EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Chemical Assessment and Testing Unit

TM IV 2012

18/03/2013

Minutes of Biocides Technical Meeting IV 2012
26th -30th November 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 and Magdalena Andryszkiewicz.. A. Payá Pérez welcomed the new participants to TM IV 2012.
COM made some reminders regarding the submission of documents and asked the MSs to respect the timelines established in the SOP in order to give the experts a minimum time to get prepared for the discussions.. All MS and observers contributions shall be sent to the functional mailbox ENV BIOCIDES (env-biocides@ec.europa.eu).
All documents are distributed electronically by COM-JRC via the confidential site of CIRCABC, using a nomenclature referring to the agenda of the TM. Documents for the open sessions are distributed by COM-JRC to the observers directly.
The deadline for distribution of the documents is 5 weeks before the TM for the consolidated RCOM and 3 weeks before the TM for all other documents not related to the discussion of a CAR. Documents for information only can be accepted 2 weeks before the TM.

In addition, COM informed that on 2013 most of the staff allocated to the Biocides area at the JRC will start working in ECHA and elsewhere. Although recruitments are on-going they do not know yet the precise time of the enter into service of the new staff.

As regards the preparation of the transition from the Directive to the Regulation with start into application (EiA) from 1 September 2013, the chair asked all MS to finalise all possible 2nd discussions and to inform COM on the timelines for the finalization of the final draft CARs. At TM I and II 2013 TM experts would need to give priority to the finalization of BIPs (Biocides Implementation Projects) and discussion at the TM. JRC would not like to initiate 1st discussions which would need second discussions and it would not be finalised before the EiA.

1. Approval of the agenda
Agenda was approved by TM without comments.

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2. Adoption of the minutes

- Omissis -

3. Action List TM

This agenda item was presented at the TOX and ENV session

1. Finalisation of the 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. Due to the transfer of staff from JRC to ECHA, this task will be taken over by ECHA. MS will receive more information at the next TM I -2013.

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 I 2013. NL is collecting information from applicants which could be provided to a guidance for the TM including the non-confidential information. Other member states are kindly requested to send information on PT13 emissions characteristics in their country to NL: what are the different use types and what are the emission routes coupled to those use types.

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

5. Finalise guidance documents on environmental risk assessment for PT 21: COM informed that UK is preparing the document and implementing the outcome of the discussions on the various e-consultations on PT21. UK could have the document ready for TM I 2013.

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 (postponed to 2013).
6c. Guidance on the transfer of biocides to food: Action followed by DRAWG. 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. Action completed.

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8. Evaluation of Disinfectants by Products: NL to prepare a paper for the next CA meeting (December 2012) 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.

COM will inform at the next TM.

9. IPBC discussion: DRAWG to prepare a paper identifying the worst-case dietary exposure scenarios for PT6.

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

At the ENV session **NL** asked COM to give an update on the OECD work on ESD (Emission Scenarios Documents). **COM** presented briefly the OECD Task Force on Biocides work programme 2013-1016 and she will request the OECD secretariat to send a more comprehensive overview of the ESD work under the OECD Exposure Group. More information will be made available at the TM I 2013.
COM also indicated that the information of the OECD TFB is available in two dedicated folders in CIRCABC.

4. Members of the Technical Meeting

SE asked for an amendment that was immediately done by COM.

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TOXICOLOGY SESSION

1. GENERAL DISCUSSION

1a. Evaluation of disinfectant by-products

NL gave an update on the status of the DBPs assessment. At TMIII NL suggested to finalize the DBP approach with a proposal to let IND take further lead for a testing proposal. On request of MSs and IND another commenting round with the deadline of 16th of October was set. SE, DE, FR, AT and IND sent comments. The comments were incorporated in the approach. IND has sent a constructive approach as well as an appeal to discuss the way forward. As the proposal has been sent in mid November they could not be considered for this TM. The draft final DBP approach, a commenting table and the questions for the CA is to be discussed at the CA meeting in December. **NL** added that awaiting the decision of the CA on the approach and timelines, they are looking forward to a constructive cooperation with IND.

CH asked why their national limit values were not integrated in the document. **CH** will resend the information accompanied by monitoring data e.g. on bromate and chlorate. **AT** will also send further monitoring data (including THM values) that can be used in the future.

DE and **COM** thanked the NL for their work in developing the documents.

Conclusion
The TM is waiting for the outcome of the CA discussion on how to proceed with DBPs.

3. AOB

3a. Update HEEG

Background
Two HEEG Opinions were presented. They were finalised during the HEEG workshop held on 3-4 October 2012.

3a.1 HEEG Opinion on the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints
NO summarised the main points of the document.
A paper on occupational exposure during application and removal of antifouling paints was published in 2007. The paper presents exposure measurements from a field study in the

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Netherlands. The application techniques were airless spraying and rolling and the removal technique was sand blasting.
The study provides useful additional information to what is given in the TNsG on Human Exposure (2002 and 2007), especially for scenarios not covered in the guidance document (i.e. sand blasting and grit filling).
A HEEG opinion on the paper was prepared by **UK** after a pre HEEG consultation involving some HEEG members and other consulters. The paper was endorsed at the TM I 2012.
After endorsement, the raw data from the Links' study were made available. A preliminary analysis of the data was performed for a possible inclusion in the BEAT database. Unfortunately, the provided data could not be incorporated without further information. Further efforts will be made to get access to the missing information.
A discussion on the field study took place at the HEEG workshop in October 2012 and a HEEG Opinion has been prepared by **SE**, **NL** and **NO** and agreed by HEEG. The relevant exposure scenarios for application and removal of antifouling paint are described in the paper and HEEG recommendations on the use of the Links' data are given.
NO summarized the recommendations of HEEG:

- As for the application of antifouling paint by airless spraying, after a thorough evaluation of all available data, HEEG recommends to pool all the available data sets to get one larger set of measurements (the Links' data and the two data sets included in BEAT). For the time being, no sufficient information was available on the individual measurements in the Links study. Therefore, at the moment, the spaying data in the old guidance document can be used;
- With reference to the application by brushing and rolling, HEEG is of the opinion that the exposure data from the Links study could be used for assessment of exposure during professional application of antifouling paint by roller as well as for the combined task of application of paint by brush and roller. Access to some of the raw data allows for calculating of 75th percentile exposure values, which could be used. In addition, as for exposure to non-professionals during application of antifouling paint, the Consumer product painting model 4 should still be used;
- In relation to the assistant workers, there are no models available in the old guidance document (TNsG 2002) to assess exposure to ancillary workers. The Link's paper addresses exposure to assistant workers located on the floor, in the vicinity of the paint sprayer. As the assistant workers carry out the tasks of both potmen and ancillary workers, the data cannot be easily used for assessment of the individual tasks of these exposure scenarios. Therefore, exposure data included in the existing guidance documents will have to be used. As for exposure to ancillary workers, the exposure is considered to be no higher than the exposure to the paint sprayer. Thus, an assumption could be made that the exposure is covered by the exposure data for the spray painter;
- With regard to sand blasting, the publication by Links et al. is the only available source of exposure data. Exposure data from the Links study might be combined with estimates from

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OECD ESD. The same time duration of 180 minutes as for paint spraying is considered for the task of sand blasting;

- Concerning grit filling, exposure measurements for grit fillers were presented in the Link's study, but only for three workers. HEEG is of the opinion that the maximum exposure levels found for grit fillers should be used as a first tier approach. If a higher tier is necessary, exposure data from the sand blaster might be used, under the assumption that the exposure of the grit filler is not higher than for the sand blaster.

NL thanked HEEG for the preparation of the document. **NL** commented that for some scenarios the 75th percentile value could be calculated and asked whether a harmonised value was available and could already be used.
NO answered that Nick Warren from the Health and Safety Laboratory in **UK** should provide the values to use, but the timeline for presenting them was not known at the moment.
UK commented that, as the data for spraying application give lower exposure values, they should not be used in isolation, but as a pooled data set. Nick Warren was working on this.
NL asked when the actual numbers would be made available.
NO agreed with **UK** that the data for spraying from the Links' study should not be used alone and added that for application by brushing and rolling the raw data were available and it was possible to calculate the 75th percentile. The numbers could be provided for sand blasters as well. However, the timeline to deliver the data had not been discussed yet within the HEEG.
FR commented that the available guidance documents could be used, as the Links' study was taken into account to make refinement in risk assessment.
COM mentioned that at the moment some information was missing with reference to the raw data from the Links' study and that it was still not clear whether access would be granted.
NO added that access to the missing information was not strictly necessary for all scenarios; the data already available could be used while awaiting further information. For instance, the raw data were available for the rolling scenario, and the 75th percentile values could be calculated based on these data. For sand blasting, the proposal was to assume a log normal distribution and the data available in the published paper could be used for the calculation of 75th percentile values. Exposure data from the Links study concerning sand blasting might be combined with estimates from OECD ESD. **NO** also agreed with **FR** that the Links' study was used to refine the risk assessment. However, it should be kept in mind that for the process of paint removal no exposure data could be found in the guidance documents.
SE asked whether the first HEEG Opinion on the Links' study, endorsed at the TM I 2012, would be replaced by the HEEG Opinion presented at the TM IV 2012.
The TM agreed to replace the previous document with the new one and to include in MOTA only the last HEEG Opinion in order to avoid confusion.

Conclusion

The "HEEG Opinion on the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints" is endorsed by the TM and will be included in

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MOTA as usual practice. This version will replace the previous document endorsed at the TM I 2012.
Point closed.

3a.2 HEEG Opinion on Biocidal products: model for dipping of hands/forearms in a diluted solution

COM presented the "HEEG Opinion on Biocidal products: model for dipping of hands/forearms in a diluted solution". The HEEG Opinion was prepared by **UK** in cooperation with HEEG and was finalised during the HEEG Workshop in October.
The purpose of the HEEG Opinion is to propose a means to assess human exposure where an individual dips the hands or hands and forearms into a diluted solution. An example of this exposure scenario could be a person pulling weed out of a biocide-treated garden pond.
In the HEEG Opinion, the total amount of liquid retained is obtained by multiplying the area of hands or hands and forearms by the thickness of the liquid film on skin. With reference to the values used in the calculation, **COM** clarified some points:

- The described approach uses an estimated thickness of the liquid layer on the skin to be 0.01 cm. This value originates from the TGD 2003, but it is currently under consideration by RIVM. It will be probably changed in due course, since the assumed layer thickness has no scientific basis nor does it necessarily reflect the worst case conditions of the exposure. Preferably, the exposure is to be assessed using diffusion coefficients and exposure durations. However, such information is rarely available, moreover at this moment there are no accepted or proposed methods available. So, the currently available approach described in the Cleaning Products Fact Sheet is suggested by the HEEG to be used;
- As for the default total surface areas for both hands and for both hands and forearms, the approach uses the values obtained from the "Nordic Exposure Group Project 2011: Existing Default Values and Recommendations for Exposure Assessment" and the US-EPA Exposure Factors Handbook, volume 1, August 1997 data, respectively. These default parameters are currently under discussion by the HEEG and a HEEG Opinion is under preparation to identify the human factors, such as body weights and surface areas of the body, which should be used in biocidal product exposure assessments. Therefore, although the values indicated in this HEEG Opinion may be changed in the future, the rationale of the approach and the logic of the calculation presented will stand regardless of the values used. It should also be highlighted that, according to the HEEG Opinion on default human factors, the values indicated in this HEEG Opinion will be changed, if needed, and the HEEG Opinion updated;
- A final point to rise is that the model presented in this HEEG Opinion is meant to be used for diluted solutions and similar viscosity to water [1 centipoise; or alternatively, having a similar density of 1 kg/litre=1000 mg/cm^3 (estimate density of pure water)]. However, it is acknowledged that density, viscosity, temperature and surface tension can influence the amount of liquid remaining in contact with the skin. Therefore, the RMS will need to consider this when using the proposed default values.

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Conclusion
The "HEEG Opinion on Biocidal products: model for dipping of hands/forearms in a diluted solution" is endorsed by the TM and will be included in MOTA as usual practice.
Point closed.

Overall conclusion
The "HEEG Opinion on the paper by Links et al. 2007 on occupational exposure during application and removal of antifouling paints" and the "HEEG Opinion on Biocidal products: model for dipping of hands/forearms in a diluted solution" are endorsed by the TM and they will be included in MOTA as usual practice.

3b. Update DRAWG

COM informed the TM that the guidance on transfer of biocidal residue to food is under revision. As agreed, it will be separated into two documents, for professional and non-professional uses. Only IND sent comments on the previous version for which the reply has been uploaded to CIRCABC. **COM** informed that there are on-going discussions among EFSA, EMA and the COM on the evaluation and procedures for the future.

DE proposed to extend the mandate of DRAWG to develop a discussion paper on how to link the biocidal procedure and the MRLs setting procedure. **DE** stressed that, without clarification it is foreseen that it will not be possible to authorize products that need a new MRLs or an adaptation of an existing MRLs. Clarification is needed on:

- Who should be checking and when;
- If an existing MRLs covers the biocidal use or needs to be adapted;
- Who is informing the Applicant and what the timelines are in order that product authorization may proceed.

A discussion is needed with DG-ENV, DG-SANCO, EFSA and EMA. MSs need to imitate further action. **COM** welcomed the proposal and will come back with the answer. **COM** said that although they are working on the procedures it is going forward rather slowly due to a number of factors. **COM** questioned whether DRAWG will have the appropriate mandate to propose the way forward. **COM** believed that a workshop bringing together all interested parties (DG-ENV, DG-SANCO, EFSA, EMA, ECHA, JRC, MSs and maybe IND) could also be considered.

SE welcomed the proposal adding that the issue is causing concern at their authority too; thereby **SE** is supporting any initiative that will help move forward the process.

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IND acknowledged that they should provide the assessments. They have offered their continued input in the guidance development. **IND** commented on the need of consistency and pragmatism and asked for their comments to be reconsidered. **IND** proposed a screening process to identify where MRLs setting is not necessary and avoid setting MRLs where risk is not manifested. **COM** responded that their comments are considered, however, MRLs setting will also depend on whether the scope of Regulation 396/2005 will be extended to biocides. In case of an enlargement of the scope, biocides may need to comply with the default MRLs or need to request an amendment of an existing or default MRLs. **COM** reiterated the need to discuss the way forward together with all interested parties present. **COM** also noted that further guidance on conducting residue trials will need to be developed.

Conclusion
Comments on the DE proposal should be sent to COM and DE by 15th January 2013.

3c. MOTA Version 5
COM presented the 2 documents uploaded in CIRCABC and asked MS to take vision of the changes and to send comments via ENV BIOCIDES functional mail box until 18/01/2013.

3d. Evaluation Manual for Product Authorisation

Evaluation manual version 1 will be revised by **NL** including the comments received during the public consultation period. This revised version will be tabled at the next PA&MRFG and CA meeting in December. For the TM, a document containing the agreements and proposals to be included in the next revision of the evaluation manual, which is the same version as uploaded for TM III was uploaded on CIRCABC.

NL informed on the plan to prepare the next revision of the evaluation manual which will be presented to the TM I 2013, including the agreements presented in the maintenance table.
At the last meeting, MSs were asked to submit comments by the deadline of 26th October, and no comments have been submitted for the TOX session.

Conclusion
NL will present at TM I 2013 the next update of the evaluation manual (version 2).

3.e Substances of Concern

COM gave a short introduction to the agenda item and the comments received and uploaded on CIRCABC.
UK presented the case and explained the purpose of the discussion. **UK** gave a proposal to the PA&MRFG addressing both the human health and environmental aspects of the substances of

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concern which are present in the biocidal products. **UK** received lot of technical and detailed comments on their original proposal. They responded to the individual MSs but recognized that for some of the issues there were different views which required agreement in a face to face meeting. Therefore the working group on SoCs within the PA&MRFG referred the issue to TM. **UK** prepared 12 questions which identified the major issues that need to be discussed and resolved.

COM asked MSs for the opinion on the first following question: *'Do you consider an initial screening step, prior to SoC evaluation, a useful tool? E.g. criteria as the draft proposal from SE (suggestion for identification/screening of potential substances of concern). If so, what criteria/questions should be included?'*

UK explained that in the original proposal they were only suggesting the substances that are classified and present in the biocidal product in the concentration that the product gets classified. However, they got many comments, particularly from SE, suggesting that some pieces of the legal text (ie. the "other grounds for concern") should be addressed as well. Therefore, the checklist from. SE was proposed to be discussed first before going further discussing how to evaluate SoCs.

NL explained that they did not have any objections to the screening tool and considered it very useful. The only drawback was that they would not do too many screening steps because at the end all substances would be SoCs.

UK proposed to go through the checklist one by one in order to see what MSs were thinking. **UK** explained that the starting point in the SE proposal is that every co-formulant in a product should be considered by default as a SoC unless the contrary can be demonstrated. **UK** considered such starting point to be very demanding.. **UK** agreed that the "other grounds of concern" should be considered but the starting point should be different. For **UK**, the co-formulants present in a product are not SoCs unless they meet a number of criteria. **UK** did not agree that the existence of a DNEL should be a criterion taken into consideration for screening SoCs unless the substance is classified. **UK** expressed the same opinion in the context of OELs. **UK** was of the opinion that when the substance is not classified but has a DNEL or OEL should not be considered as a SoC.

SE clarified that the perspective from where they look at the proposal is that co-formulants are covered by REACH – this, means that the company placing products on the market should know a certain amount of information about the co-formulants. Therefore, if the co-formulant is in a biocidal product its properties should be known and it should be looked at. This is only a screening stage and not in-depth evaluation. There are plenty of information sources and it does not need to be some burden task. Therefore, **SE** did not consider this as unreasonable starting point because it is consistent with REACH. **SE** explained that information on classification or other information in the SDS can be taken as a starting point. If these were insufficient then a proportionate search of other sources of information should be carried out **SE** considered that criteria (such as OELs) were intended to make the whole screening stage not so burdensome, because they were easy. Concerning the active substances present in other product types that were included in biocidal product, they should be taken into account in the risk assessment of the biocidal product. This is consistent with Annex VI.

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UK explained that if the substance has an AEL or a DNEL or an OEL and it is classified, then the very first criterion will be met and it should be considered as a SoC. If it ends up in the band where the quantative assessment is required, then the AEL should be preferred to the DNEL or OEL in the evaluation or the OEL should be preferred to the DNEL. If there is an active substance (with its AEL) as a co-formulant e.g. an in-can preservative in a wood preservative product, but this active substance and it is not classified then it should not be considered as a SoC.
NO was of the opinion that the mere existence of existence of a DNEL or OEL for a substance should not define the substances as a SoC.
AT explained that the co-formulants are only covered by REACH if they are high volume chemicals and that in this case many co-formulants cannot be covered by REACH. Therefore for many co-formulants there cannot be data in place.
UK agreed with AT but still some data can be found in the CLP Inventory because even low-tonnage substances need to be notified. However, **UK** is still of the opinion that BPR cannot solve the problem of industrial chemicals and that the legal text is clear that the information can be required only if it is available.
SE explained that in their proposal they did not suggest generating the data. The companies should make an effort of checking the information sources first from regulations (e.g. REACH, CLP) and then other information sources (e.g. the proposal that was sent by ISL). Concerning the reference made to REACH, the company placing the substance on the market should know something about it and in case of placing a biocidal product on the market, it should know enough about it in order to apply for authorization. And the authorization process is based on the risk assessment which covers the active substances and SoCs. And SoCs in the legal text are not those which are classified. Therefore, there is a real argument to go beyond just classied co-formlants.
UK explained that regarding other sources of information the SoC guidance document will , make it clear that industry has got a responsibility to look in all available information. But it is probably already done during the preparation of SDSs. It cannot be expected from the authorities to look at every possible source of information. Therefore, it will be made clear in the paper that when the industry is preparing SDS, they check all available information. The authority could only check C&L Inventory and REACH dissemination website on the top of it.
SE explained again that it will be the industry responsibility as they are putting co-formulants in the products on the market, so they should know what they are including in their products and they should look at the information sources available.
NL explained that they understand the position of SE in a way that the responsibility of checking all available sources of information is not on the authorities but on the industry. Only the evaluation of the correctness of the data could be discussed during the meeting. Characterisation of SoCs should be based on the intrinsic properties of the substance and if the industry can submit information on DNEL and critical endpoints (e.g. in SDS) then there will be a complete overview of the information there is unless they do not need to be checked in all these databases.

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DE reported that at the conference in Vienna they introduced a database that they have been using for 10 years in Germany to collect there every piece of information from applicants regarding BP and PPP areas on co-formulants. This can be a way out that all information is available in one place and there is no need for authorities to collect or to check the correctness of these data.
IND made a reference to the legal text that it is clear that a SoC is a substance that is classified unless there are other concerns. **IND** also expressed its doubt why specifically AEL and OEL should be those other grounds of concern. IND reminded that the list is already in place and that the TM should not create another list that would be exhausted for every co-formulant in the product.
UK suggested writing in the SoC paper that this is **IND** responsibility to consider all available information on co-formulants (including their sources) before sending it to the authorities. **UK** added that the authority would check only few of these databases. **UK** proposed to go through the checklist prepared by SE.
In favour of keeping criterion b) (*'Active substances that are notified according to the biocides review programme, even for different PT')* from the checklist were: **FR, ES** and **SE**. And against the following MSs: **DK**, **AT**, **CH**, **IT**, **NO**, **FIN**, **UK**, **NL**.
SE reminded that the issue how the substances for other product types in a formulation are going to be dealt with will be raised again at the mutual recognition stage because one MS consider that something should be taken into evaluation and the Ref MS hasn't done so. Therefore, there should be another discussion at TM or PA&MRFG meeting.
UK agreed that synergists (criterion C) in principle should be considered but still needs to clarify whether the BPR has provisions for for data requirements for synergists because if the authority cannot ask for data to perform an evalution fo the synergist then there is no point in calling it a SoC.
In favour of keeping a criterion c) (*'Substances that contribute to the efficacy of the product, e.g. synergists')* from the checklist were: **SE**, **ES**, **FIN**, **DE**. And against the following MSs: **AT**, **CH**, **CZ**, **SI, UK**.
NL agreed with UK on the approach that could be taken for synergists, but they have still doubts what be the consequences if it was taken out of from the checklist.
CEFIC suggested taking the opinions of the MSs on the checklist's criteria as an agreement or the decision of TM.
SE explained that in their proposal a full set of data is not required , but only the available information -this is in line with Annex VI of the BPD. Concerning the synergits, when we do not know much about them, we should not take them out, because this is exactly the kind of things we are looking for when we left SoCs open beyond the classification criteria.
UK agreed that if data can be required for the synergits is in the legal text, then criterion c should be included in the checklist.
JRC proposed to give more time for the TM participants to reflect on the checklist again and send written comments on this.

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UK agreed with this proposal and added that the legal aspects should be checked once again in order to be sure that the guidance document is not going beyond the legal text. Therefore COM may bring somebody with the legal expertise of the directive and the regulation. The discussion on these criteria is not only a scientific debate amongst the people at the TM but it goes beyond to the policy and legal level.
UK added that the downstream impact of setting up these criteria can have major consequences in terms of regulatory process. Therefore it might be appropriate to have some impact assessment to understand what are the ramifications including these proposed criteria from the guidance document. What is the benefit of undertaking these more rigorous assessments? There is a danger of doing more work with not much gain. It should be very carefully balanced. And it might be that some impact assessment may be important to be undertaken in this context.
UK suggested going on with the rest of the criteria in order to see other MSs' opinions. However, before any final list is endorsed in the guidance, it should go to the PA&MRFG and even to the CA level to make sure that the proposed guidance does not go beyond the legal text.
SE referred to Annex III Introduction Part II par. 4 where there is an indication to the possibilities for requiring the information.
In favour of keeping criterion e) (*'Substances that have been included in the list established in accordance with the REACH Regulation, art. 59(1) for reasons other than those referred to in point (a))')* from the checklist was the majority of the MSs.
UK agreed to keep the criterion e) with a change saying that this criterion deals with endocrine disrupters on the candidate list.
SE explained that mentioning only the endocrine disruptors is not enough and that reference to the candidate list should be made in this criterion.
In favour of keeping criterion e) (*'Substances for which there are Community workplace exposure limits')* from the checklist were the following MSs: **NL**, **CZ**, **SE**.
NL explained that they had a formulation and one of its co-formulant had an OEL. There was no classification. When NL assessed whether there was an exposure, this showed no concern. So at the end there was no risk for the SoC but it should be checked whether the SoC presents a risk when there is a limit value. It is like a screening tool to check whether there are SoCs.
UK agreed that if the majority of MSs wants to keep criterion f) in the checklist, then they will also go with the majority.
AT explained that it will be inconsistent if we just leave in this point but delete the criterion b (as agreed by the majority of the TM in the discussion before). : It should be the classification that defines a SoC and not a listing in whatever regulatory program.
CEFIC explained that if a positve screening tool is established then there should also be a negative screening tool. The example given by NL is that even if it would have been triggered that the substance has to be taken into account, the applicant is bound to defend the product with the full risk assessment including almost all substances.
NL explained that to make the assessment mentioned above took them very little time, so it is not a big effort.

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CEFIC disagreed with NL statement and added that once the substance will be classified as a substance of concern then the data requirements are triggered and potentially the company cannot complete all this information. The risk assessment should be done perhaps on very limited information on that specific SoC and then worst case approaches like mixtures' assessment verifying the exposure limits with the calculated exposure. The SoCs trigger whole route of investigations.
DE suggested having another written commenting round because it needs to be decided what will be the consequences if some of the points will be taken out of the checklist.
NL explained that the title of the checklist is very important and it matters if it is identification or screening tool because then it has an influence on the comments.
SE explained that this is a screening tool for identifying which substances cannot be SoCs.
CH appreciated SE explanation and admitted that SE proposal refers to screening.
IND explained that REACH was covering general attributes of co-formulants in there and that we should be conscious of dual regulation of these things (to duplicate the work).
JRC explained that the outcome of this discussion will be forwarded to PA&MRFG

Conclusions

SE proposal for the check list: the opinions on which criteria to be taken into consideration while identifying/screening for SoCs differed between the MSs and common agreement could not be reached. Therefore SE was asked to prepare a paper clarifying the issue and send it to TM and PA&MRFG participants by Dec 7. UK was asked to prepare a paper addressing their further concerns on the checklist and send it to TM and PA&MRFG participants by Dec 7. Other participants of TM were asked to send their further comments/concerns on the mentioned issue as well to TM and PA&MRFG participants by Dec 4.
Banding approach: the issue was only briefly presented by UK and not widely discussed because of lack of the time. However, TM participants were provided with the revised UK approach and its explanation. A separate document was forwarded after the end of the toxicological session.

In addition to the above, TM participants were asked to feedback the conclusions of the discussion to their colleagues participating in the PA&MRFG.

3e. BIP, 6.1 –Guidance for Information Requirements

Action points as discussed at TM will be provided by ECHA together with the revised version of the document.

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

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3.i.1 Applicability of the default values of the EFSA Guidance on Dermal Absorption to Biocidal products

COM introduced the topic. At TM-III-2012 the TM was requested to send comments on the applicability of the default values proposed by the EFSA Opinion (EFSA Journal 2012; 10(4):2665) to biocidal products. Comments were received from UK, SE and DE. The following default values are recommended in the guidance:

- A default dermal absorption value of 25% may be applied for products containing > 5% (50 g/kg for solids or 50 g/L for liquids) active substance.
- A default value of 75% should be used for products or in use dilutions containing ≤ 5% active substance.
- If log Pow < -1 or > 4 and MW > 500 a default dermal absorption value of 10% may be applied.

COM acknowledged that dermal absorption of active substances in biocidal products depends on many factors, such as the presence of enhancing co-formulants, irritation, concentrations. However, **COM** emphasized that conservative default values were selected. The conservativeness was further supported by preliminary results of on-going studies in the PPP area (DE, IND). Experience shows that it is difficult to define general rules on correlation between formulation and dermal absorption.

Of over 30 biocidal active substances for which study based dermal absorption values were agreed upon, covering several PTs, the values were well below the default ones. Among these biocidal product formulations some contained emulsifiers, some solvents like acetone, or were mineral oil based formulations, yet were still below the **EFSA** default values. Though formulations may vary among PPP and biocides, there is a high variability within the groups. PPP formulations can also be e.g. water based, solvent based, oil based, suspensions, and granular ones.

COM proposed to endorse the default values with the reservation that higher or lower values may be applied in case there is robust evidence supporting the divergence from the default values.

UK, FR, DK, NO, and **NL** supported the endorsement of the default values.

DE proposed checking the application of the default values with different biocidal PTs in order to gain experience on biocidal actives as DE was opposing to apply the default values for all PTs. **DE** added that based on the data the default values may be updated for specific formulations or PTs. **COM** agreed that in case new robust information will indicate that for some special cases the default values are not protective the default values may be updated.

Conclusion: the EFSA default values were endorsed by the TM; however, on a case-by-case basis divergence to higher or lower values may be possible when supported by robust evidence.

3.i.2. Applicability of the EFSA Guidance on Dermal Absorption to Biocidal products

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Based on requests from MSs, **COM** proposed to broaden the scope of the discussion to the whole Guidance document (GD). **COM** asked whether the general principles set in the GD can be agreed or a point by point discussion was necessary.

UK believed the EFSA opinion is the best available guidance, based on the best available evidence and science; it has been peer-reviewed and could be endorsed. **UK** did not consider a point by point discussion necessary. **DK, NL** supported the opinion of UK.

SE requested a clear notation in MOTA that on a case-by-case basis, if diverse experience indicates that some part of the document is not applicable expert judgment can be used. **NL** suggested to emphasize in MOTA that it is only guidance and should be used with flexibility. **COM** supported that guidance documents are intended to be used with appropriate flexibility. They are not legally binding documents; therefore deviation is possible if there is robust evidence supporting it. The section on dermal absorption in MOTA needs to be updated according to the agreement of the TM.

DE, SE and **CZ** requested to postpone the endorsement of the document to the following TM and allow to comment on the guidance before endorsement. **DE** inquired whether in the case of fatty acids, having higher absorption values, bridging to other related substances is possible instead of using the default values. **COM** responded that the approach of dermal absorption assessment will be discussed at the following PA&MRFG meeting and in particular whether it is necessary to undertake a default assessment using 100% dermal absorption or go straight to the new EFSA default values (in the absence of data). To avoid potential inconsistency with the decision to be taken on the order of using default values, **COM** also supported to endorse the guidance document at the following TM.

IND asked why the guidance developed by EFSA is not considered applicable in the biocides area as pesticide and biocides have similar chemical properties and formulations. **COM** answered that as some formulations, like antifoulings may be different from pesticides the PA&MRFG requested the TM to give an opinion on the applicability of the default values. **IND** supported the adoption of the guidance as it offers consistency in evaluations across the board, can be used as a standard, has been reviewed by a number of experts and if justified MS have the possibility departing from it.

Conclusion

MSs were requested to send comments on the EFSA Guidance Document till 15th January to the COM. The document is expected to be endorsed at TMI-2013. The section on dermal absorption in MOTA shall be updated as appropriate

3l. Mixture toxicity assessments

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COM briefly introduced the item.
The draft proposal was prepared by **FR** and aimed at setting down principles and a tiered approach for mixtures' risk assessment. It had already been discussed thoroughly at the TM III 2012. A consolidated version of the draft proposal, reflecting the inputs from the TM and the comments received after an additional commenting period, was prepared by **FR**. The consolidated version of the proposal had been uploaded to CIRCABC for discussion at the TM IV 2012. Some late comments on the consolidated proposal were received from **UK** and **IND**. The comments from **IND** were circulated within the TM as room documents.
FR thanked **IND** and MSs for their comments, in particular **DE** for the help and co-operation in the refinement of Tier 3. **FR** briefly presented the consolidated version of the proposal and summarised the major changes introduced.

3l.1 Dose additivity

FR explained that in the document, all the definitions would be added to avoid possible misunderstandings. In particular, "additivity of effects" had to be considered as "dose additivity". With reference to the points raised by **UK**, **FR** explained that if dose additivity was not confirmed in Tier 3, the assessment would be carried out substance by substance in Tier 1.
UK suggested better clarifying this point in the text. However, **UK** disagreed that this approach would save time and resources as at Tier 2 not only active substances but also many SoCs will be risk assessed all together by assumed additivity.. This is most likely to lead to the identification of,., unacceptable combined risks would be found in the majority of the cases cases and so to the need of proceeding to the more time-consuming Tier 3 of the assessment. **UK** was in favour of assuming additivity by default only when common target organs of toxicity were identified. However, **UK** was willing to accept it if the majority of the TM was in favour of the proposal by **FR**.
COM commented that the outcome of the discussion of the item at the TM III 2012 was that additivity was assumed by default as a pragmatic approach, as it relied on worst-case and could be refined in further tiers.
FR acknowledged that the proposed approach was conservative and in principle it could be possible to proceed directly to the refined Tier 3. However, Tier 2 was proposed to save resources and time in order to avoid checking the dossiers, identifying the different organs and determining the NOAEL for each organ.
AT, **DE**, **NL**, **NO** and **SE** supported the **FR** proposal.

<u>Conclusion</u>
The majority of the TM was in favour of considering dose additivity by default at Tier 2.
Point closed.

3l.2 Target organ-specific AEL values

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SE raised concerns about the amount of work required to harmonise and define at the TM level target organ-specific AELs for each substance. This could delay the implementation of the proposal.
COM noted that the same issue was raised by **UK**. **UK** was unclear how target organ-specific AEL values could be harmonised at substance evaluation stage, as indicated in the proposal.
Also **NO** shared the concerns of **UK** and **SE**.
FR explained that the set-up of a European Working Group for harmonization of AEL organ was proposed. The proposal was that the Group could work on the validation of the NOAEL/AEL of organs for each substance at the product authorization level, but this activity should focus on the active substances already discussed at the TM level. For the others, the proposal was to validate the NOAEL/AEL organ during the discussion of the active substance. **FR** added that the set-up of the Group would help in avoiding the derivation of different values of NOAEL/AEL of organs for the same substance.

Conclusion
The details related to the set-up of the European Working Group for harmonization of AEL organ will be discussed at a later stage.
Point closed.

*3l.3 Comments raised by **IND** on the consolidated proposal*

The comments raised by **IND**, incorporated in track changes in the consolidated proposal by **FR** (documents uploaded to CIRCABC: "TMIV2012-TOX-Item_3l-Mixture_methodology_TM_FR_nov2012_HMH2.docx" and "TMIII2012-TOX-item3l_Mixture_methodology_DE_comments 10-10-12.docx"), were circulated as room documents within the TM.

3l.3a Working Groups set up in light of the preparatory tasks for the implementation of the Biocidal Products Regulation
(Procedural comment, page 1)

CEFIC mentioned that groups of experts were set up in different preparatory activities of the Biocidal Products Regulation. The focus of one of those groups was on mixture assessment. Although the names of the experts were provided, the groups had never started working together.
CEFIC encouraged the involvement of the working groups in those specific subjects.
COM asked CEFIC to provide more details on the groups.
CEFIC referred to the Document 5.1.a of the CA meeting and mentioned that a list of preparatory Biocidal Products Regulation activities (42 tasks in total) was established under the hospice of the CA meeting. The list of **MSs** and **IND** representatives involved was also prepared. A group of experts was formed as well to work on specific issues and provide inputs. The conclusions drawn by the working group should then be put forward to the appropriate forum,

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i.e. the TM and the CA meeting. However, the issues in mixture toxicity assessment were discussed on very short notice in the TM, largely without involving the relevant experts. **CEFIC** encouraged the direct participation of the appointed experts in the discussion.
COM proposed to first consult the CA Document before starting a consultation with the group and organizing the work.
UK suggested that the **FR** proposal should be finalized and then taken into account by the BIP for the implementation of the BPR.
ECHA agreed with **UK** to finalise the **FR** proposal and the other works in progress related to the topic and have them considered by the Working Groups to address mixtures and criteria overall for all chemicals across regulations.

Conclusion
No clear conclusion was reached on this point, due to the limited time for discussion. Further consultation will be needed to clarify how to proceed.

3l.3b Substances of Concern
(Comment #1, page 2)

The point was pending on the outcome of the ongoing discussion on the issue (see Agenda item 3e).
CEFIC suggested including a remark to indicate that the understanding of Substances of concern had not been fully clarified yet.

3l.3c European Working Group for harmonization of AEL organ
(Comment #3, page 3)

Please see the discussion under point "3l.2 Target organ-specific AEL values" above.

3l.3d Specific case of synergistic effects
(Comment # 4, page 3)

IND was asked to clarify the comments. It was proposed to solve the issue bilaterally between **FR** and **IND**.
FR agreed on the comment provided by **IND** and added that synergy should be a rare case. **FR** also agreed to include the paper by Boobis et al. (2011) as a reference in this point of the paper. This publication mentioned that synergistic effects are very rare and the safety factor would be more than 2 or 4. **FR** suggested a safety factor of 10 and proposed to indicate in the document that the choice of this safety factor was based on a conservative approach.

Conclusion

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IND will provide more clarification on the comment in written. A bilateral discussion will be set up between **FR** and **IND**.
Point closed.

3l.3e Definitions
(Comment # 6, page 4)

FR will include a more detailed definitions in the terminology used in the proposal. In particular, with reference to the different definitions of mode versus mechanism of action, **FR** commented that in the document "mechanism of action" was defined as a molecular sequence of events producing a specific biological outcome, while "mode of action" was identified as the key events by which a chemical exerts its biological effects. These definitions would be included in the new version of the document.

Conclusion
More detailed definitions in the terminology used in the proposal will be provided, including definitions of "mechanism of action" and "mode of action".
Point closed.

*3l.4 Additional inputs proposed by **FR** on the proposal*

- **FR** proposed to consider Tier 1 as a preliminary step, and to change Tier 2 into Tier 1 and Tier 3 into Tier 2, in order to harmonize the approach with the strategy proposed in the environmental mixture toxicity paper.
- **FR** also suggested changing the terms “hazard quotient or hazard index” into “risk quotient or risk index”, since the calculations refer to risk, not to hazard.

Conclusion
The TM is invited to react in written to the points raised by **FR**.

Overall conclusion
In light of this discussion, the MSs are invited to provide comments and inputs on the **FR** proposal and on the comments by **IND**. The deadline for sending them is 14th December 2012.

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GENERAL SESSION

Welcome and introductory remarks
(Please read the text reported in the Introduction to TM – Toxicology Session)

1. Tracking System: Progress reports

No comment was raised by the TM.

3. AOB

3a. MOTA Version 5

COM presented the two documents uploaded in CIRCABC and asked MS to take vision of the changes and to send comments via ENV BIOCIDES functional mail box until 18/01/2013.

3c. Evaluation Manual for Product Authorisation

Evaluation manual version 1 will be revised by NL including the comments received during the public consultation period. This revised version will be tabled at the next PA&MRFG and CA meeting in December. For the meeting, we uploaded to CIRCABC a document containing the agreements and proposals to be included in the next revision of the evaluation manual,
NL informed on the plan to prepare the next revision of the evaluation manual which will be presented to the TM I 2013, including the agreements presented in the maintenance table.

At the last TM MSs were asked to submit comments by the deadline of 26th October. Comments on the UK proposal regarding the extrapolation of the pack size have been provided by NL and FR. UK provided a comment in the evaluation manual on the surface tension point.

Regarding the extrapolation proposal by UK (presented at the end of maintenance table uploaded on CIRCABC), **NL** disagreed with the extrapolation of HDPE (shelf life) to PET packs (as PET is a different material, it cannot be considered comparable with HDPE), extrapolation of PET (shelf life) with all other HDPE variants (with seepage data) as packaging differs too much. Also **NL** considered that the size is not an issue and no extra data should be required above 20 L.

FR also agrees with NL on their comments regarding the extrapolation points HDPE-F to be extrapolated to HDPE-PA and HDPE-EVOH. HDPE/EVOH and HDPE/PA have a lower permeability to oxygen than HDPE-F but no resistance to hydrocarbons. HDPE-F has higher

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resistance to hydrocarbons but has permeability to oxygen higher than HDPE-EVOH and HDPE/PA.. (no extrapolation from HDPE to PET and from PET to HDPE variants).

UK responded to the comments from NL and FR. **UK** accepted the FR written comments that the packaging is not the same, and the arguments provided. But **UK** does not want to ask industry to generate the data for all sorts of different types of packages, as they will not affect the physical and chemical properties, but industry has to have the seepage data to show that the packaging is stable. **UK** agrees with NL that a worse case package should be identified, but then if industry decides to change the packaging for various reasons, they should not be asked to submit physical-chemical data, but seepage data. **UK** asked if the MSs have the data to prove that the phys-chem properties change on packaging, to submit those data.
UK will continue the bilateral consultation with NL and FR on these points, including possible data. Other MSs are encouraged to express their opinion regarding this issue.

NL agreed with the comment by **UK** on the tension surface.

Conclusions
NL will present at TM I 2013 the next update of the evaluation manual (version 2).
On the **UK** proposal on the packaging extrapolation, other MSs should send further comments and supporting data to UK by the 18th January.

3c. Evaluation of shelf life – PT 21

Background
From the last meeting**,** CEPE revised the guidance based on the outcome of the TM III discussions. Further comments were received and uploaded to CIRCABC from UK, FR and DE, and an email consultation took place with NL.

Discussion
CEPE presented the main revisions performed in the version 2.
Storage stability at low temperature and effect of light had been added in the text at point 3.3

Accelerated storage stability
Accelerated storage stability discussions have been incorporated as comments to the text. Regarding this point, **DE** had a written comment asking CEPE whether it is intended to use accelerated storage stability testing of shelf life of 4-5 years. CEPE proposed to use accelerated storage stability studies for shelf life of 2 years, in accordance with CIPAC method, and not to submit also later on ambient storage data; CEPE has asked for the possibility to submit more data to support this position. For claims of more than 2 years, CEPE proposed to use the ambient

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studies from the beginning, and have the experiments designed in order to permit the extrapolation to longer periods of time.
UK is willing to analyse the **CEPE** information to support the acceptance of the accelerated storage stability testing without the need to submit further ambient storage data, but this in the context of the PT21 products, and not applicable for all PTs. However, **UK** did not support to extrapolate a 2 years ambient study for shelf life of 4-5 years.
FR is of the opinion that the same guidance should apply for all PTs. Requirement of a long term storage stability study should be made if a 2 years shelf life is granted based on accelerated storage stability study. FR also did not support the extrapolation argument, as it should be either a study or QC data to show that the product is stable after the long shelf life of 4-5 years (provided that 2 years stability data are provided)..
NL and **DE** supported the position of **UK** and **FR**.

FAO limits
FAO limits should be checked by MSs to verify if the version 2 accurately reflect the decisions of TM III.

Permitted active substance variation
The discussion on permitted active substance variation of up to 10 % or higher variation, allowed with proper justification, have been incorporated to version 2. In the comments received there was a difference of opinion between **UK** and **DE** on the t(0), t(end), t nominal, and they were asked to consult bilaterally on this if necessary.

Analysis of copper
NL commented on this during the bilateral consultation. At TMIII-2012 Cu_2O was brought up as an issue, but no discussion was possible. Cu_2O is hard to specifically determine. Cu(II) and Cu(I) are argued to be comparable. This is reasonable as once Cu(I) is exposed to oxygen and moisture, it will very rapidly oxidise to Cu(II). However, if a label claims a product contains cuprous oxide (Cu_2O), then an analytical method for monitoring should be available to specifically determine the Cu_2O content, unless this is not feasible. A solution may be to commonly agree to express Cu(I) and Cu(II) as a total amount of copper within a formulation, similar to expressing sodium hypochlorite as active chlorine, as long as the original copper salt is specified within the dossier.
FR does not want to make a specific case of Cu in this guidance. **FR** welcomed comments from MSs and IND about this to be used for the assessment of the dossiers. **CEPE** would propose to incorporate some kind of stability issue for the Cu in the guidance.

DK agree with the comments made by **DE**, and welcome a workshop, especially on how to deal with heterogeneous products.

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FR asked if CEPE would provide more information on bridging between products / formulations as discussed at TMIII, to derive general guidance (if possible) for "similar" or "comparable" products in order to avoid duplication of tests.. Such discussion could be suitable for the workshop, and if **CEPE** is willing to submit it, **FR** would want to participate to analyse this.

MSs and IND welcomed the organisation of a workshop: from TM III **NL** and **CEFIC**, and during the meeting **FR**, **DE**, **DK** and **UK**, and after the meeting also **IT**. Other MSs can express their intention to participate to the workshop by the 18th January. Then **JRC** will check the organising details and confirm the possibility to organise the workshop in connection to the TM I 2013, where the discussion can take place not only on PT21, but also on other PTs.

Conclusion
Further consultation between **DE** and **UK** on t(0), t(nominal) to take place if necessary.
CEPE is welcomed to submit any further data they may have to support the acceptability of submitting the accelerated storage stability over the ambient storage stability testing, but to submit information not only on the active substance degradation, but also on the phys-chem properties and packaging compatibility.
MSs to send intention to participate to workshop on storage stability and discussion paper by 18th January, then **JRC** will come back with info on the workshop towards the beginning of February.
MSs can further comment on the revision 2 of CEPE guidance by 18th January.

3d. BIP, 6.1 –Guidance for Information Requirements

Comments 13.1 (CEFIC) & 73 (UK) were on the use of data of either the purified active substance or the substance as manufactured:
UK stated that for all properties it needs to be clarified if to be tested with the purified active substance or the active substance as manufactured. **UK** further stated that only for classification purposes & thermo-stability endpoint, the active substance as manufactured is necessary. All other tests should to be done with the purified active substance. **UK** concluded that the footnotes need to be changed, as they are confusing or inaccurate. The TM agreed and COM will forward the request to commission. In addition to the comments by UK, **COM** proposed to have a footnote 'The information provided should be for the active substance as manufactured'. This footnote would be applicable for endpoints on classification purposes & the thermo-stability as pointed out by **UK**.

The **COM** response to comment 46.1 (CEFIC**)** on the terminology regarding major metabolites was confirmed by the TM.

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NL asked for clarification on comment 65 (impurity of technical concentrates). **COM** explained that this will be dealt with at the drafting of the Technical Equivalence (TE) guidance and it will be discussed via e-consultation in the near future. **NL** is of the opinion that this is not only a matter for technical equivalence but being part of identity and requested this to be included in the BIP6.1 guidance. **UK** and **FR** agreed with **NL**. **FI** on the other hand preferred the terminology to be discussed in the TE guidance. **UK, FR** and **NL** agreed to send a guidance draft to COM within the next three weeks (by 14/12/2012).

DE commented on the determination of UVCB phys. chem. properties (comment 74) and proposed additional text to clarify the possibilities to derogate from standard information requirements in case it is scientifically unreasonable. The TM agreed to use the text as proposed by COM in the reply to DE. Also, COM will add relevant REACH guidance reference to the text.

Comment 78 (raised by NL) will be clarified by COM.

Comment 84 was raised by UK, on the acidity endpoint (active substance). The TM agreed that data should be required for the active substance as manufactured.

On comment 93 (UK/surface tension), the TM agreed to include critical micelle concentration (CMC) threshold. The need to update the MOTA was highlighted by **NO**. **NO** informed the TM that currently in the TNsG and hence also in, MOTA and the present draft of the BIP6.1 guidance list a threshold of 50mN/m is given instead of 60mN/m, the threshold in the REACH & PPP guidance. However, already after TM_III 2012, COM agreed to use 60mN/m (reply to comment 281).
COM agreed that MOTA needs to be updated to 60mN/m.
COM will correct Guidance text.
COM will correct text in MOTA
As already agreed when discussing comment 13.1, the TM approved to use 'active substance *purity as manufactured*' for the endpoint '3.11 Thermal Stability' (comment 102b,c by **UK**).

In response to comment 112.1 by CEFIC, the TM agreed to change the wording on 3.17 'Stability in organic solvents' as proposed by **ECHA** (*the information is only required in case the active substance as manufactured is delivered in an organic solvent*)

On comment 124b by NL (endpoint '4.17.3 Dust explosions'), the TM agreed to add the specification '*Dust susceptible to dust explosions may have a particle size up to 1 mm*' as proposed by **NL**.

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On comment 143 on the repeatability of analytical methods, the TM agreed to the **UK** proposal to include the Horwitz ratio (a normalised performance parameter on inter-laboratory precision) as a requirement.

Furthermore, the TM agreed to use the term Acceptable Exposure Level (AEL) instead of Occupational Exposure Level (OEL) (comment 147 on endpoint 5.2.2 analytical methods for monitoring purposes by **FI**).

UK highlighted a wording issue in comment 182. **COM** agreed to change the wording in line 1908: '*any relations'* will be changed to '*any presumptions of exposure'*.

The discussion on comment 196 (DE) on the 'likely tonnage to be placed on the market' – was postponed to the ENV session on Thursday.

Comment 202 (1) by UK on endpoint 6.7.1 *Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies*: It was agreed to discuss that point at the toxicology session. **COM** will contact **UK** to solve the issue bilaterally.

Comment 202 (2) by UK: it was agreed to replace '*amateur'* with '*non-professional*'.

DE commented on the wording issue (comment 460). **COM** will contact DE to solve the issue bilaterally.

The TM agreed to add a reference to CIPAC method MT75.3 for the endpoint on acidity/alkalinity as proposed by **DE** (comment 484 by DE). In addition a reference link will be inserted to chapter II endpoint 3.3 (active substance).

The TM agreed with **UK** comment 487b on endpoint '*3.4.1, Effects of temperature*': (2 years ambient storage does not necessarily have to be investigated. The ambient storage data must be in line with the stated shelf life, which might be shorter or longer than 2 years.)

In comment 487.1, **AISE** (absent) stressed out that the accelerated storage stability tests should be performed in sales packs. At the TM, **UK** clarified that CIPAC MT46.3 requires conducting the test in a glass jar. However, **UK** agreed to conduct the ambient storage stability test in sales packages. **NL** prefers the test in sales packages to be conducted in a 'worst case' packaging (e.g. HDPE - high-density polyethylene) and intends to amend the evaluation manual due at the next TM. **UK** agreed with NL that HDPE is the worst case packaging.
TM agreed that the ambient storage stability test will be conducted in 'worst case' sales packages (HDPE).

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In comment 487.2 (3.4.1 Storage stability tests), **AISE** (absent) proposed to extrapolate alternative methods to determine the storage for readily decomposable active substance. However, because **AISE** was not present at the TM the comment could not be sufficiently clarified. Two member states objected the proposal. **UK** made clear that it would not accept extrapolation of efficacy data in order to determine the degree of active substance degradation. **UK** argued that efficacy does not necessarily correlate with active substance amount but could also be caused by degradation products with potentially higher toxicity. **NL** agreed with UK. As no Member State supported AISE, the proposal was dismissed.

In comment 487.2, **AISE** (absent) claimed that in table 3.7 (Effects of temperature) an unsuitable test method is listed (CIPAC MT46.3). **UK** disagreed and informed the TM that it is widely accepted to use accelerated storage data to extrapolate chemical stability to 2 years. As no Member State supported AISE**,** the proposal was rejected.

In comment 507, **NL** stressed that surface tension needs to be tested on the undiluted product. **DE** and **UK** agreed. **UK** added that the test on the undiluted product should be done for classification purposes, as required for products with a hydrocarbon concentration CH>10%. For those products, viscosity (40C) and surface tension (25C) need to be determined. **UK** furthermore reminded the TM that for all liquid products the maximum in-use concentration needs to be tested as agreed at the product evaluation manual. The TM agreed with **UK**.

In line with comment 507, **DE** asked in comment 509 for information on the surface tension if the kinematic viscosity threshold is exceeded. The request was granted by the TM. **UK** pointed at the similarity to discussions on comment 507, i.e. the hydrocarbon (CH) content threshold as well as the maximum in-use concentration test for all liquid products. In addition, **UK** informed the TM about recent changes in the criteria for classification of a compound/product as an aspiration hazard as compared to the CLP, in addition to the requirements as mentioned above.

In comment 537, **UK** highlighted the need to make sure that the intended use on the label is in line with the one stated by the applicant in the risk assessment for product authorization. **NL** agreed. **UK** agreed to draft a text proposal.

Regarding comment 539b on endpoint 7.3 'Detailed description of the use pattern(s) for biocidal products…', raised by **UK**, **COM** asked for Member State's experiences. **NL** reported the use of a *'practical use for biocides'* - table for their product authorization procedure. **DE** supported the idea by NL on the use of a table on the intended use. **NL** agreed to send a copy of that table to COM. **COM** proposed to disseminate the Dutch list among TM participants for a written commenting round.

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NL referred to comments 158, 159 and 159b on the inclusion of a time delay for efficacy tests. **COM** agreed to include the condition "*where applicable*" and will possibly add a link towards the possibilities to derogate from standard requirements.

COM reminded MSs to timely send any so far missing comments to **COM**.

3f. Guidance on Efficacy of PT 21

IND gave a brief introduction. At TMIV-2011 CEPE submitted a new version of the CEPE methodology (5 pages *vs*. half page original) and offered to amend the TNsG Annex on PT21 with minor changes. At the workshop during TMI-2012 comments were submitted on both the CEPE methodology and the TNsG Annex. On request, IND rewrote the TNsG according to a new format and has added substantial new text. The updated version of the CEPE methodology was submitted to TMIV-2012 with the changes accepted by IND. IND has also provided an RCOM table with the responses to the comments on the documents. The key comments on the CEPE document on positive controls and acceptance criteria are also covered by the comments on the TNsG added **IND**.

COM thanked CEPE for taking the lead and investing substantial resources to develop the new draft TNsG Annex. **COM** also thanked IND for the changes made in their document adding that the discussions should focus only on the draft TNsG document.

3f.1 Spectrum of activity (TNsG 1.5)
FR requested to include the categories listed in the CEPE methodology. **IND** clarified that the original text has not been changed as it stresses that the effect the three major types of fouling have on a vessel or a boat is the key factor. In section 2.3.1 of the TNsG the references as suggested by DE were included. Although, during the assessment of a panel the different types of species may be considered, the overall assessment of the fouling of the panel matters from an efficacy point of view.
FR and DE proposed to mention also these categories in the paragraph 1.5
DE wishes to see the data IND has. **DE** claimed that since the evaluation of the panel is not done by biologists, the refined categories ensure that trained operators are able to differentiate between the major categories and thus may serve as indicator of reliability. **DE** referred to the draft weighing proposal of FR; suggesting that if the categories are not refined, like for animals encrusted or not, distinctions cannot be made within the major categories and the worst case will be considered (e.g. all animals as encrusted). **IND** clarified that the comment of FR on the exact rating of the panels related to the CEPE methodology and in that methodology all raw data read from the panels is supposed to be submitted.
Sub-categories were not mentioned in the referred TNsG text, argued IND, as the boat/vessel owners are not concerned about individual species, only about the result of the overall assessment, the extent of effect the fouling has on the vessels i.e. the three main categories.

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FR believed the objective of the efficacy test is to describe what types of species are on the panels. **IND** explained that the efficacy test would involve that, but the point of the test is to evaluate what is the concern of the product user. The aim is to document a label claim, whether it has an effect as an antifouling on slimes, animal macrofouling and/or weeds. As reflected in the TNsG and the CEPE methodology, in order to generate the overall assessment the types of organisms listed need to be evaluated.

COM proposed as a consensus to refine the categories as described later. **IND** agreed to include examples in parenthesis. **DE** proposed another phrasing for the end assessment of efficacy these three types are relevant, however, data should be given on the main categories. **DE** said even if IND does not have the data for an organism the assessment would not be rejected. **DE** agreed for the label claim the three categories are relevant and not the individual species. **DE** added that for the rating the subcategories will be needed. **IND** agreed though had reservations on repeating text from 2.3.1.

DE requested to add that data should be submitted. **NO** disagreed, as the chapter only specifies the three fouling groups. **NO** supported that no changes are needed.

NO asked whether categorization depend on the water systems, e.g. for fresh water barnacles may not be relevant. As a two tiered approach, inquired **NO** further, are the results used to design the test, which animal or which category to look at; and thus different efficacy claims are made for the fresh water lakes than for the North Sea. **IND** agreed adding that there may be different organisms at different tests sites at different part of the world. **NL** supported to have for one use different criteria than for another; **NL** requested to describe the uses and the criteria in separate chapters. **NL** believed that harmonized criteria are needed for the efficacy assessment. **AT** asked to make a list for freshwater; **AT** supposed products used in fresh waters are less concentrated; and species may be different. **IND** explained that specific tests are rarely ever carried out for freshwater conditions; freshwater uses are also very limited. **NL** asked to point out if there was a difference for marine use and freshwaters requirements. **IND** agreed that it could be interesting to differentiate, however, has difficulties expanding the text as read across from marine water to freshwater is usually applied. **AT** was concerned that this may lead to too high concentration uses. **IND** believed that it relates to risk assessment and not relevant for efficacy assessment. **NL** pointed out that the lowest efficacious concentration should be used.

3f.1 Cut off criteria

IND was not supporting the use of cut-off criteria. **IND** argued that cut off criteria for antifoulings are not practical, do not reflect the nature of the label claims which are based on a coarse methodology, carried out in a natural environment where conditions cannot be controlled. It is not possible to establish whether a panel is 10, 25 or 50% better or worse than another panel

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as the following month the results may be the opposite between the two panels. These tests in a natural environment are not suitable for a detailed relative comparison between products and fined tuned establishing level of antifouling. Due to the unpredictability of the test, to ensure that the product meets a pass criteria would lead to excessive and unnecessary biocidal use.

The present practice is i) to rely on previous experiments, a long development period of years of testing or ii) the new product is a modification of an existing product.
IND explained that the cut-off criteria are not relevant due to the nature of the label claims. The products will be used for very different end uses and will be specified in accordance with the actual use. A product may be good on flat bottom and poor on the waterline of the vessel. For the paint specification different recoating intervals, different speed, different trade etc. has to be considered for each individual case. **IND** referred to the Workshop at TMI-12 where FR was showing identical products showing completely different amounts of fouling in the same test.
(FR not present to answer, can precise after the TM that the purpose of the presentation at the workshop was to show the importance of the replicates in a test and it was not related to the pass criteria)

COM asked whether it is possible to submit to the authorities how the internal decisions are made for a specification.

IND explained that the two scenarios described earlier are used: a minor modification of an existing product to make it cheaper, increase polishing rate a little where there is abundant experience with the existing commercial product. The performance of the coating is logged; a report on the state of the vessel is made for professional vessels when docked. Thus, **IND** has a large information base based on the existing use of the products.
The other scenario is for a new biocide, a new technology, when tests are carried out for several years, compared with products of proven performance and the formulations are narrowed down.

CH asked how the reports are carried out without quantification; if IND cannot provide authorities criteria. **IND** clarified that evaluations are very quantitative done by experienced paint advisers; they evaluate the extent of the major categories of fouling, include it in their format and make a report – these data are not submitted for the product approval as part of an efficacy package. The traditional way of documenting efficacy is to defend the broad label claims (applicable for ocean going vessels or recreational crafts etc.), that the product has an effect preventing fouling compared to a blank panel.

COM asked whether an extract of the report results could be provided for existing products. **IND** clarified that efficacy tests are carried out for regulatory purposes for both existing and new products with the same methodologies, test procedure and same reference. **NO** pointed out that efficacy data submitted for Annex I inclusion of the a.s. were simple raft studies with no cut-off criteria. **NO** evaluated and accepted the data.

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NL explained that the simple tests showing the basic activity are accepted for the active substance evaluation; however, at product authorization more is required. **NL** said that though products have been authorized they have difficulties determining the efficacy of a product. Products were authorized due to the transitional period where national law allowed lighter criteria. **NL** would like to have criteria for specific uses to avoid unnecessary efficacy. **DE** supported NL or suggested to compare with a tested product, a positive control and use an identical claim. **DE** was concerned for mutual recognition if no cut-off criteria are set.

IND reiterated that the claims and the methodology are very coarse; the unpredictability of the studies in natural environment etc. **IND** elucidated that the details are discussed between supplier and the professional user when products are specified for a certain vessel – different thicknesses, different products at different parts of the vessel – depending on the needs and requirements of the owner.

As **COM** inquired about the experiences of other countries **NO** explained that for the active substance evaluations they have accepted the simple raft tests. **NO** believed that as the establishment of a cut-off is not possible due to variation in time and location setting a percentage may not be the appropriate solution. **FI** agreed with NO and added that their main concern in the evaluations was the leaching rate and not efficacy.

NO added that though it is not a scientifically based argument, they would not be concerned about the professional market as dry docking costs are so high and therefore, IND will not put inefficacious products on the professional market. Therefore, efficacy may be more an issue only for pleasure boats. **DE** believed efficacy is a requirement in the BPD that has to be met.

COM requested the TM to send opinions and comments on the TNsG, with special focus on cut-off criteria by 10 January 2013.

Conclusion
Due to unresolved issues the guidance document has not been endorsed by the TM. The TM was requested to send their comments and positions by 10 January 2013 to the COM.

3g. Guidance on Efficacy of PT 2

NL gave a brief introduction on the history of the draft efficacy guidance document (GD). Comments arrived from FR, DE, NL and IND.

COM thanked the NL for the enormous work done, leading the guidance development. **COM** proposed to endorse the latest version of the GD, circulated through CIRCABC without any

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major modification. Minor changes can be considered, but major modifications, where no agreement has been reached cannot be considered. However, at a later stage the guidance may be amended.

UK disagreed with the additional data requirement on maximum 5 minute contact time added by the NL. **COM** responded that modification is considered a major change that will not be included in the GD. **IND** though generally agreed to use some norms but was doubtful to integrate it from a draft CEN14885 document.

The comments of FR and AT on including a statement that products used in public swimming pools shall also comply with national criteria were discussed. **COM** believed the addition of the text is redundant, since national requirements at product authorization will have to be met. However, the guidance is intended to be used at the European level and national requirements should not apply for other MSs having different national legislations. **NL** believed a reminder could be added in Chapter 1.6.1 on decision making. **FR** added that it was meant to be a warning for field tests in swimming pools to respect the national levels and limits of microorganisms. **CH** pointed out that field tests are deemed to include the particularities of the country. For field tests of swimming pools the tests should be carried out in the respective country. **CH** believed that the guidance already covers that local requirements need to be considered. **FR** agreed.

IND supported the endorsement of the GD and also believed that amendments should be allowed at a later stage. IND has raised the comments submitted: a method included in the guidance on target organisms which may be amended; using the standard methods of OECD and CEN – IND would prefer to use validated methods; the comment on textile should be further discussed, the issue will be addressed in the CEN draft for laundry disinfection. **CH** responded that norms are living documents; some are updated every second year. Same is true for mentioning OECD guidelines; it should be mentioned in the text of the guideline.

AT made a literature search on Current Contents (1997-2012) on the biofilm reference substances. The efficacy of sodium hypochlorite is acceptable, however varies substantially among bacteria species; peracetic acid may also be added; H_2O_2 is not effective against candida; and chlorine dioxide seemed the best. **AT** proposed not to modify the text. **COM** had reservations in specifying the reference substance. **COM** argued that there has not been an in-depth review in the selection of the reference substances and as the application will depend on specific circumstances, e.g. pH; in many cases another substance may be more appropriate. **NL** argued that the substances are only given as examples. **CH** supported to leave in as a further consultation might jeopardize the endorsement of the guidance document.

NL will revise the GD document according to minor comments; major comments will not be included.

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Conclusion

The TM endorsed the efficacy guidance document on disinfectants in the version circulated before the meeting. The guidance document will only be amended with minor, editorial changes.

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ENVIRONMENTAL SESSION

1. GENERAL DISCUSSION

1a. Evaluation of disinfectant by-products

NL presented the status of the DBPs assessment. At TMIII 2012 NL suggested to finalize the DBP approach with a proposal to let IND take further lead for a testing proposal. On request of MSs and IND another commenting round with the deadline of 16th of October was set. SE, FR, and IND sent additional comments which were uploaded in CIRCABC. These comments be were incorporated in the approach. IND has sent a constructive approach as well as an appeal to discuss the way forward. One bilateral issue has to be resolved with SE, which will be taken up post TM. The draft final DBP approach, a commenting table and the questions for the CA will be discussed at the CA meeting in December.
NL added that awaiting the decision of the CA on the approach and timelines, it is hoping that IND is now able to start completing their dossiers following the proposed way forward
COM thanked the NL for their work in developing the document and to IND for the constructive opinion to the document.

Conclusion
At the next TM COM will inform on the outcome of the CA discussion on how to proceed with DBPs.

3. AOB

3a. MOTA Version 5

COM presented the two documents uploaded in CIRCABC and asked MS to take vision of the changes and to send comments via ENV BIOCIDES functional mail box until 18/01/2013. It was agreed to add the following information into the MOTA: (i) information when plant test can be considered acute and chronic, and which AF shall be used, (ii) decision on PT21 risk assessment shall be summarised in one document by UK and a link added to the MOTA, (iii) amend the Q7 "Can the freshwater data be used for the derivation of a PNEC for marine system?" as agreed at TMII2012 based on propiconazole PT9 discussions: by the same way as marine data can be used for the derivation of a freshwater PNEC, freshwater data can be used for the derivation of a marine PNEC. AF for marine PNEC is, however, always 10 times lower., (iiii) information about relevant metabolites shall be added as agreed during TMs.

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NO proposed to change the surface activity from 50 to 60 . mN m^{-1}. **DK** noted that temperature is relevant to the determination of surface tension and asked to include this. **NO** suggests to cover this latter issue with a reference.
NO will draft a text on the derivation of $PNEC_{soil}$ and the selection of the appropriate assessment factor with respect to the availability and outcome of the plant toxicity test (OECD 208), when this test is regarded as an acute test. The text will be shared with **DK**, **NL** and **DE**.
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NO proposed to recollect all decisions on PT21. The chair informed that UK will provide a documents at the next TM I 2013 with all decisions made at the TMs. Post meeting note: the UK representative had left the meeting at this point, be we will try and produce this list in time for the TMI 2013 meeting. At this meeting the UK will also aim to present the finalised PT21 guidance documents that they have been preparing with help from the PT21 e-consultation group. **NO** proposed to remove all issues on PT21 in MOTA and use the consolidated document the UK is preparing. (Action list nr. 5).
NL mentions that the subject 'relevant metabolite' should be included. NL to draft a proposal.
DE notes that an agreement was made on pooling of fresh water and saltwater toxicity data at TM II during the discussion on propiconazole and asks this to be included.
NL will send PT13 items to **COM**, to be included in the MOTA.

Conclusion
All MS should send comments via ENV BIOCIDES functional mail box until 18/01/2013.

3b. Evaluation Manual for Product Authorisation

Evaluation manual version 1 will be revised by NL including the comments received during the public consultation period. This revised version will be tabled at the next PA&MRFG and CA meeting in December. For the TM, a document containing the agreements and proposals to be included in the next revision of the evaluation manual, which is the same version as uploaded for TM III was uploaded to CIRCABC.

NL informed on the plan to prepare the next revision of the evaluation manual which will be presented to the TM I 2013, including the agreements presented in the maintenance table.
At the last TM, MSs were asked to submit comments by the deadline of 26th October, and no comments have been submitted for the environment session.

Conclusion

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NL will present at TM I 2013 the next update of the evaluation manual (version 2). ☐

3c. BIP –Guidance for Information Requirements

3.c.1. Likely tonnage to be placed on the market (196)
DE asked about the term 'risk-based'. An explanation will be added in the next draft. **DE** asked for legal implications for increasing tonnages after the assessment. **ECHA** will try to give further clarification on this. **NL** asked how to handle different outcomes of tonnage-based or use-based exposure scenarios. This will be discussed in a different section of the guidance.

3.c.2. Metabolites (e.g. 374 ff)
ECHA will draft a clarification according to the input from TM participants by 14/12/2012 and send it out for a written commenting round.

3.c.3. Biodegradation during manure storage (411 ff)
DE explained that the ISO test is usually not performed in manure matrix and therefore not suitable for this endpoint. The OECD guideline under preparation will be added here.

3.c.4. Water & sediment: Inorganic substances: information on fate and behaviour in water (417 ff)
DE stated that the final report of a study on Simple treat will come Q1 2013; **DE** might be able to report on the outcome and possible applications on inorganics.

3.c.5. Laboratory study on rate and route of degradation, text proposals (431 ff)
It was agreed to include the first text proposal with certain amendments related to dependence of degradation on soil properties.

3.c.6. Definition of Residues and Monitoring Data; Chapters 3.10.5 and 3.10.6 (456)
NL will prepare a draft for the respective chapters and **NO** will comment. **UK** pointed at updated definitions of residues in the PPPR that should be looked at and taken into account.

3.c.7. Testing strategy for abiotic degradation (593, 594)
It was agreed that phototransformation in sea water is not to be taken into account in a first instance, only for very clear water (not in harbours, just in open seas). No definition for clear water can be given. The text will be revised according to the discussion.

3.c.8. Testing strategy on biodegradation of biocidal active substances, Temperature (601)
DE made the remark on different factors in different legalisation and wanted to point out the differences; still the Q10 in PPPR was not analysed for ionic or polar substances, therefore they find it questionable if it can be used also for these substances. **UK** added that the original Q10

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factor also based on a.s. used as pesticides as well, under the PPPR they now gathered more data. There is thus no point in sticking to old data, even if based on only a.s. under the PPPR, they are still similar datasets. Harmonisation should be aimed for anyhow. **DE** stated that the Q10 2.58 was checked under REACH and it was agreed not to use the new one, but stick to 2.2. **NL** will check the UK statement with their experts. They pointed out it would also influence REACH assessment as the Q10 factor of 2.2 is used effectively in EUSES.

Ecotoxicology part

3.c.9. Comments 248, 252, 275, 279, 366, 367, 368, 369, 652, 657, 658, 681, 698, 714, 716, 724, 729, 730, 732, 749, 750, 751, 757, 761, 762, 765

Member states and Industry are invited to submit their opinions on general, as well as PT-specific, conditions and considerations for interchangeable use of marine and freshwater ecotoxicity data via a commenting round for the document "TM_IV-2012-items-ENV3c-BIP6.1-Guidance_text proposal freshwater ecotoxicity data for marine PNEC derivation.doc". The document is available on CIRCA BC biocides, meeting documents, technical meeting IV 2012.
See amendments proposed to point 3a. MOTA Version 5: pooling the data.

Conclusion

MSs to send comments. The deadline for commenting on the document is December 14.

3.c.10. Comment 235.

The UK text proposal for statistical derivation of ECx and NOEC was discussed. NL will consider this proposal for drafting a section in the guidelines on these issues.

Conclusion

JRC/ECHA will contact NL bilaterally to discuss timeline

3.c.11. Comments 249, 293, 295, 300, 367

The Appendices I and II decision tables for further testing for aquatic respectively terrestrial effects were discussed. In line with the comments received, JRC/ECHA proposed to delete the tables. This was accepted by the TM.

Conclusion

The decision tables will be deleted for the next draft of the guidelines.

3.c.12. Comments 275, 276, 279

The BPR Annex II point 9.1.3.2. - "effects on growth rate of cyanobacteria or of a diatom", was discussed. JRC/ECHA informed the TM that after consultations with COM, this point is not to be considered as a core data requirement but as an additional data requirement. This was accepted by the TM. The TM concluded that requirement 9.1.3.2. should be considered particularly for substances with a herbicidal and/or antimicrobial action.

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Conclusions
1) conditions triggering 9.1.3.2. will be added to the guidelines for the next draft.
2) JRC/ECHA will contact COM to investigate the possibilities for changing the legal text to 9.1.3.2. - ADS.

3.c.13. Comment 304
The UK text proposal for endocrine effects was discussed. As proposed by DE the TM agreed that this should appear in section 9.10 of the guidance. The remaining text on 9.1.6.1. - "Fish full life cycle test" will be redrafted by JRC/ECHA. SE informed the TM about the on-going work in a COM working group on endocrine effects. (ED Expert Advisory Group). The further drafting on endocrine effects in section 9.10 should be kept short, avoiding doubling the work done by the COM.

Conclusions
1) The text proposal from UK in comment 304 will be included in section 9.10 of the guidance. 2) JRC/ECHA will redraft 9.1.6.1. 3) JRC/ECHA will look into COM working group on endocrine effects.

3.c.14. Comments 313, 320, 321, 322, 719, 722
This discussion concerned test methods for point 9.1.6.2 (Long term toxicity testing on invertebrates). On the basis of DE comment 313 the TM agreed to the addition of a sentence to 9.1.6.2c stating that the *Chironomus* assay using spiked water, should be particularly considered for insecticidal substances. NL has also remarked (comments 719 and 722) that endpoint 9.1.6.2. should contain also a test with a pelagic insect. Also, during the TM NL remarked that *Chironomus* is not always the most sensitive species for insecticidal substances. A *Chironomus* assay without sediment is available, but is short-term only. NL pointed out that strategies for insects testing are available from the PPP area, and it could be looked into whether they can be used for biocides.

Conclusions
1) Point 9.1.6.2c will be amended to indicate that the Chironomus assay should be considered first for insecticidal substances, considering also route(s) of exposure.
2) Member states are invited to submit to JRC/ECHA until 14 December suggestions for protocols on pelagic insect testing.
3) JRC/ECHA will look into the PPP area for pelagic insects assays.

3.c.15. Comment on line 3889 -protocol for testing on mussels
JRC/ECHA will contact UK bilaterally.

3.c.16. Comment 326 - Protocol for testing on Zostera

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JRC/ECHA will contact UK bilaterally.

3.c.17. Comment 337
Discussion point concerning 9.2.3. Acute toxicity to plants. Discussion requested by JRC/ECHA on the necessity for testing six species. FI proposed that at least one mono- and one dicotyledon species should be required. DE added that a test with a nitrogen fixing species should also be required and indicated *Leguminosae* (peas, beans). SE supported the necessity of a nitrogen fixing species, in particular if the active substance is antibacterial. DK proposed results from six species should be submitted. Data from existing studies can be reused. This was acceptable by the TM.

Conclusion
Guidelines will be amended to indicate that the six species should represent mono- and dicotyledons as well as a nitrogen fixing species.

3.c.18. Comments 349, 350, 653, 654, 655, 707, 708, 748
The discussion concerned, especially, the avian acute oral toxicity test (9.4.1). DK remarked that this information might be valuable for comparative assessment. However, the TM agreed that this study would typically not be required.

Conclusion
I\It will be indicated that 9.4.1 is normally not required. Proposed conditions for further tests are available from UK (comment 349) NL (comment 748) and CEFIC (comment 350b)

3.c.19. Comments 719, 722
Discussion based on the remarks from NL that for PTs 18 and 19 tests with terrestrial insects should be required. This was accepted by the TM as always required for PT 18 but not PT 19.

Conclusions
Insect test will be added to 9.2.2. (and 9.1.6.2).
Member states should submit suggestions for proposals for insect tests to include in the guidelines (pelagic and terrestrial) to JRC/ECHA until 14 December.

3.c.20. Comment 733.
Reopened by DE. The TM agreed that for PT21 (Lines 7598 and 7599) it should be indicated that the studies should be chronic.

Conclusion
It will be indicated in the guidelines that the studies should be chronic.

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Environmental fate and behaviour

3.c.21. Comments 455, 456 (on chapters 10.5.1, 10.5.2, 10.6 and 10.6.1)
A draft text is still missing and **NL** will look into this and send their first draft text proposal, including new definitions on residues under PPP, to **NO** for commenting.

3.c.22. Comments 594 (on chapter 4, testing strategy)
Guidance will be amended with respect to the use of photodegradation, stating that photodegradation will not be taken into account.

3.c.23. Several comments on chapter 4, testing strategy (385, 614, 615 etc.)
Different views exist on when to require simulation studies. ECHA will draft a text proposal on this and will distribute it for commenting.

3.d Study CEPE regional marina scenario

Background
The document was prepared by **CEPE** and uploaded on CIRCA for TM I 2012, however the discussion was postponed until TM IV. Comments have been send by **SE**, **NL**, and **DK**, welcoming the work done by CEPE, and highlighting various proposals for revisions of the document, and way forward. Prior to the meeting, **CEPE** provided written responses to the MSs that sent comments.

Discussion
CEPE introduced the document, aiming at defining regional marina scenarios to be used by the MSs in the authorisation of antifouling biocidal products and mutual recognition process. CEPE highlighted the fact that the OECD Emission Scenario Document (EDS) does not accurately reflect a typical European marina, and can not accurately define the PEC values of marinas across Europe. The study provides a robust data set of marina dimensions for which a typical EU marina can be defined to validate the current ESD and establish whether separate scenarios are required for EU (study covers the Baltic, Mediterranean and Atlantic areas).

SE asked CEPE how they chose the marinas for SE, as some of them are from fresh water, and others are marinas where antifouling paints usage is not allowed for pleasure crafts. **SE** pointed out that some input parameters in the study differ significantly from the SE worse case Baltic scenario (vessel occupation, DOC value and salinity), which influence the PEC value and the availability of different antifoulings.
CEPE admitted the mistakes in choosing the marinas for SE, but highlighted the fact that although the valid data sets for SE was 5, the number of data sets for the whole Baltic was 48, so this should sufficiently cover the Baltic region. **CEPE** referred to the results of the study, that the parameters that influence the analysis are the tidal height and salinity, and not the dimensions of

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the marina. **CEPE** recognised that further consultations with SE are necessary on the average regional values, considering also the monitoring data, and they agreed to revise the paper to correct the parameters accordingly. **CEPE** proposed to make a validation of the scenarios to understand whether they return PEC values when modelled with MAMPEC that reasonably reflect those observed in the real world.
Further bilateral consultations may be needed to clarify these issues in detail.

NL commented that based on the data collected in the study, they want to propose a conceptual model for the layout of the marina (further detailed in the written comment), or a similar based model to be developed based on the collected data. **CEPE** welcomed the proposal regarding how the maximum vessel occupancy could be calculated for the proposed regional marinas. However, **CEPE** asked that the current proposals are validated against measure data in the environment before any changes are made to the models. If the PEC values derived from the models in MAMPEC are significantly different to those measured then they would agree to use the NL method (or a refined version of it) as a way to determine a more appropriate model. **NL** supported that the conceptual model as a first step, and then to look to the monitoring data.
NL had also a textual comment on page 30 that **CEPE** agreed to clarify in the document to reflect the ICOMIA position. The interpretation given by **NL** that 1.5 times the boat length should be left between the rears of the berths in the marina was confirmed by CEPE.

DK commented that given the size of the data sets provided for each regional sea, the typical marina defined can be considered representatives for each region, but DK wanted to investigate further if the marinas chosen are representatives for the DK (e.g. marinas of Bornholm were missing).
CEPE responded that the marinas were chosen randomly, and they did not consult national experts from DK. However, CEPE reminded that in the TM meeting few years ago, MSs were asked to provide data on national harbours, and CEPE received input from few MSs on this, but they did not receive any data from DK. CEPE included in the study 9 marinas from the Danish coast line and considered that the data set is acceptable as a representative sample of Danish marinas in the context of those marinas representing Baltic marinas (48 in total). Therefore the addition of marinas from Bornholm would unlikely affect the final result in that marinas found in the Baltic area, irrespective of country. CEPE gave also details of the quality control step in choosing the marinas.
DK asked if the division from Table 14 can be done into more areas within the three areas of the study. **CEPE** responded that the intention of the study was to provide regional scenarios rather than local ones. Further analysis of the data set would be required to establish whether marinas separate out into more than three regions. However, CEPE reminded that breaking the data set down into smaller and smaller groups would affect the utility of these scenarios as they will become closer to local scenarios as opposed to regional ones.
CEPE agreed with the **DK** request to include the standard deviation of the parameters in Table 14, adding the raw data in the document.

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CEPE agreed to send (or revise) written comments to the DK questions.

FI supported the document, but highlighted that the Finish marinas are not very well represented in study, asking for the possibility to submit written comments to CEPE.

UK thanked CEPE for the study, and asked how to use the collected data forward, highlighting the need for defining a protection goal for marinas (e.g. 75 %, 95 %). The scientifically valid way to use the collected data would be to calculate a distribution of realistic worst case PECs for all marina's selected, from which a percentile value could be drawn, corresponding with the protection goal (probabilistic approach). UK reminded about a document presented at TM II 2010 regarding the exchange volumes for OECD marina and harbour, where they gave information on the different sections that contributed to the total exchange volumes: tidal height, horizontal exchange, horizontal exchange at the mouth of the marina, and density induced exchange volumes. UK offered to work further with CEPE on this study and ways to go forward, like average exchange volumes for the marinas in the study by developing probability distribution samples.
CEPE gave few explanations on the UK comments, but commented that on the probability distribution they do not have the resources to do it.

COM asked **CEPE** if they would be willing to incorporate into the study also data on another European Sea, the Black Sea, where 2 MSs have shorelines (Romania and Bulgaria). **CEPE** agreed to extend the study to the Black Sea as well.

Conclusions
CEPE can provide a document on the validation of the model against monitoring data and is willing to revise the document with the agreements of the meeting and discuss further the proposals received, like defining the protection goals of marina, clarify the exchange of water, probability of distribution.
MSs that want to comment (e.g. representative marinas in their countries) to send the comments to **CEPE** by the 31st January.

3.e Substances of Concern

Background
After numerous discussions on SoC at the PA&MRFG meeting, 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 MSs to perform the risk assessment of SoC in a harmonized way, to avoid different outcomes and problems in the Mutual Recognition process. The guidance document should help to provide a high level of protection, without missing any

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SoC, while maintaining a pragmatic approach. 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.
For the ENV session, UK took the lead to produce a revised paper. DK put forward an alternative proposal to the UK one, where the chemical risk factor (CRF) approach has been removed.
SoC agenda points were table at the TM III for both ENV and TOX sessions for information only, asking the MSs to submit comments by 26th October. On the ENV session, the following comments have been submitted: on the UK paper from DK; on the DK proposal from NL; Other MS supported the DK proposal, namely **DE** and **SE. COM** informed on the outcome of the SoC discussions on TOX session and on the future discussions on the PA&MRFG meeting on the Summary of Product Characteristics (SPC), where some SoC could be considered as non-active substance(s), of which knowledge is essential for proper use of the product. The SPC will be part of the authorisation, and it is important at the time of mutual recognition to have a harmonised approach into identifying and assessing the SoC.

Discussions

UK introduced the paper and the comments received. The paper was drafted as an internal document for the UK evaluators on how to handle SoC assessment. Then due to the discussions at the PA&MRFG meeting, this document was shared with the other MSs, and then revised according to the comments received at the time. The philosophy of the paper was to concentrate on the active substance (a.s.) risk assessment, and through the CRF approach to identify the SoC with lower risk than the a.s. (tier 2 of the scheme) for which it would not be justified to perform a risk assessment as for the a.s. Also UK presented the initial screening step when the product is provided as net formulation and later on diluted (e.g. wood preservatives) prior to potential environmental exposure occurring.
DK introduced the proposal, as a 3 tier approach. **DK** found the CRF proposal problematic as in this calculation you assume that SoC act as the a.s. However for example regarding the leaching behaviour, behaviour can between a.s.'s differ a lot, this will be the same for SoC's. **DK** has had many product authorisations, some also with SoC assessment and they found their approach suitable. **DK** also encourage having a dialogue with the applicants to reconsidering if they really want to have a SoC in their products, and if it is possible to exchange them.
One common principle that both **UK** and **DK** seemed to agree with in their proposals was to find the appropriate scheme to allow demonstrating an appropriate risk of SoC, without necessarily asking the applicant for the full basic data package, and perform and a.s. type risk assessment in every case when it is not justified. The main difference between the 2 proposals seemed to be oriented towards CRF, on the advantages and disadvantages of this approach.
UK explained that in their latest version of the paper they incorporated worked examples of wood preservatives to show how the assessment can be done using the CFR, taking into account all the elements of the risk assessment e.g ecotox, fate and exposure aspects. **UK** proposed to make a side by side comparison of the 2 proposals, to see how much work is involved in actually following the DK approach and see how often the CRF approach would reduce the resources in

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the evaluation process. **UK** has experience in evaluation mainly of wood preservative products, but also a few insecticides and rodenticides. However this scheme has to work on all PTs, so UK does not know how the scheme may fit for all PTs, but is willing to make the comparison for the PTs that also DK evaluated.

DE did not agree with the use of the CRF, and proposed working further with the DK approach and possible incorporate some of the elements of the UK proposal. The discussion on SoC is linked with the mixture toxicity and the cumulative assessment of biocidal products. The goal of the assessment of SoC is to have the PEC/PNEC ratio to use it in the mixture toxicity. The assessment of the biocidal products is the main goal, and the SoC assessment is part of it. **DE** would like to have the PEC/PNEC ratio of the SoC to have the input for the mixture toxicity assessment. **DE** thinks that also under DK proposal a lot of SoC would be screened out. For the wood preservatives, **DE** tried to find an appropriate threshold of the risk factor approach, but it was difficult, so they decided not to use this approach.
UK gave further explanations on the cumulative risk assessment, and the example given on page 6-7. If you have a product with e.g.1 a.s. and 2 SoC, and if the the active substance PEC/PNEC for the a.s. is less than 1/3, and the CFR of the two SoC would be less than the one for the a.s., then you would be confident that the aggregated risk quotient would be less than 1. **UK** is willing to expand further the explanation in the paper if this is needed. **UK** does not envisage that the CFR approach would work for all the SoC, but would screen out the less risky SoC and concentrate on the high risk SoC for which it would be needed a full active substance type risk assessment.

NO agreed with the screening steps 1and 2 in the UK proposal which are missing in the DK proposal. **NO** agrees to identify the SoC in the concentrate, even though you don't do a risk assessment of it in the diluted product. **NO** welcomed the addition in the revised UK document of the explanations relevant for the mixture toxicity assessment. In their practical experience with the authorisation of the wood preservatives, using the DK approach with the worst case scenario would have identified risks. The applicant has provided data on the leaching of SoC, therefore they could do a risk assessment that showed safe use of the product. **NO** proposed investigating further the CRF approach made by UK.

NL agreed with NO and UK proposal. **NL** would welcome a comparison of the 2 approaches on the real or hypothetical data sets.

DK thinks that the workload on the CRF approach would be similar to the one of the DK proposal at the second tier. PEC estimation is not problematic, but PNEC would be often problematic to estimate because of the missing data. Regarding the CRF approach, there are a lot of uncertainties, for example how much of the SoC is evaporating, distributing in the STP to water and sludge, then all these uncertainty would add up, leading to losing of transparency of the whole approach. Using the DK proposal, you would not have uncertainties by using the worst

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case scenario (e.g. wood preservative, a 100% would leach), but if you want to more realistic scenarios you can refine with the real data. **DK** asked the TM if it is acceptable to have all these uncertainties.
UK responded that the CRF is part of a tiered approach, and if you do not have enough data to demonstrate that the risk of a SoC would be lower than the a.s. if you have a lot of uncertainties, then you would go to the next tier and calculating PEC/PNEC (still a lot of uncertainties if you have very little data). If in the PEC/PNEC approach you use a lot of parameters as worse case scenarios as proposed by DK, then probably a lot of SoC would fail that tier, and then you have to go to tier 3 where you would need to be generating more data, something that UK specifically tried to avoid. **UK** had the experience of not having good data to do full biocides risk assessment for SoCs, that's why they developed this approach to try to screen out less risky SoC and not do full calculations for them.
FR supported the DK approach taking into account the environmental fate of the substance. However, as UK proposes to take into account these parameters through an argumentation, it should be determined which approach, complete calculation (DK approach) or partial calculation associated with comprehensive argumentation (UK approach) is less time consuming.
AT would want to see further developed with the CRF approach, and not to decide at the moment between the 2 approaches.
NO supported the side by side comparison of the 2 approaches, to check also the robustness of the CRF approach that has incorporated the mixture toxicity arguments.
IND asked clear definition of the SoC, to avoid the assessing the SoC both under REACH and biocides. **DE** responded that the basic definition of the SoC under BPR is in Art. 3f.

Conclusions

DK proposal was generally supported by DE, SE, NL, FR, while the UK proposal was generally supported by NO, NL and AT. As a way forward, some MSs supported the side-by-side comparison of the 2 approaches before having a TM decision of which approach to develop further. In contrast, DK was of the opinion to that the results of the TM discussion should be brought to the WG, and they should decide if further TM discussions are needed
Until the TM I 2013, there will be two PA&MRFG meetings in December and February. The draft minutes of the TM discussion will be forwarded to the WG meeting on the 10th December. Further input from the WG on the SoC will be required before deciding if this point will come back to the TM with the comparison of the 2 proposals, or just with one of the approaches. WG on SoC will be asked to give clear directions on how to proceed further at TM level.
COM invited IND to participate to the WG meeting on the 10th December and give their input at the meeting.

3.f City scenario - Leaching from paints, plasters, and fillers applied in urban areas

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NL introduced the scenario. The city scenario was first discussed in TM II 2012 and a number of MS submitted comments. More information on default values and additional treated materials are included in this version. However, further information is needed on application rates of plasters, and surface area of silicon caulks.
The city scenario concerns emissions to STP and subsequently surface water and sediment from urban applications of biocides (PTs 7-10). A city scenario was proposed for the ESD for PT 10, but only for one house. This scenario contains a more substantiated assumption of the number of treated houses, and also application phases and leaching rates. **NL** proposes two approaches. One for which leaching data is available and the leaching rates from new and older applications are assessed on the basis of the service life of the products. Defaults for service life for paints, plasters and other materials are proposed. The other approach is proposed for cases where no leaching data is available and assumes 100% leaching/emission over the service life of the product. For this approach information is needed on the densities of paints and plasters and the application rates.
DK remarked that they supplied information on application rate of plasters but the value of 25 m^2 given is probably not very realistic, so DK will look into this again. Also, regarding the f_{house} (fraction of houses on which paints, plasters, or fillers are applied) it is important to look carefully at this value and use either the market share value or the actual number of houses treated with plasters (as a simultaneity factor). **NL** proposed that the default f_{house} value of 0.5 should be used as it is not realistic that all houses would be treated with the same substance. **DK** responded that the same nomenclature for this parameter as in the PT10 ESD should be used. For the default value there has been previous discussions, where available tonnage data can be used to lower the value, and for PT2, it was decided that 0.5 should be used from start.
DE remarked that 1) for f_{house} the default value in the original proposal was 0.5, where it is now 1 and can be reduced when sufficiently substantiated with tonnage data and this is agreed by DE. 2) For application rate, the higher values are only relevant for application rate for mineral plasters which are thicker and have high water content. Synthetic resin plasters which typically contain biocides are thinner and therefore the original proposed value of 4 kg/m^3 seems more realistic for biocides. 3) for the surface of silicone caulks (joint fillers), **DE** suggests to use the length 12 m of the sealants in the bathrooms of a typical house. An assumed thickness of 1 cm gives a total surface area of 0.12 m^2 (remark; the discussion of Tebuconazole PT7 and 10. See point 2.1b. ended up with a valute of 0.2 m^2 .Also, **DE** added that the value of the f_{house} does not seem to be used consistently throughout the documents.
IND remarked the number of treated window frames per house needs to be checked, as the original data was based on old, wooden houses, which does not properly represent more modern constructions. Also, in the footnote on page two, should refer not to the number of houses per hectare, but the number of apartments per hectare. **NL** however stressed that the figure should represent number of houses, and is derived from the PT 8 ESD.

<u>Further discussions</u>

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AT added that for the Nonanoic acid (PT 10) CAR the applicant has provided sales figures that demonstrate that an f_{house} value 0.5 would be an overestimation.
SE added that that in 2010 there was a CA document on leaching rates [Technical Notes for Guidance. Guidance note on leaching rate estimations for substances used in biocidal products in product types 7, 9 and 10. Endorsed at the 36th CA meeting],, stating that the assessment should assume 100% runoff to water and soil. The question is therefore which guidance to use. **NL** responded that the city scenario assumes that all runoff goes to paved areas and therefore assumes there are no emissions to soil. **NL** believes that the CA document does not compete with the city scenario. What the city scenario adds is the ratio of number of treated houses, considering further leaching rates between older and more recent applications. It does assume that 100% of the application will eventually reach the STP, but not in a one time event but distributed over longer time periods.
NO added that on emissions to surface water respectively STP, it was originally suggested that calculations should be performed for both situations, and this should be added to the scenario. **NL** responded that direct emission to surface water was not included in the city (urban) scenario for two reasons: 1) there is an information gap (rainfall, unpaved surfaces, etc.) that currently prevents accounting for direct emissions. 2) **NL** proposes to refer to the PT 8 bridge over pond scenario for direct emissions to surface water, noting that it is however quite conservative. **NO** responded that it should be feasible to add also other types of water bodies.
CH remarked that for more modern urban areas there is typically infrastructure that limits runoff via storm water. In agreement with the NO remark on emissions to surface water, an option to account for this situation could perhaps be to simply remove the STP from the scenario. **NL** responded that the emission directly to surface water situation should be more relevant situated in the vicinity of water bodies, and they would typically only constitute only a minor fraction of the houses in a city.
DK supported the inclusion of a scenario in the document for direct discharge to surface water. This would also facilitate pending assessments. The omission of the STP from the city scenario would however constitute a too simplistic assumption. **DK** added that they are planning for a research project on this issue. **CH** also remarked later on that also they are planning for a research project on PT 10.
NL responded that they would welcome further additions to the scenario, but at the moment there are data gaps. **NL** also added that a revision of the PT 8 bridge over pond scenario is on-going.
DE commented that the city scenario assumes an STP volume of 2000 m^3 in mixed proportions of waste and rain water, equal to 0.2 m^3 per inhabitant per day. A bypass STP could be simulated in EUSES by setting the emission factor for wastewater directed to effluent to 1. This will be useful for assuming severe weather situations with STP bypass. It is however different from a situation with mixed drainage systems where rainwater is directly emitted to surface water (separate sewer system). DE suggested direct emission of rainwater may be simulated by using EUSES STP bypass scenario if the amount of water is reducted. It may be assumed that 70% of the 0.2 m^3 per inhabitant per day is wastewater, and the remaining 30% rain water. Then

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in EUSES the water volume may be reduced from 2000 m^3 to 6000 m^3. **DE** added that they have data from different regions on the distribution of mixed vs. separate sewer systems. **SE** added that for Stockholm, which consists of many islands with houses directly on the waterfront, a scenario assuming a larger fraction of direct emissions would be relevant.
DK remarked that there was a very recent case where there was a runoff of an algicide from a house to a storm water pond which caused fish death. This shows that it is important to account for these scenarios at Annex I inclusion stage.
Conclusions of the further discussions
There is a need and high interest among MS to develop further emission scenarios for PTs 7-10. NL was asked whether they could consider coordinating such work TM, and would come back on this

Overall conclusion
NL will consider the TM consultation for modifications of the City scenario, with the aim to adopt the scenario at TM I 2013. The main modifications concern: 1) The value for application rate (DE suggested 4 kg/m^3); 2) The value for surface area of silicone caulks (DE suggestion: 0.12 m^2); 3) The default value for f_{house} and approaches to lower this factor (1, with use or tonnage or market share data, or number of treated houses, as possible approaches for refinement); 4) Further minor modifications may be needed in accordance with the comments and questions raised in the discussions.

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

NL informed on the work carried out since the TM II 2012 for PT 7 and PT10 and thanks OMS for the comments sent to this document.

Conclusion
COM asked OMS to send comments to NL and to ENV BIOCIDES mail box until 18/01/2013 and so that the document can be endorsed at the TM I 2013.

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