for all PTs, where the container materials may be different than the metal cans for the antifouling paints; mentioning that if appropriate explanation is given then the test can be waived.

Accelerated storage stability
CEPE mentioned in the document that the CIPAC MT 46 method is used to test liquid formulations under accelerated storage stability conditions and subsequently extrapolate the results to real time stability. Satisfactory results would indicate that the paint will have an acceptable shelf life of at least 2 years in the tropic and temperate climate. **NL** commented that CIPAC MT 46 was exclusively validated for a.s. content and not for other technical propertied (foaming, dilution, stability, viscosity), and proposed to accept this as a provisional test for active substances. **CEPE** agreed with this, and clarified that it is a common practice in industry to use other tests appropriate for the technical properties.

Regarding the acceptability of accelerated storage stability tests for biocides product authorisations, **DE**, **UK**, **NL** and **FR** commented that this is acceptable as a provisional test, but to be confirmed with additional data of real time storage stability.
UK mentioned that this is the same approach in PPP.
CEPE would like to avoid duplication of tests, especially for shelf life of 2 years, as according to their experience, both accelerated storage stability and real time testing would give similar results. **CEPE** informed that it is a common procedure in industry to request shelf life time of 1-2 years for AF for paints for big vessels, whereas for pleasure crafts the shelf life time should be 3-4 up to 5 years.

DE did not accept only the accelerated storage stability test for shelf life up to 2 years, as also other parameters such as viscosity and the degree of settling are relevant and would need to be determined over the complete requested shelf life period.
NL suggested the possibility to develop a strategy for "comparable" AF products: if a shelf life study for one product is available, then it could be used for comparable products, but the issues here would be to define the "comparable" criteria.
For PT 21, **NL** did not see differences between the results of the accelerated storage stability and real time tests, confirming the **CEPE** position, but they saw differences in other PTs.

CEFIC asked which would be the points to be proven during the storage stability testing for active substance, degradation into the volatile or toxic compounds. **CEFIC** and **NL** proposed a workshop to be organized with experts to discuss these topics.

Tolerance limits
It was noted by **DE** and **UK** that the FAO table used in **CEPE** document is not precise and they provided the right table to be used in their comments.
On the topic of the acceptable variation of the active substance (a.s.), **DE** sent written comments considering AF paint a low concentrated heterogeneous formulation, and a variation of a.s. should not be higher than 15 %. **UK** and **NL** disagreed with **DE**, as the exact FAO limits do not apply to the change in the a.s. content during the shelf life. The FAO limits are only relevant to the amount of active at the point of manufacture; hence the permitted variations from batch to batch of manufactured pesticide are not relevant to biocides.

During the discussion, for **UK**, **NL** and **FR**, a 10 % change could be acceptable for all PTs. **UK** mentioned in their written comments that a wider variation limit should only be considered on a case-by-case basis for individual products where the nature of the a.s. and its properties are known, and it can be fully assessed that a change in the a.s. for more than 10% is acceptable (it has adverse effects and it would not affect the efficacy of the product). **NL** agreed with the **UK** approach.
NL also mentioned that the FAO is meant for enforcement, and the use of small size samples give raise to high errors, proposing to increase the number of samples and their sizes; **FR** agreed with this. **FR** was of the opinion that the maximum variation of 10 % in a.s. should be applied to all PTs, and that PT 14 should not be an exception.
Determination on copper content
NL and **FR** asked the opinion of **OMSs** in respect to the analytical methods for the determination of the copper content in the product.

Conclusion
CEPE should revise the document incorporating the comments received, and the general recommendation on the overall format of the guidance in the style of PPP Technical Monograph nr 17, this point will then come back to the next TM.
OMS should send comments for the relevant points to **CEPE**, **NL**, **UK** and **FR** by the 26th October.

4c. BIP –Guidance for Information Requirements

4c.1 Presentation by COM on new ECHA guidance structure and on BIP6.1 progress
UK + **NL** commented that BPR efficacy requirements differ to principles agreed in document "The role of efficacy in the evaluation of active substances for BPD Annex I inclusion", EC2010c (agreed at CA). **COM** will look into CA meeting decisions to align the documents.
NL asked where in the guidance the chapter on 'intended users' will be. **COM** will discuss with ECHA and report.
NL highlighted the necessity of having information in one place, which would consequently result in overlapping information in different chapters. **NL** argued that this would avoid that the user would have to consult several guidance sources in order to e.g. conduct the risk assessment for a single product (a practical example mentioned was an insecticide)
DE mentioned that several comments were missing in the RCOM table. **COM** will investigate, will inform **DE** bilaterally and place points for discussion for TM IV 2012 if necessary. SE comments were also missing in the RCOM table.

4c.2 REACH guidance usage
FI commented that references currently present insufficient guidance and make it difficult for the user to decide which one to use. **FI** proposed that **COM**/**ECHA** would name the ones that apply for biocides. **COM** agreed.

4c.3 Calculating dry weight specifications
This issue is currently discussed within the Technical Equivalence working group. Once concluded, the results will be included in BIP6.1 guidance by **COM**.

4c.4 Difference aggregate state vs. physical state
A wording issue on how to use the term *aggregate state* or *physical state* respectively was resolved: the terminology is going to be used as proposed in the BPR.

4c.5 Endpoint 3.3 Acidity
Currently, outdated CIPAC guidance is referred to; Reference will be updated to CIPAC MT75.3; **NL** will look into this issue and solve it with **COM** bilaterally.

4c.6 Endpoint 3.9 Ionic strength
It was discussed whether *ionic strength* is needed as parameter for water solubility – TM agreed that ionic strength is not needed.

4c.7 Endpoint 3.15 Viscosity
TM agreed to remove the exclusion phrase on PT5 active substances.

4c.8 Endpoint 4.17.3 Dust explosion
NL asked for clarification on the actual required information. **UK** also pointed out that criteria are needed to define when a material can be considered as dust. **NL** will

investigate cut-off criteria ("What is dust?"). **COM** invited all TM participants to submit ideas and proposals on what information is needed.

4c.9 Endpoint 4.3 & 4.17 Flammable explosives

COM agreed to include references to the UN manual of criteria and, if applicable, EC methods.

CLP references are considered as sufficient source of information in order to determine the endpoints on safety relevant information. **NL** stated that the original EC test methods are limited in their applicability.

4c.10 Chapter V Methods for detection and identification

It was discussed if high resolution mass spectrometry (HRMS) could be considered as 'commonly available'. The TM concluded that HRMS should not be considered as 'commonly available' for the time being. Furthermore, the TM proposed that the guidance should be a living document, i.e. regularly updated concurrent with the available knowledge. **COM** assured that the guidance will be revised regularly. It was agreed to use the RCOM proposal by **DE**-BfR without mentioning HRMS.

4c.11 LOD vs. LOQ

It was discussed whether to use 'limit of quantification' or 'limit of determination'. The TM agreed to solely use 'Limit of quantification' (LOQ) as proposed by **FI**.

4c.12 Acceptable exposure limit vs. OEL

The point was postponed to TM IV 2012 Human Health session.

4c.13 Efficacy: Information on time delay

UK prefers to require information on time delay 'where applicable'. **NL** agreed to bilaterally consult with **UK** and **COM**.

4c.14 Analytical methods for monitoring purposes

DE commented in the RCOM table: "We agree that a specific method with official status (e.g. published by ISO, CEN, OSHA) does not report all required validation data but could nevertheless be acceptable for the purpose. But without any validation data the assessment of a method seems to be not possible. Therefore, the two sentences should be revised."

COM replied "It is nevertheless possible that a specific method is not FULLY validated but can still be concluded to be acceptable for the purpose if it is a specific method with official status (e.g. published by ISO, CEN, OSHA). Some flexibility should be allowed for such situations." **DE** agreed to **COM**'s text change proposal.

DE furthermore asked to add TNsG information on calibration as important validation parameter. **COM** agreed.

4c.15 Analytical methods: level of reported interferences

It was discussed whether the limit for reported interferences should be 30% or 3%. The TM agreed to use 3%.

4c. 16 Likely tonnage to be placed on the market per year

DE supported the approach presented by COM in the RCOM table, that the tonnage over the last 3 years should be submitted by the applicant and the inclusion of the information obligation if the tonnage is distinctly increasing during the authorisation period. **DE** stressed out that the sentence "tonnage is distinctly increasing" has to be discussed and needs a precise definition, as it is essential for environmental risk assessment and a higher tonnage might result in a higher risk for environment. Maybe based on further experience during a.s. evaluation and product authorization a per cent rise could be derived (e.g. 20 percent more etc). **DE** agreed also, that new questions will arise from that regarding the legal consequences. Thus, **DE** asked if the legal service of the EU Commission could clarify the problem. **DE** also asked for the discussion of that topic in the environmental session as the tonnage is a crucial input parameter for environmental release estimation. **COM** agreed.

DE asked for the RCOM table to be updated in 'track changes' mode. **COM** agreed.

4.e Efficacy guidelines for PT18-19

Background
COM gave a brief introduction to the document.
A proposal for a harmonised evaluation of efficacy of biocidal products against insects and other arthropods in the EU was presented to the TM in 2009 and 2010 for comments.
In 2010 it was accepted by the TM and CA meeting and it was published and opened for comments for six months. This commenting period ended in 2011 and the guidance document was revised accordingly.

Discussion
COM said that comments were received from DE, IND and FR and were incorporated by **NL** in the document that was uploaded on CIRCABC for MSs consideration.
That revised document was presented to the TM for approval. A date on which the guidance will be checked for revision should be added.

COM informed the TM that at the PA&MRFG meting a paper from CH was presented to ask how to proceed with some issues relating the dossiers of repellent products containing a specific active substance. In the paper there are also some proposals on a method to derive a protection time for products used as repellents for ticks and mosquitoes. According to **NL**, such method, if approved, it could be useful for the present guidelines.
As the paper is still under discussion at the CA level, **COM** proposed to finalise the guidelines and in case amend them in the future, if the proposals in the CH paper will be accepted and considered still useful for the guidelines.

COM thanked the work **NL** has done for the guidelines.

NL chaired the discussion.

NL said that most of the received comments were editorials and will be added and no discussion should be needed on them.
SE added a comment on page 27, section 14.1: they would like to have this section removed from the document as it is more related to medicinal products
NL replied that the intention is not to claim for medical treatment, but just to point out the importance of killing of repelling mosquitoes.
TM and **SE** agreed to keep the section.
DE thanked **NL** for the work.

COM proposed a period of one year or shorter if any new input arrives from the CA of the MSs as date of revision. **COM** also reminded that as from 1st September 2013 all tasks will pass to ECHA and also the guidance documents management and this might involve different procedures and requirements.

FR proposed a period of two years, as it was decided for the guidelines for PT 8.
COM then proposed to accept the 2 years deadline for revision, unless something more urgent will appear.

COM asked if anybody opposed to the endorsement of the document.
TM agreed to endorse it.

AT and **CEFIC** asked for clarification of the procedures and what will be the next step of the document.
COM replied that after TM and CA endorsement of the first draft of the document, it was opened for public consultation. After that, the revised document has been amended, and now the TM should endorse it. After TM endorsement there will be the CA endorsement (hopefully at the CA in December) and then the document will be publicly available.

Conclusions
The Guidance document was endorsed.
Point closed.

PARALLEL SESSION ON HEEG

During the Workshop the preparation of the HEEG Opinions on the Links' study for antifouling application and removal, dipping of hands and forearms, and default human factors values has been finalized. Some additional topics under consideration by the group, such as the development of Human Exposure Scenario Documents, have been discussed and work is in progress.

More detailed minutes of the special session will be circulated within the participants group.

ENVIRONMENT SESSION

1. GENERAL DISCUSSION

1a. Evaluation of disinfectant by-products

The chair informed on the conclusions agreed at the TOX session (item 1a).
The chair informed on the document submitted by EUROCHLOR on Friday 28th September and which was distributed as room document. The chair reiterated the invitation to other industry sectors dealing with disinfection by products to comment and send information or data which can contribute to improve the document.
NL informed that the document has been re-written considering the comments from previous TM, since then **NL** has not received extra comments.

In summary, on the basis of the documents presented and the discussions at the TM, **NL** will submit 2 documents for discussion at the next CA meeting in December, one is the document submitted to TM <TMIII2012_TOX-ENV_item1a_DBPupdate TOX and ENV_NL> and a second one with specific policy advice for the way forward on the evaluation of disinfectants by products for Annex I inclusion.

MS and IND can submit comments to NL and COM until 16th October 2012. After if no further comments NL will submit the documents for discussion to next CAs meeting in December.

3. AOB

3a. Evaluation Manual for Product Authorisation

Background
EM Version 1 was endorsed at the 44th CA meeting in December 2011 and released for 6 months public consultation period, which ended on the 30th June 2012. **NL** will prepare the updated version 1 of the EM including the comments received from CEFIC, and it will be sent to CA meeting in December. Version 2 of EM will be prepared toward the end of 2012 including the agreed points in table 1, and will be brought back to the TM next year. MSs were asked to update the meeting on the status of different points presented in the table 2 for discussion uploaded on CIRCABC.

Discussion
NL presented the updated table, mentioning the ongoing discussions on mixture toxicity, aggregated risk assessment, RMM and products testing. One issue is still unclear, the evaluation of granules for primary poison of birds and mammals.

On the **DE** document "Encoded standard phrases for human health and environment", during the HH session **NL** commented they will send suggestions for few phrases that could be deleted from the list. **OMS** were invited to send written comments.
DE updated the TM on a recent finalised RMM paper on PT 1 to PT 5, and they wait for comments from OMS until 19th October.

Conclusion
NL will prepare the revised version 1 of EM and send it to the CA in December. **NL** will send to **DE** the comments on encoded standard phrases. **OMS** can comment to the table 2 by 26th October, and to the **DE** paper on RMM for PT 1-5 until the 19th October. The next revisions of the EM will take into consideration the agreed points from the TM.

3b. BIP –Guidance for Information Requirements

3b.1 Presentation by ECHA on new ECHA guidance structure
FI asked for clarifications on the chapters on risk assessment and evaluation in the environmental part of the newly structured information requirements.
ECHA explained that the risk assessment sections (part B in the scientific volumes) will be biocides-oriented and only when the REACH guidance are deemed to be relevant it will be referred to.
DE was also interested in which document will be integrated in the new structure and in particular if the ESD documents are considered part of the new structure. **ECHA** reassured the experts that the new guidance structure will cover all the relevant documents and that most likely, but not yet agreed, the ESD document will be stored in a dedicated ECHA-Biocides-webpage for guidance and in particular under a "volume IV" web-space.
NL asked if MOTA will be integrated in the new structure of the guidance. **ECHA** explained that the actual project foresees the integration of MOTA into the new structure.
NL asked during the question time after the presentation and also during a more informal one to one discussion how the decision taken during the BPC meetings will be recorded and eventually integrated into the relevant guidance document. **ECHA** explained that the rule and procedures of the BPC are still under discussion but that a system to record the decisions taken and report them in a "MOTA-like" document will be most likely implemented.
NL also encouraged a system to periodically add the decision taken during the BPC meetings and listed in the MOTA-like document to the guidance.
DK mentioned difficulties to find the right guidance and the lack of overview on REACH guidance. **ECHA** and **COM** assured that they are aware of that and will look into improving this.
NL asked for commenting possibilities. **ECHA** responded it would be ensured that TM would be consulted on changes as regards technical issues in the guidance. **ECHA** and **COM** pointed at time limitations they face.
DE asked how active substance & biocidal product evaluation will be split and proposed to have one risk assessment only as it is similar. **ECHA** argued that there is

added value in the split between AS and BP and also pointed out that while avoiding repetition is the main goal, the guidance for AS and BP would be clearly distinct.
Furthermore, **ECHA** gave clarification on the content of the evaluation volume, stressing that those will be non-physical, i.e. online documents that can be download and printed on demand.
DK asked for clarifications on the organisation of the risk assessment part and **NO** asked about the use of REACH guidance, in light of avoiding duplicating information
ECHA indicated that the analysis of REACH guidance on the applicability for biocides will be time consuming but assured that the focus is on the readability of the document, i.e. the reader will not have to go though the whole REACH guidance in order to find the information that is relevant to the biocides assessment. **ECHA** furthermore explained that guidance will be maintained in the future and may have to pass the Biocidal Product Committee. The updating procedure is still under discussion.
ECHA agreed to reply to further questions by email and will disseminate both the presentation and the respective communication paper via CIRCABC.

3b.2 Presentation by COM on BIP6.1 progress
No further discussion at this point.

3b.3 Decision table on additional terrestrial testing: significant factor size
It was discussed whether to use factor five or factor ten. **NL** and **DE** suggested discussing it in a dedicated meeting/session.

3b.4 Inorganic substances fate and behaviour in water and sediment
NL, which initially volunteered to draft guidance, reported that they could not find useful information and questioned if the evaluation of the model SimpleTreat could contribute to this item. DE informed that the final report for this project will be available at the beginning of 2013. Thus, at. a later TM, **DE** will present the results and then **DE** might be able to report if or how the model could be applied to inorganic substances.

3b.5 Field studies on two soil types
For endpoint 10.2.2 'Field studies: two soil types (ADS)' a proposal by **NL** exists in addition to the one by **COM**, which equals the text of the TNsG on data requirements. The TM participants were asked to decide which proposal to use in the future.
FI and **DE** prefer the proposal by **NL**. This proposal, however, would be in contrast to the legally binding two soil types. **DK** also preferred to use four soil types: two southern and two northern Euopean soils. **DK** would furthermore like to see a reference to OECD 307 (lab studies) in the 10.2.1 section.
NO, DK and **COM** will bilaterally discuss the NO comments connected to this endpoint .
COM asked the TM to help filling the current gaps and missing chapters by either volunteering or forwarding information on experts who have got the potential to contribute.

3b.6 Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)
NL asked for a definition for the term 'large area'. No suggestions were given by the TM participants.

3b.7 Endpoints at the Ecotoxicology
FI commented that TNsG text was only partly included so far. **COM** replied that it will include more bullet points taking into consideration MOTA decisions; especially the one on necessity.

3b.8 Short term toxicity testing on fish
UK asked for a justification for testing two species of fish Marina and freshwater species. The issue could not be resolved and **COM** proposed to put forward a new draft for discussion taking into account MOTA decisions.

3b.9 Pooling of data: Factor of significance for differences in sensitivity in organisms groups
In addition to required data on fish species, also algae data requirements were discussed. **COM** proposed to consider organism groups in guidance. **COM** will draft guidance on data pooling and testing strategies for different exposed environments.

3b.10 Effects on honey bees
NL commented a suggestion to update information on the bee test. The TM will wait for finalisation of bee risk assessment guidance before concluding on the issue.

3b.11 Effects on arthropods
DE proposed to replace 'neonicotinoid substances' with 'systemic insecticides' in the RCOM table. The TM agreed and concluded that bees risk assessment is triggered by exposure and not mode of action.

3b.12 Terrestrial bioaccumulation
NL recommended an evaluation of differences between REACH guidance and TGD-2003. The question here is either to stick to the old approach or to point specifically to the REACH guidance parts that apply. **NO** agreed that for some endpoints, e.g. terrestrial bioaccumulation, there is quite extensive and useful guidance under REACH, much more (and also more up-to-date) than what is given in the TGD. **NL** proposed that REACH guidance should be scanned for useful additional information. **DE** favours the references to REACH guidance if applicable to risk assessment and stressed to include MOTA into consideration as well as TGD-2003. **COM** summarised and concluded that a) most recent regulatory and scientific progress needs to be reflected in the guidance, b) principles, on how to decide on the use of further guidance, should be included in the guidance.

3.c Substances of Concern

This agenda point was for information only.

The **UK** representative could not attend to the meeting; therefore JRC gave an overview of this agenda point. **UK** felt that deferring discussion to the November TM, will allow them to explore further aspects of the problem and ensure key specialists are available to speak about the paper on the next TM.
As a result of numerous discussions at the PA&MRFG meeting on various issues regarding the substances of concern (SoC), in May 2012 COM invited MSs to participate to an ad-hoc working group (WG). The final aim of the WG is to draft a guidance to be addressed to both applicants responsible to identify SoCs and to provide appropriate information/data and risk assessment, and MSCAs to perform the risk assessment of SoC in a harmonized way, to avoid different outcomes and problems in the MR process. The guidance document should help to provide a high level of protection, without missing any substance of concern, while maintaining a pragmatic approach. It was also considered relevant to take into account the upcoming legal framework of Regulation 528/2012.

On 2nd July 2012, 10 MSs participated to the first meeting of the WG, namely **DE**, **DK**, **ES**, **AT**, **NO**, **SE**, **FR**, **CH**, **NL** and **UK**. The WG decided, as a key step before drafting the guidance, to consult TM on a number of technical issues during the HH and ENV session. All documents related to the WG meeting and follow-up actions are available on CIRCABC in the folder of PA&MRFG meeting (open session) at:

https://circabc.europa.eu/w/browse/7939038c-ab73-4dd1-84da-5576d22753a8
https://circabc.europa.eu/w/browse/e2e8e813-3c95-4e1a-8a1f-f5bc7e6e08fd).

UK took the lead to produce the ENV paper, and the document was recently uploaded to CIRCABC. UK provided us with the following updates. UK recognises that the environmental risk assessment of SoC is a complex issue. They are also aware that the wording in BPD is open to interpretation. In light of previous debate and comments by various MSs, the **UK** paper is:

- Addressing OMS concerns,
- Reiterate the UK's perspective on this with a view to a pragmatic sensible way forward,
- Gives a worked example explaining their tiered approach. They will also refer to other legislation and the implications for data requirements and the practicalities in generating this.

In addition to this document**, DK** submitted an alternative proposal (and a cover letter the proposal), where the chemical risk factor (CRF) approach has been removed as they are concerned the CRF concept would make it impossible to take the cumulative effect into account as described in Article 19(2) of the BPR. DK is also concerned that this concept will make it impossible to make the risk assessment according to the principles described in Annex VI e.g. point 5, 6, and 7. DK reminds that the concept of substances of concern also is used alone (without direct correlation to the active substance in a biocidal product) e.g. in Article 25 where it is stated that the biocidal product must not contain any substance of concern.

DE expressed the agreement with the **DK** proposal.
NL reminded the TM on the connection of this agenda point with the mixture toxicity discussions during the workshop. **DE** updated on the plan to finalise the guidance on the mixture toxicity for the TM I 2013.

Conclusion
MSs are invited to send written comments to the two documents by 26th October. The full discussion of this agenda point will take place during the TM IV.
The TM discussions will be used as basis when drafting a future guidance on SoC/chapter in the Technical Guidance Document on data requirements under BPR.

3.e Aquatic higher tier guidance

Background
COM introduced this agenda point. In 2009 COM asked for the development of guidance for higher tier testing strategies pertaining primarily to the consideration of data obtained within the PPP framework, for use for biocides environmental risk assessment. IND gave a presentation outlining guidance at TM I 2012. Since then IND has finalised a draft proposal. Substantial comments to this draft have been given by SE, DE, and NL. However, the view of these MSs is that they currently do not have the resources to contribute to the guidance, and moreover, that the continuation of this project should await the finalisation of equivalent guidance from EFSA. Possible ways forward therefore needs to be discussed. For example, NL suggested that the draft from industry could serve as a basis for future work, with higher focus on methods used for the setting of environmental quality standards (EQS) in the water framework directive (WFD) area.

Discussion
NL said that mesocosm studies from the PPP area are generally not applicable to biocides mainly because of differences in exposure assumptions. This is also reflected in 2011 guidance for EQS derivation under the WFD. This guidance provides ideas to the use of PPP mesocosm- and other higher tier studies for deriving EQS. This is more closely related to the exposure assumptions for biocides and should therefore provide useful input. Another relevant report was recently published by Alterra *(Brock T.C.M., Arts, G.H.P., ten Hulscher, T.E.M., de Jong, F.M.W., Luttik, R., Roex, E.W.M., Smit, C.E., van Vliet, P.J.M. (2011): Aquatic effect assessment for plant protection products: A Dutch proposal that addresses the requirements of the Plant Protection Product regulation and Water Framework Directive; Wageningen, the Netherlands: Alterra. Alterra report 2235, 139 pp.)*. All in all there is thus currently much background information that is usable, but at this point NL does not have the resources to contribute to developing guidance. **DK** supported **NL** that the EQS guidance is more relevant for biocides than the PPP guidance.
IND responded that indeed WFD guidance as well as the Alterra report would serve as a good starting point for biocides guidance, mainly on the use of data from mesocosm studies. Parts of this material are already included in the draft proposal.

IND then proposed as a way forward that the guidance should be reduced to only focus on mesocosm studies, and focus on methodologies from the WFD area.
In line with the proposal from IND, COM asked the TM whether MSs agreed to this proposal and also if MSs would like to participate in an internal review group before putting the guidance forward to TMII 2013.

Conclusion

IND will redraft their proposal focussing on mesocosm studies and WFD EQS approaches until the end of November. This will then go through an internal review process open to all MSs (**NL, DE, SE, FR** and **DK** expressed their interest in participating in this process). The aim is to present a final draft proposal to the TMII 2013. A dedicated folder for this work has been created in CIRCABC biocides - environment; "Guidance for higher tier approaches in aquatic effect assessment".

PARALLEL SESSIONON ON EFFICACY OF PT 2

5th Workshop Efficacy Guideline for Product Authorisation of Disinfectants in PT2

The draft guidance document was discussed and will be submitted for endorsement to the next TM.

More detailed minutes of the special session will be circulated within the participants group.