EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Institute for Health and Consumer Protection
Chemical Assessment and Testing Unit

23/09/2013

Minutes of Biocides Technical Meeting II 2013
10th -14th June 2013

- OPEN SESSIONS –

INTRODUCTION

1. Approval of the agenda

DE asked to add an informative item at the end of the Tox session.
Agenda was approved.

2. Adoption of the minutes

Minutes were adopted.

3. Action List TM

COM reported that the Action List document was uploaded on CIRCABC.

3.1 Action 1: Finalisation document "Harmonisation of environmental risk assessment for PT. 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. Action on-going.

3.2 Action 2: Development of "swimming scenario" for PT 19 environmental risk assessment: comments on draft to DE. At TM III2012 DE informed that a project started on 1st October 2012. TMII-2013 (Action on-going).

3.3 Action 3: *Finalise guidance documents on environmental risk assessment for PT 21.* COM informed that UK is preparing the document and waiting for the outcome of the discussions on the various e-consultations on PT21. UK will present the document at TM II 2013 under ENV agenda item 3.b. **Action Completed.**

3.4. Action 4:Biocides Higher tier guidance. IND will provide MSs an RCOM with comments on high tier GD. Several MS expressed their interest in attending the workshop on GD development. A Workshop will take place on September 18th in a parallel session to TM III in Arona. More information under TM II ENV Item 3.d. Action on-going.

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3.5. Action 5: Use of OECD guidance for PT13. IND consultants of Fraunhofer-Institute will report at TM II first findings under ENV session agenda item 3.f. Action on-going.

3.6. Action 6: ESD PT 13. IND will inform under ENV session agenda item 3.g. This action goes together with Action 5. Action on-going.

3.7. Action 7: Regional marina scenario for PT 21. After TM I 2013 MSs will submit comments to CEPE that will revise the documents. Specific information under ENV agenda item 3.e. Action on-going.

3.8. Action 8: PT 21 efficacy guidance. MSs to submit comments, CEPE and MSs to revise the guidance, e-consultation on the draft guidance discussed during the Workshop at TM I 2013 then a revised draft will be submitted for discussion at TM III 2013. Action on-going.

3.9. Action 9: Evaluation manual for products authorisation version 1.1 was endorsed at the TM. It will be sent further to the CA, then to public consultation. **Action Completed**

3.10. Action 10: Storage stability guidance. CEPE document on storage stability for PT 21 was initially discussed at TM III and TM IV 2012. The outcome of the discussion was feed to the workshop on storage stability for all PTs, discussed at TM I 2013. **ECHA** was informed on the outcome of the workshop. Information to be used in the guidance for data requirements in support to BPR and evaluation manual for products authorisation. **Action Completed**

3.11. Action 11: Update of the human health part of the 'Evaluation Manual for Product authorisation'. **NL** will collect all the comments until TMIV 2013 and include them in the package that will be handed over to ECHA for the next revision of the document. (COM to check with NL) Action on-going.

3.12. Action 12: Development of the 'Guidance document on efficacy of PT8'. FR to revise the document according to the comments received and a new version will be uploaded on CIRCABC for TMII 2013-for endorsement. Post TM: The CAs at the July 2013 meeting endorsed the document and will be sent for a 6 months public consultation. **Action completed**.

3.13. Action 13: Development of the 'Guidance document on efficacy of PT22'. FR made a new version which was uploaded on CIRCABC for TMII 2013-for endorsement. Post TM: The CAs at the July 2013 meeting endorsed the document and will be sent for a 6 months public consultation. **Action Completed.**

3.14. Action 14: Extreme sensitizers with human data. Discussion at TM II 2013 under TOX session item 3.a HEEG: opinion on default human factor values for use in exposure assessment. **ECHA** follow-up: to revised the document and submit it for inclusion in MOTA v.6).

3.15. Action 15: Review of local risk assessment guidance. Discussion at TM II 2013 under TOX session item 3.d. **(ECHA** follow up: to revised the document and submit it for inclusion in MOTA v.6).

3.16.Action 16: Guidance on the transfer of biocides to food. **DE** to update at TM II 2013 on the DRAWG developments. Action on-going

3.17. Action 17: IPBC discussion. To prepare a paper identifying the worst-case dietary exposure scenarios for PT6. **DE** to update at TM II 2013 on the DRAWG developments Action on-going.

3.18. Action 18: Can the TTC concept be used for the purpose of waiving nature-of-residue studies? **DE** to update at TM II 2013 on the DRAWG developments. Action on-going.

3.19. Action 19. City Scenario – Leaching from paints, plasters and fillers applied in urban areas. A revised document will be submitted by **NL** for endorsement at TM III 2013. Action on-going.

3.20. Action 20 2nd Leaching Workshop for Wood Preservatives. Co-organised by ECHA/DE/JRC during TM II 2013. **ECHA** Follow-up after TM II 2013. Action on-going.

3.21. Action 21: Workshop on Substance of Concern. Co-organised by ***UK/JRC*** during TM II 2013. Follow-up after TM II 2013. Action on-going.

3.22. Action 22: Calculation of groundwater concentration for substances leaching from wood, masonry and films (PT 07 and PT 10) to soil using PEARL. A revised document has been submitted by **NL** for discussion at TM II 2013. Action on-going.

3.23. Action 23: Use of Koc in PEC calculations for antifoulants. SE will submit a revised document for endorsement at TM III 2013. Action on-going.

3.24. Action 24: Overview of the ESD work under the OECD Exposure Group. JRC will informed at TM III 2013. Action on-going.

4. Members of the Technical Meeting

SE asked to have only the functional email addresses and to remove all the other names.

5. Next Technical Meetings and CA meetings

TM III	16-20 September 2013
TM IV	25-29 November 2013 (Helsinki)
CA IV	25 - 27 September 2013
CA V	11 - 13 December 2013

TOXICOLOGY SESSION

3. AOB

3a. HEEG: Opinion On Default Human Factors For Use In Exposure Assessments

Background

The HEEG Opinion concerned the default human factors for use in exposure assessment for biocidal products. The paper has been prepared by **UK** in cooperation with HEEG.

ECHA thanked greatly **UK** whose contribution to the preparation and finalisation of the paper was substantial. **ECHA** also thanked the numerous HEEG members who provided their comments and inputs to prepare and consolidate the Opinion.

ECHA presented the HEEG Opinion. The HEEG Opinion on Default Human Factors is considered necessary, as at the moment there is not an accepted harmonised list of default human parameter values for use in exposure assessments of biocidal products. The aim of this HEEG Opinion is to harmonise the default human parameters within the biocidal products' regulatory framework only. A list of accepted default factors for biocidal products would contribute to any discussions on harmonisation of human default factors across regulatory frameworks within the EU.

In the paper four representative human age groups have been selected (infant, toddler, child and adult) in order to provide a snapshot of exposure to each major human group and the human population as a whole.

The revised version of this HEEG Opinion also considers the 25^{th} percentile values for the bodyweight and surface areas of body parts; those for the female being worse case compared to the male. Compared to the previous version, in which the mean values were used, the 25^{th} percentile used in the current version covers a wider section of the human population. In addition, in the revised ratio calculations of body surface area/bodyweight ratios the body weight correlates to the particular identified body surface area. Moreover, using the 25^{th} percentile does allow determination of worse case for both local dermal exposure and for systemic dose via the oral route. Finally, the 25^{th} percentile default bodyweight for the adult bodyweight is 60 kg and for the toddler is 10 kg. Traditionally in biocides assessment these bodyweight values have been used for the adult and for the young child, respectively. Therefore, these parameters will remain the same and will not affect the exposure calculations in previous CARs.

The HEEG Opinion also takes into consideration the short-term and long-term inhalation rates.

ECHA concluded by mentioning that it is recognised every issue yet to be met in exposure assessment cannot be foreseen. As exposure assessments progress, the suitability of the human factor default values in this Opinion can be determined and if relevant can be amended; also, other human parameters can be included. **ECHA** added that there may be situations where one or several of the accepted agreed default values do not make sense. In such cases, deviations from the agreed values may be used, but such deviations will need to be thoroughly justified in the assessment.

Discussion:

AT appreciated the HEEG Opinion but indicated that in future from a scientific point of view the use of deterministic default values should be replaced by probabilistic approaches.

NL wanted to have included in the minutes the fact that they were not completely in favour of considering the data from the USA EPA Exposure Factsheets Handbook (2011) and would prefer to include an additional age group of 3 to <6 years for the child. However, **NL** confirmed that they were satisfied with the content of the HEEG Opinion.

DE, **NO** and **PT** supported the HEEG Opinion and thanked **UK** for the extensive contribution to the paper.
FR asked from when the HEEG Opinion on Default Human Factors should be started to be applied. **ECHA** replied that the HEEG Opinion was effective immediately after endorsement.
NL wanted to clarify whether the calculations in the Draft Final CARs under preparation should take into account the agreed factors. **ECHA** answered that there was no need to revise the calculations of the Draft Final CARs under preparation.

Conclusions
The HEEG Opinion on Default Human Factors is endorsed at the TM and it will be incorporated in MOTA as usual practice. The HEEG Opinion in MOTA will include the list of accepted default values with source references removed and a cover paper.

3b. DRAWG: Dietary risk assessment for PT6 biocidal products

The TM had to discuss and approve the DRAWG Opinion on identifying worst-case uses for PT6 biocidal products, for inclusion in MOTA as well as the Manual of Product Authorisation.

In the name of the DRAWG chairperson, **DE** gave a brief state of play of the situation, explaining that identifying worst-case dietary exposure scenarios for PT6 biocidal products, which comprises a wide range of uses, allows to reduce the number of uses to be assessed for dietary risk assessment. **DE** described briefly the different steps of the method.

UK, **FR, NL, PT**, welcomed the document
SE while approving it as well, asked to add a comment on treated articles, and wondered what the relation with food contact material was. **DE** will take these remarks on board, though **CEFIC** noted that FCM is not covered by PT6.

Conclusion
The document has been agreed by the TM, and will be included in MOTA and in the Manual of Product Authorisation.

3.c. Establishing protective measures for the professional use of biocides

COM explained that the relevant document was prepared by Germany and uploaded on CIRCABC. The comments were only submitted by UK. Further COM explained that TM might not be a right forum for the discussion of this issue as it demands the interpretation of a secondary legislation such as the Directive 98/24/EC concerning the protection of the health and safety of workers from the risks related to chemical agents at work.
DE explained that in the paper they proposed to agree on the technical and organizational measures to be claimed first by the Member States and PPE is only acceptable when higher ranking measures have been discussed and excluded for being impractical. At the moment, it is done the other way round, first PPE is asked and when there is still risk with PPE then technical measures are considered. Regarding the comment of UK, DE explained that Directive 98/24/EC is addressed to the employer and not directly to the competent authority or the applicant, however in DE point of view, a competent authority is responsible for the authorized product concerning restrictions, conditions and overall

possibilities that the product can be used in compliance with the European law. If control measures are restricted to PPE, the employer could be in doubt if he shall follow mentioned directive or he should follow the conditions of product authorization where only PPE is mentioned. Therefore, DE sees the main conflict for the user and in the opinion of DE, the competent authority is able to solve this conflict when proposing technical and organizational measures. Furthermore, UK sees difficulties to take into account technical and organizational measures. DE agrees with UK that they cannot recommend e.g. a special ventilation system or how to install it in a workplace as it will depend on the workplace and several parameters. However and according to DE, the ventilation can be claimed for to reduce inhalation exposure by e.g. factor of 80% depending on the risk assessment. Moreover, the employer will not know OELs because he does not derive OELs values for the biocides. Therefore, only the competent authority knows the reference value and this is different to other regulations like e.g. REACH where there are DNELs derived. In summary, DE considers that this proposal would only work when there is an agreement between the Member States and DE would appreciate if the Member States could give the written comments to this proposal and DE could offer to summarize the comments and maybe they could be discussed at the next TM.

UK admitted that they know from where the proposal comes from, however an issue in that case is how the same measures can be ensured across the whole Europe when authorizing the biocidal products (e.g. if the same appropriate LEVs are used in all the places across Europe). Definitely the responsibility in this case is on the employer to follow the Dir. 98/24/EC, but at the same time the competent authorities authorize the product what is their responsibility, therefore UK is not sure if there is any solution to solve this problem. There is a conflict between those two pieces of legislation.

NO had the same reservation as UK that in many instances technical and organizational measures will be site specific, so it will be difficult to decide on those measures in the CAR. NO agreed with the principle that PPE should be used as the last resort, but commented that it is important to have knowledge of the actual workplaces before deciding on specific technical and organizational measures.

CEFIC was of the opinion that it should be not a rule of thought that should be discussed immediately but the following points should be reflected further, e.g. how would you authorize the product where you have to use such RMMs as ventilation. How do you see that this authorization is taking place? Is that conditions only delivered to companies where client declares that he has ventilation system in place. How do you see the enforcement? Of course RMMs say when reducing an inhalation exposure about 80%, we are safe. If this is due to PPE or ventilation, you can take this conclusion, but it is about how to put it in place.

DE explained that they think to put on the label that there should be a ventilation system and also the efficacy of this ventilation system. Then it is up to enforcement to control these workplaces.

CEFIC asked whether the dossier with advice of 80% inhalation reduction due to proper ventilation that comes to TM can be accepted. Is that a way forward or an additional prove would be needed that such measures are possible and can be put in place.

DE was of the opinion that for the active substance evaluation, the tasks and the application methods should be looked at and if there was also an industrial use it would be appropriate to go for the ventilation system and there should be a discussion in the CAR on what could be done in the workplaces. DE is not against PPE as such, it depends on the application method. At the product authorization stage it also depends on the application method because it is not appropriate to go for a ventilation system when there is for example a spray application and PPE is needed. It is only a new view for all applications.

COM added that RMMs might be also country specific and they might not be harmonized in all MSs.

DE admitted that it can be difficult but it is up to the national regulations to decide on how to deal with it. At the product authorisation there is also responsibility of the competent authority of the country on how they go with it.
COM reacted that it would be difficult to control those RMMs if they are country specific and there is no rule for it.
UK explained that all PPE and RPE mentioned in the' inclusion directive' can be used in a way as it is a worst case. These are the lower determinants. However it can be rephrased in the CAR that the engineering controls and other technical measures can be applied if applicable and PPE and RPE are the last resort in that case. But if in a small or medium size company there is no specific technical measures, then they should use PPE or RPE in the worst case. This is a compromise.
NL was of the opinion to go for a compromise otherwise we would need to solve the issue at a CA level. They agreed that PPE/RPE can be used as a last resort to ensure a safe use, but using other measures should give an opportunity to go away from a last resort.
CEFIC referred to the discussion on tolyfluanid where it was desired to ensure that the gloves are changed every shift and pointed out that this is a last resort to ensure that there is no dermal exposure. The intention of DE paper is also to highlight that the issue is with dermal exposure, with inhalation exposure and it is up to the user to ensure that he is protecting his employees. CEFIC understood DE intention, that there are other legislations contributing to this and we do not have to go always for black and white decisions.
DE explained that their idea is to ask IND if IND sees other technical things that could reduce the exposure because DE and member states are very limited in their view to stick to PPE and they are not flexible in their decision then. This is also something that can be used to get more ideas about the measurements to be taken into account. And therefore from the legal side, it was proposed that member states collect all the information in the CAR and then decide on it.
COM proposed to launch a written commenting period of one month with a deadline of July 1. Then based on the comments received it will be decided whether the issue will be discussed at the next TM.

Conclusion
It was agreed that the comments will be submitted to DE by 1 July 2013. Based on the comments, it will be decided whether the issue will be discussed at the next TM.

3.d Guidance on local risk assessment: Risk Characterisation for local effects including sensitization

AT proposal on MOTA text

The proposal was not agreed by the TM because it was argued that the AEL should always be presented for possible future need. **AT** argued that MOTA is a record of TM agreements that are collected together for reference, and it would be a consistent approach to include the earlier TM agreement that the systemic assessment may, in rare cases, be omitted. It was however argued that MOTA is also seen as guidance and although an agreement was reached earlier, the TM was not willing to agree on such guidance.

Guidance document "Risk Characterisation for local effects and sensitisation"

AT presented the document, introducing text changes that had been agreed in discussions together with AT, UK, NL, DE and ECHA. It was agreed that these were aimed at improving the text rather than changing the approach.

IND wanted to combine the two highest hazard categories (very high and high) in order to be consistent with REACH. The TM preferred to keep the categories proposed in the document.

Several details of wording and definitions were discussed and agreed, but no major issues were brought to the discussion.

A 2-week commenting period was agreed to enable MSs to check the agreed text changes and to express any further concerns. Following this period the document would be considered as endorsed unless any significant issues were to be brought up.
AT will modify the document as agreed at the TM, and then finalise the document based on comments made during the 2-week commenting period.

Post-TM comment: no major issues were raised during the commenting period and the document is thus endorsed).

3.e BIP 6.4 HH- Block I (Hazard, effect-, exposure, and risk assessment)

The comments received during the commenting period were discussed.
Any question or request of further information should be addressed to ECHA.

3.f Preparatory activities for WGs

ECHA presented the activities and the structure of the WGs. The presentation can be found on CIRCABC.
Any further question or request should be addressed to ECHA.

3.g MRL workshop

DE announced that BfR is planning to host a workshop early in 2014 on setting MRLs for biocidal uses.
MRLs for biocidal uses in animal husbandry will be established in the framework of Regulation (EU) No 470/2009, while MRLs for all other uses will be regulated by Regulation (EC) No 396/2005, which is being amended to include biocides. There is currently no harmonised procedure at EU-level for coordinating the setting of MRLs between these Regulations and the authorisation procedure for biocides under Regulation (EU) No 528/2012.
The workshop aims at discussing options to effectively co-ordinate MRL assessments for biocides at EU level. This includes co-ordination between the internal procedures at EMA and EFSA with the national authorisation procedures for biocides in place in the Member States. DE will host the workshop (venue, logistics). In addition, a committee is being set up to decide in detail what questions to address at the workshop.
DE would like to invite more MS representatives. Those interested in being involved, should contact the chair of DRAWG by July 1st. A preliminary agenda for the workshop has been drafted and can be distributed to those who are thinking about joining the committee.

GENERAL SESSION

1. GENERAL ISSUES

1.1 Reporting on the 51st CA meeting

The CA meeting had the 2nd discussion for the inclusion of *Cypermethrin* for PT 8 and *Propiconazole* for PT 9 into Annex I, IA or IB to Directive 98/8/EC.
For *Cypermethrin* an issue was raised on the possibility that one of the metabolites fulfills 2 out of 3 of the PBT criteria, so RMS will verify it and in case the a.s. will be rediscussed before the Standing Committee vote in July.

The CA meeting had the 1st discussion on the inclusion of 8 a.s:
IPBC for PT 6, of *Tebuconazole* for PT 7 and 10, of *Benzoic acid* for PT 3 and 4, of *Aluminium phosphide* for PT 20, 4 of *Etofenprox* for PT 18, of *Nonanoic acid* for PT 2, of *Bromoacetic acid* for PT 4, and of *Copper sulphate* for PT 2 into Annex I to Directive 98/8/EC. For these substances a 2nd discussion is foreseen at the 52th CA meeting in July, followed by the vote of the Standing Committee.
A 1st discussion took place on the *Note on the principles for taking decisions on the approval of active substances*. Technical conclusion taken for active substances under the BPD are valid also under the BPR, but there are new provisions required by the BPR that are not present in the BPD and thus new elements should be taken into account also for the dossiers on-going (that are evaluated under the BPD). Thus, when there is the need, specific measures/details/limitations could be added, respecting the BPD, but trying to be in line also with the BPR. Practicalities, timing and specific details need much further discussion and consideration for the MSs. The discussion is on-going but the provisions mentioned in the Note can have a high impact on the work of the TM and on the evaluation process of the active substances, and will form the basis of the new Review Regulation that should be ready by the end of the year.

The JRC reported the outcome of the TM I 2013. The CA52 endorsed the following guidance documents:

- Guidance document on the evaluation of efficacy of disinfectants PT2, the Food and feed derogation,
- the Evaluation manual for product authorisation (previously endorsed at the TM)
- The CA meeting endorsed the opinion on chlorine generated by combination of urea and sodium hypochlorite.

For the July CA meeting discussion will continue on the following guidances:

- Preservatives in dipping baths.
- The Guidance on environmental risk mitigation measures for PT 1-5
- Appropriate PT for biocides used in oil extraction.

COM informed on the Annex I-inclusions - Deadlines for decision making, on the Use of copper in PT2, 5 and 11, and on the Report on Risk mitigation measures for rodenticides, and a discussion started on the Establishment of a work programme to meet the 2024 deadline and on the Questions on in situ generated CO_2.

As regards treated articles 3 papers were presented by SE (RMS) and will be discussed at the 52nd CA meeting in July. These papers will have a high relevance for the General open

issues of the First Draft CAR of silver zinc zeolite for which the first discussion has been postponed until the HH and environment part are discussed again, so that the substance can be finalized

Several topics were discussed on the preparation of the implementation of the new Regulation and on Product Authorisation. In the frame of the new regulation, among others the discussion on treated articles will have a high impact on the TM future work, above all for what concerns the discussion of Silver zinc zeolite.

On request of one CA, COM decided to reduce the commenting period on the Draft Final CARs that should be of 30 days instead of 60, to speed up the process and allow a smoother preparation of the CA discussions, given the new schedule proposed by COM.
This implies a revision of the TM SOP that the JRC will perform and present to this TM. Given the approval of the proposal, the change and the new version of the SOP can be considered as already endorsed by the CA meeting and thus only the information to the TM is necessary.

1.2. Tracking System: Progress reports

TM had no comments.

1.3 Information on the handover of Biocides Review Program activities from JRC to ECHA

COM informed the TM on the advancements of the handover of the Biocides activities in support of the Review Program from the JRC to ECHA.

For the physical and electronic archives stored at the JRC two phases are foreseen for the transfer.

The first phase consisted in:

- Shipment of the physical archives stored at the JRC.
  All the material for the shipment was prepared under the constant supervision of JRC personnel, to ensure that the confidential material was never left unattended. All the boxes have been signed by JRC personnel on top of the closures (both on the bottom and on the top), so that it could be easily verified that they have not been opened during the transport.

  The transport left the JRC on the Tuesday 2nd April via courier, on trucks closed with lockers, protected by code that were sent to ECHA via email and were unknown by the drivers, and safely arrived in ECHA on Friday 5th April.

- First sending of the electronic archives: the JRC, in collaboration with ECHA, identified the all documentation that has been already finalised at the TM process.
  The transfer of these files took place through secure ftp server, and a backup copy of the files was also sent on a hard-drive in April.

The first phase is now successfully concluded.

The second phase will take place in December, with the second sending of the remaining electronic archives.

For the management of CIRCABC, the Biocides TM Interest Group that is currently administered by the JRC, will be used and administered by the JRC until the 31st December 2013, and then starting from the 1stJanuary 2014 it will be under the responsibility of ECHA. Thus, from that date ECHA will be able to transfer it/change it as more appropriate for their management of the process.

For the management of the current JRC biocides webpages, following ECHA request to provide a mapping of it, the JRC prepared a standalone version ready and easy to be installed and launched on any IT environment, as a tracking of the ESIS Biocides section of the IHCP web site.
It serves to building recursively all directories, getting HTML, images, design and other files and documents from the site, respecting the IHCP web site tree for Biocides.

The Technical Meetings will continue to be managed by the JRC until the end of 2013. TM IV 2013 though will be held in Helsinki and will have the Wednesday dedicated to ECHA for the description of the new process of the BPC and the Biocides Review Program managed by ECHA.

Moreover COM also informed the TM that, in agreement with DG-ENV and ECHA, it was decided that for the remaining TMs only substances that will need only one TM discussion will be put in the agenda. This is intended for a smoother and more effective handover of the tasks to ECHA. Thus RMSs are kindly invited to evaluate their dossier before submission for TM III and TMIV ensuring that those presented for TM discussion have all the necessary data and consistent comments properly addressed, so that the discussion can be finalised within one TM.

1.4 TM SOP version 5

COM informed the TM, that due to the strict schedule for the CA discussion of the active substances decided by the CA meeting, at the last CA meeting a shortening of the Draft Final CAR commenting period was agreed. Thus the SOP of the TM was amended accordingly, fixing the commenting period to 30 days instead of 60. As the reduction of the commenting period was already agreed by the CA meeting no further step is foreseen and the change becomes operational as from the present TM.
For easier identification of the amendments, the fifth version of the SOP placed on CIRCABC was in track-changes format.
DE pointed out that in page 8, in the 7th bullet point it is still stated 60 days. COM will correct it. In the opinion of DE the agreement at CA meeting for a shortening of the commenting period was not a result of a voting. COM confirmed that there was no opposition to the decision and that the 30 days period was decided on proposal of some MSs.
TM endorsed version 5 of the SOP.
NL asked if the new timing will be used also by ECHA and COM replied that the new timing regards the phase after the TM, so the transfer of the TM tasks to ECHA should not affect it.
AT communicated that the guidance on efficacy of PT 18-19 are not available in the JRC website and COM will check and in case upload the documents.

3. AOB

3a. Guidance on Efficacy of PT 8

COM explained that the draft guidance document was already discussed several times at previous TMs. At the last TM, FR was asked to revise the document with the aim to have it endorsed at this TM. The document was revised and uploaded on CIRCABC for commenting. The comments were submitted by SE, NL and DE and taken into consideration while revising the document. COM thanked FR for the revision of the document and all MSs for submitting their comments.
FR explained that all the comments were solved bilaterally. Nevertheless, they had an interesting discussion with NL on the possibility to have insecticide products alone authorised in class 2. In FR opinion it is not allowed according to EN599, indeed products in class 2 need to be first fungicides and the insecticide activity is optional. However, FR understands the concern of NL about the possibility for people to apply on the one hand for fungicidal product authorised in class 2 and after insecticidal product alone authorised only for class 1. In FR opinion, it is misuse and they will continue in line with EN599.
NL explained that they have already insecticides on the market that are allowed for use class 1 and 2. Therefore, at product authorisation they would get a problem with FR for mutual recognition. Thus, NL would like to have it very clear in the guidance if this is allowed or not. It should be said clearly in the guidance that for use in class 2 only combined products for fungicides and insecticides are allowed and then IND might comment on that if they really need products that different users may like separated. NL agreed to wait for the commenting round in order to get known IND opinion on this.
IND explained that they were not involved in the development of the guidance document, however they have a general opinion that the biocidal product (e.g. insecticide) should be used only when is absolutely needed. Therefore, when only combined products will be allowed then the case might be that when the fungicide use is not needed for this specific application, there is no point not to allow the product that is only used as insecticide.
NL reacted that IND example is not possible. For use class 2, the wood can be used outside and then it needs to be always protected for fungi, so insecticides will be not used alone. However, wood for use class 2 can protected against fungi and insects by treating it with a product that includes a fungicide combined with an insecticide, or by treating it with 2 products, one fungicide, one insecticide which are authorised separately for use class 2 products. When insecticides can only be authorised for use class 1 the risk assessment is not done for the wood used outside. Therefore these products cannot be used for use class 2. However, when insecticides are authorised for use class 1 and 2 wood, the user can decide to combine this insecticide with all fungicides for use class 2 that are available.
IND agreed that in use class 1 there is no need for fungicide, so only if needed insecticide would be applicable. IND wondered why there should always be a need for a combined products when as the first step could be used a fungicide and then insecticide.
COM explained that it is highly recommended to have the guidance endorsed at this meeting; otherwise ECHA would have to take it over.
FR added that the guidance can be endorsed with the remarks done by NL that will be incorporated in the document. FR can solve it bilaterally with NL before CA meeting and IND can further comment on the document during the public consultation period.
NL agreed.
COM summarized that FR will solve the issue bilaterally with NL and add some clarification to the guidance. Further comments can be submitted during the public consultation period.

Conclusion

The guidance was endorsed by TM and FR will submit the final version to DG ENV for the discussion at CA meeting in July.

3b. Guidance on Efficacy of PT 22

COM explained that the guidance document was prepared by FR and presented at the last TM. Some comments were already submitted before that meeting, however additional written commenting round was set up and the MSs were asked to submit comments by 15 April 2013 in order to see whether the guidance will be developed further. Based on the comments received, FR started developing the guidance. The document was uploaded on CIRCABC and the comments were submitted by NL, UK and DE. All of them were closed during the bilateral discussions. We also received a written confirmation from UK that they support the document. COM thanked FR for the preparation of the document and all MSs for their contributions.
FR confirmed that all the comments are solved and additionally asked NL for re-confirmation.
NL explained that one comment was missed and that they forward it to FR after the meeting.
DE informed that some active substances present in the annex to the guidance are no more in the Review Programme and should be deleted from the annex.
FR agreed to revise it accordingly.

Conclusion
The guidance was endorsed by TM and FR will submit the final version to DG ENV for the discussion at CA meeting in July.

3.c Reference values in ground water for rodenticides: 0.01 µg/l analytical level

Background
COM introduced the topic and reminded that during the TOX session of last TM it was discussed the proposal of **FR** of lowering the reference values for several rodenticides and the applicability of the measuring values of 0.01 µg/L. As agreed during TMI 2013, the issue of the limits of quantification would be a matter of discussion during the GEN session.

FR presented very briefly the topic of the discussion about limits of quantifications of analytical methods for the determination of residues of rodenticides in groundwater. A room document was distributed with a PowerPoint prepared by **FR**. The value of 0.01 µg/L is proposed by **FR** as a reference value for four rodenticides (difenacoum, difethialone, bromadiolone and brodifacoum). In the course of the discussion, the toxicologist experts wondered whether it was realistic to measure such low values and the question asked by the toxicologists is about the analytical feasibility. The question asked was: could limit of quantification lower than 0.01 µg/L be achieved by monitoring methods for the determination of residues of difenacoum, difethialone, bromadiolone and brodifacoum in water?

Discussion
For these substances, in France, monitoring methods are currently based on LC/MS/MS and can achieve limits of quantification of 0.02 to 0.05 µg/L. Therefore, the value of 0.01 µg/L is not reached but limits of quantification are well below the 0.1 µg/l current

reference value and comply with the regulatory purpose. **FR** would like to have the information about the situation in Europe and what are the limits of quantification of the monitoring methods used by other MSs. **FR** asked if it would be possible to achieve a limit of quantification of 0.01 µg/L by changing the analytical conditions, for example by pre-concentration. **FR** asked for inputs by other MSs in order to reply to the toxicological experts.

NL stated that in Holland the responsible of drinking water monitoring do not have the equipment to reach a limit of quantification of 0.01 µg/L in drinking water unless they have a new high level resolution mass spectrometry available, which is very uncommon. For MRL monitoring, they probably do have the equipment available to reach this limit of quantification and would be possible to reach limits of quantification of ng/L with the appropriate sensitive methodology. **NL** reported that this equipment would be very expensive and not possible to be available in many MSs. NL stated that most of these substances absorb to the soil, and therefore it would be a theoretical discussion, as it would be very difficult to extract residues.

FR reported that this last point raised by **NL** had been discussed by toxicology experts, which were wondering if there would be any substance in groundwater. **FR** agreed with the **NL** that this issue should be solved in the TOX session and the question for the GEN session was the feasibility of these low limits of quantification.

NL reported that **NL** would expected **DE** to have laboratories with sufficient sensitive equipment. If there was a decision to lower the reference values to 0.01 µg/L, this might pose difficulties since buying this equipment requires hundreds of thousands of euros, which is an investment that governments might not want to make. **NL** added that according to the Biocides guidance High Resolution Mass Spectrometry is not considered a commonly available technique for monitoring methods, but it is considered commonly available for the Plant Protection MRLs monitoring programmes.

COM suggested to **FR** to prepare a survey for MSs to ask them about their potential capacity of analytical methods able to measure this value (0.01 µg/L). The outcome of this survey would be forwarded to the toxicology experts. **FR** agreed to prepare the survey, recollect the data and circulate the results in order for other MSs to be aware of the outcome. **COM** informed that this outcome of the survey would be transferred to the TOX session, unless there was a specific topic which needed GEN discussion.

FR proposed to launch the survey by mid-July in order to have a 4 week discussion. **COM** replied that the duration of the survey would depend on the number of questions and the documentation that **FR** would distribute to the MS. **COM** asked if it would be possible to distribute the survey by the 1st July and then leave up to the 16th August to receive replies from the MSs. The recollected information could be presented at TMIII 2013 even if there would not be a proper discussion. **COM** asked if **FR** would have enough time to prepare a document to give some feedback and to submit it by the end to August in order to be uploaded to CIRCABC. **FR** agreed to the schedule and to give some feedback at next TM, so that all MSs have an overview of the situation and this issue can be continued.

Conclusion

FR will launch a survey on the potential capacity of MSs for analytical methods to measure down to 0.01 µg/L, by the 1st July and then leave up to the 16th August to receive replies from the MSs. The recollected information will be presented at TMIII 2013 even if there would not be a proper discussion.

3d. Guidance on Efficacy of PT 21

Background

CEPE presented the 2 versions of the document: the document uploaded on CIRCABC has tracked changes made after TM IV based on the TM I workshop, and the subsequent version (distributed as room document) was based on the most recent comments submitted by MSs tracked in comparison with the uploaded document. In the room document **CEPE** took on board the majority of the received comments with 2 exceptions:
- **DE** comment to include more text in the section 1.7.1 to include fresh water conditions - CEPE wrote it more general, deleted the word coastal
- **DE** comment no. 6 on replication for the point 1.8.4. - CEPE included new text in the section 2.2.1. that has an opposite meaning.

CEPE prepared also a separate document to respond to some of the comments from MSs, this was also uploaded to CIRCABC.

3d.1Panel size, number of replicates

Discussion

COM asked clarification on what is meant in the guidance by panel being too small. **CEPE** replied that in the CEPE methodology the panel size is mentioned minimum 100 cm^2, but not in the guidance itself. **COM** found this surface to be too small to consider it acceptable as control in the case of one replica. Even few macrofouling organisms (e.g. barnacle) would cover the majority of the panel surface.
NL accepted the panel size to be 100 cm^2 but with at least 3 replicates. In relation to the text added in 2.2.1 **NL** proposed to delete it, and reminded that the purpose of the guidance is to clarify what needed to be done, and not to justify what has not to be done. Based on previous discussions, **NL** stated it should be stated in data requirement, or 1.8.4 or 1.2.1. that minimum 3 replicates are necessary.
FR supported **NL** to delete 2.2.1 (line 9-12). **FR** commented that at workshops there were several discussions that have not been incorporated into the text of the guidance. For example, in respect to the replicates it was already agreed to be acceptable that panels with similar products to be considered replicates, but the last paragraph in 1.8.4. states that they "may be considered replicates", which is not exactly what was decided. **COM** will ask the **UK** to check the correct drafting of the guidance according to the workshop decisions.
SE and **FI** remarked about point 2.2.1 should be more clear that if test panels are too small than replication should be required.
CEPE accepted to delete the inserted test in paragraph 2.2.1. as it was more a reaction to respond to DE comments.

3d.2Number of replicates per trial, number of trials, location of the test

Discussion

NL read a comment from **UK** on page 10 line 17 on 2.2.1 regarding issues on replication that has previously been raised, and guidance should be given on the number of trials and replicates required to support an application. To the UK question "is a single trial with no replicates acceptable" NL responded that it is not acceptable, as it was agreed that 3 replicates are needed. Another question from UK was on the number of trials which are considered acceptable. NL responded that this has not been discussed, considering that if one test is done it should be enough, but the test has to be performed in European water.

CEPE responded that it is described in the guidance that the test location has to be relevant. For products used in European water, at least one test in European waters needs to be performed.
NL asked for clarification on the location of trails. If a single test is done in tropical water and the applicant askes for the authorisation in Europe, should European tests be requested? **CEPE** responded that European waters are needed and the test must be performed in a representative site, with proper justification in the dossier. **NL** offered to draft a text with this clarification, TM agreed with this.

3d.3 Comment from UK (4th June) on cut-off criteria for control

Discussion
UK admitted that the system is too complex for a simple criterion, but proposed to include a sentence that a waiver allowing for a lower efficacy should be possible if justified.
NL asked what type of justification could be given when the test does not give enough information for the test to be assessed. For example, if the control is not too much fouled, how can you assess the efficacy of the product on the test panels. **CEPE** responded that they did not find the acceptance to be appropriate, not because of the test but because of the use. A score below the cut-off criteria would still be acceptable for the particular use. **AT** asked for clarification and **CEPE** responded that it is relevant for products for freshwater. TM and CEPE agreed to add this explanation in the text.

3d.4 Photos of the panel in the dossier requirement

Discussion
COM asked if submitting along with the pictures also an explanation of the interpretation of the photos is also considered necessary. **CEPE** responded that the guidance mentions that raw data would need to be submitted as well, and this would cover the interpretation of the pictures. **FR** has seen in the dossiers the pictures of the panels and also the raw data. **FR** stated that only pictures would not be sufficient, the raw data is absolutely necessary, and thinks that for industry this would not be a problem. The pictures that they analysed were very different between the applicants and considering this experience it would be very difficult to have examples of reference pictures to be added to the guidance.

3d.5 Field data to be included at the renewal of products – advisable or mandatory?

Discussion
In the written comments **UK** and **DE** proposed the field to be considered at the time of product renewal once the products have been on the market for several years. **COM** asked MSs on their opinion on this.
NL agreed to this, proposing to add it to the guidance in 1.8.3 field tests or/and 2.2.1 dossier requirements in testing and field trials.
CEPE added that when these tests are available they can be submitted as additional materials. **COM** pointed out that the comments from MSs were for the time of renewal of authorisation.
NL considered the drafting of the text that CEPE referred to as being non clear. NL agreed that at the time of the renewal one field test has to be required, and it should not be difficult for industry.
CEPE mentioned that in the case of field tests there would be difficulties on comparing one ship to another, following the ships and interpreting the results of the ships.

According to **DE** field test should be mandatory at the renewal. If the label claim is for few years, the applicants need to show the efficacy of the product for the period of time.
CEPE said that if you had the product on the market, and at the renewal stage you need to provide field test for one boat, it would not be a problem.
FI agreed on the field test data at the time of the renewal, but could not decide whether this test should be mandatory, they can agree with advisable.
AT said that "can be submitted" is not enough, and they recommended to draft the sentence as "field data to be mandatory/advisable".
FR had field data in their dossiers, so they considered this would not be a problem for applicants, and it would be a reasonable requirement.
NL considered it would not be a problem for applicants to provide the information, but they would give good information for the assessment. NL reminded on previous workshop discussions that a lot of companies place on the market not efficacious products, and they change the compassions and product names so often that they cannot be traced back. Making sure that the authorised products are efficacious would eliminate a lot of these problems. NL was of the opinion that field tests should be mandatory at the renewal.
CEPE added that the field data would involve a lot of work, and would not stop the examples of the products that NL mentioned.
FR added that it is important to prove the efficiency of the product after many years, to include also the possibility of developing the resistance of organisms.
SE did not agree to have the field tests as mandatory. **SE** asked if after collecting field data from applicants, a type of screening or survey on the efficacy could be performed. **CEPE** did not have an answer on this.

In conclusion, TM agreed to add to the guidance that the field data will be mandatory at the time of the renewal of the product.

3d.6 Extrapolation from raft test to the specification given for a product (protection time)

Discussion
UK submitted the question to **CEPE** to ask how manufacturers extrapolate from the raft test to the specification given for a product.
CEPE related to the text in 1.11. for do-it-yourself products, the number of services to be the same as the number of used seasons, and recommended to be renewed annually. There is no extrapolation in the test in the case of pleasure crafts. The conditions of use are similar to the ones of the test as the yachts spend lots of their time being idle. For professional use on vessels, the individual vessel represents a unique use, and maybe different products on different parts of the boat and different thickness.
NL agreed it would be quite difficult to have protection time on the label due to various uses. NL reminded that a similar decision exists for wood preservative and suggested adding this to the text of the guidance.
COM asked **CEPE** to respond to **UK** on this in written, especially if the UK question has not been properly understood and responded to during the TM.

3d.7 Fresh water testing for antifouling efficacy

Discussion
UK asked if the products tested in marine environment are assumed to be efficient in fresh water. **COM** asked for input from MSs that have experience in testing antifouling in fresh water.
NL asked to add the case of the products claimed only for fresh water to the guidance. The drafting suggestions were: for products with a combined claim for fresh water and marine

water a raft test in marine water would be sufficient. For products with claims for fresh water, test in fresh water can also be provided. NL reminded that we need to think of a cut-of-criteria specific for fresh water testing, as for example fouling on the controls would be much lower than in the marine environment. NL was concerned that products designed for marine used in fresh water would be too efficient, and would be unnecessary use of active substance.

COM asked **CEPE** if there would be products designed only for fresh use. **CEPE** confirmed this possibility. **COM** agreed with **NL** to add further text in the guidance.

AT disagreed with the sentence "products with low efficacy in the marine environment may be suited for the fresh water" as it would not give good indications. **CEPE** accepted to delete if it leads to confusions.

3d.8 Comment from DE on acceptance criterion

Discussion
DE submitted a written comment, recognising that a coverage of 25% macrofouling or more has been introduced as fail criterion. It should be clarified, if this corresponds to the overall efficacy categorization "poor". Vice versa, the categorization given in appendix 2 would mean that all products of categories excellent, good and fair can be approved.
CEPE answered to **DE** that there is no direct link between 25 % acceptance criteria and the rating and weighting presented in Annex 2. **CEPE** wanted the acceptance criteria to be independent by the companies scoring system.

NL though the weighting system would be a good approach. NL asked what the connection between the added tables in Appendix 2 is.

CEPE said that the acceptance criterion of 25 % coverage of macrofouling is based on the comments from MSs. The overall scoring on a panel was based on a comment from **FR**. The acceptance criterion has to be the same for everyone. The rating system has to show that the results of the test are appropriate to the label claim or the use of the products.

COM read the comment from **BE** stating that they can accept the ±25% fouling into account in the raft test as it might be reflected as ±10% in the field, then a maximum percentage of 15-20% in the raft test and a field percentage of about 5-10% is preferable. In this scenario we still need to evaluate the efficacy towards the blank coverage.
COM was concerned on whether the decisions taken at the workshop 2013 have been properly implemented into the guidance text, and asked MSs for feedback on this.

FR gave an example of 2 different applicants defining excellent efficacy in different way, having the same label claim.
NL said that maximum 25 % macro fouling was proposed as cut-off criterion at the workshop. It was not really based on something, just a proposal for cut-off criterion that was accepted by industry. In fact, 25% of barnacle fouling is in practice too much and not acceptable. If the Appendix 2 has nothing to do with the cut-off criteria of 25 % that was set maybe it would be better to remove it as it will lead to confusion. However, the 25 % criterion has to be clearly reflected in the guidance text.
CEPE responded that more explanation of what "poor" means would be reflected in the dossier according to companies specific weighting system.

AT asked if the 25 % cut-off criterion is also valid for freshwater testing. **CEPE** responded that they do not have a lot of experience with freshwater testing, but there might be problems with the zebra mussels and except this not a high fouling pressure. The "poor" efficacious products would be suitable for freshwater applications.

According to **FR** if you keep the criterion of 25 % the Appendix 2 can be deleted from the guidance, as this would give no additional information on the efficacy criteria. **NL** offered to draft a text to describe the link between these tables with the cut-off criteria, TM agreed to this.

3d.9 Aquaculture

Discussion
NL proposed to add further text in the guidance in connection to aquaculture – field or semi-field trial in which the claim is tested.

2 MSs, namely **FI** and **SE** declared themselves quite satisfied with the level of the recent revisions performed by **CEPE**.

Overall conclusion
During the meeting and previous discussions at the TM and workshops a lot of comments have been submitted, and a lot of agreements have been reached already. **CEPE** agreed to provide the responses in the RCOM table. **NL** agreed to draft several clarifications in the guidance text to reflect the TM decisions.
COM will take the lead and will cooperate with MSs to revise the guidance incorporating the agreements from the meeting and previous TM and workshops. The finalised guidance will be presented to the next TM for endorsement, and then it will be sent to CA.

3.e Workshop on the efficacy of repellents within PT19

COM informed that UK could not be present to the general session of the TM, so all the information is reported in the paper uploaded on CIRCABC.
COM said that UK proposed to organise the workshop to a later stage (possibly after summer) and that in the meantime the questions which CAs currently have raised can be addressed through an email consultation.
UK is coordinating the email discussions, and would like to invite those wishing to participate in the discussions and/or submit questions for discussion to contact them with the following information:

- The names and contact details of those interested in participating in the email consultation
- The names and contact details of those interested in participating in a later workshop
- Any questions related to the efficacy evaluation of PT19 products which you would like discussing through the email consultation
- Any questions, proposals or broader issues related to the efficacy evaluation of PT19 products which you would like discussing in a later workshop

This information should be sent to andrew.low@hse.gsi.gov.uk .

To ensure maximum participation of interested partied, the UK made this invitation at the May 13 PA&MRFG meeting, and will also separately contact each CA.

The discussion should have been already started, and those joining the discussion at a later date (e.g. after the TM) will be sent a summary of the discussions which have taken place before that point.
COM added that any question or further information should be addressed to UK.

SPECIAL SESSION

WORKSHOP ON SUBSTANCES OF CONCERN

Conclusions:

- Agreement was reached on most of the issues.
- It was proposed that the legal basis of the approach proposed for the SoCs in band D should be checked by the COM.

Actions:

- SE will re-draft the checklist paper (especially criteria b and c) and will send it to UK by September 2013.
- UK will revise the draft guidance document by October/November by: incorporating SE checklist, adding the evaluation elements proposed by SE and introducing the classification and labelling requirements according to CLP and the requirements on SoCs from the new BPR.
- A revised draft guidance document will be sent for comments to: the workshop participants, SoC WG members and TM participants.

SPECIAL SESSION

2nd WORKSHOP ON LEACHING FROM WOOD PRESERVATIVES

Summary of discussion of the workshop will be uploaded on CIRCABC, in the TM II workshop dedicated folder.

ENVIRONMENT SESSION

3. AOB

3.a Consolidated PT 21 technical agreements

The Document was 1st discussed at TM I 2013 and UK has incorporated further comments from SE and NO, **UK** proposed that a clean version can be used from now on.
CEPE made comments just for information on point 3 leaching rates, as the calculation methods has been refined and improved in a recent publication ISO 10890; another paper demonstrate (under preparation) that the 2 methods are in agreement for the leaching rates. In the future industry will use the ISO calculation method rather than the CEPE calculation method. On Point 3.2 the correction factor 2.9 may be applied to the leaching calculation rate, and the TM agreed that the factor can be refined if additional supporting data is supplied. A major criticism on the paper is that it was developed for Copper; the room document circulated at the TM (only for information) demonstrate that Cu and other biocides are proportionally emitted from the paint and the emissions are more linked to the matrix rather than to the biocides properties.
COM acknowledged the paper for information. **UK** considered that TM needs to read this paper and reflect on the correction factor. This document could be considered as supporting information for the assessment of PT21 at Product Authorisation stage.
COM informed on the special workshop on PT 21 issues that will take place on 8th July 2013, organised by DG-ENV. All rapporteurs of PT21 active substances are invited to contribute to the Workshop.
NL asked information on first page section 1.9. **NO** explained that it was discussed at TM IV 2011 additional information was presented at TM I 2012.
According to **NL** points 5.4 and 5.6 need clarification and UK agreed to reword them to make them clearer.
FI thanked UK for a very good paper.
UK proposed to have immediately a living document to record all the agreements, it would be more useful to have it earlier.

Conclusion:
The TM agreed with the document presented by UK and UK will revise the document according to the comments received. UK will re-circulate the revised document before the next TM for eventual comments and it will be endorsed with the minutes of next TM.
TM agreed that this document will be embedded in MOTA v.6 on a chapter on PT21.

3.b PT 21 Environmental Risk Assessment guidance documents

Background
The two guidance documents (GDs) were prepared by UK and circulated to PT21 consultation group on 4th April 2013. Based on the comments received by **IND** and MSs, **UK** prepared a discussion paper to guide TM with clear questions. The document was uploaded on CIRCABC, and no feedback from MSs was received. Except for the 7 open points for discussion the GDs reflects final agreed positions. A TM discussion was suggested on the open issues before can be incorporated for final endorsement.

Open point on the Draft GD on "Selection of kinetics input parameters":

1. *Use of FOCUS degradation kinetics guidance (specifically the use of Level PII assessments methodology in FOCUS kinetics)*

Two main comments were received by **DK** and **IND**. **DK** questioned whether the use of FOCUS kinetics developed for PPP (evaluating water/sediment studies performed PPP) was an appropriate approach for biocides. **IND** highlighted that the Level PII is a quite strict criteria to pass, especially regarding the "F_sed" criteria and definition of chi^2 acceptability. **IND** remarked that the strictness of those criteria potentially hampers the use of more relevant approach in favour of simple default values when the FOCUS guidance is followed.
In the discussion paper **UK** mainly responded to those comments:
1) MSs requested general use of the FOCUS kinetics guidance in determining degradation rates for other a.s. in other PTs discussed at TM level. **UK** expected that the new Information Requirements under the BPR will include the use of FOCUS kinetics.
2) From a technical point of view, whenever having an exposure model that simulate degradation and partitioning like MAMPEC or $FOCUS_{sw}$ Step 3, verification that the DT50 input value represent true degradation is needed.
3) One of the driving forces behind the Guidance was trying to harmonise the selection of kinetics input parameters. **UK** believes that the **IND** proposal to introduce these relaxation criteria on a case-by-case will lead to reduced harmonisation, which was a key driver in developing the guidance. Perhaps some relaxation of fitting criteria could be supported when performing qualitative comparison of MAMPEC outputs with monitoring data.

Discussion
NL asked if the FOCUS kinetics criteria could be used for biocides. **UK** explained that the technical reason why a careful selection of MAMPEC input parameters is needed is because MAMPEC has separate routine to simulate degradation and partitioning, therefore verification that the input parameter is true degradation is needed. For organic biocides this is particular relevant, not for metal based compounds where Deg50 is not an issue. **UK** remarks that there are no relevant reasons not to use this Guidance. **DE** agreed with **UK** on using FOCUS kinetics criteria as standard for biocides. **IND** asked for clarification if it is the case that using the FOCUS PII methodology provides a true degradation rate, is it then technical justified at higher tier assessment to have a separate input for abiotic degradation? Not necessarily **UK** answered, the Level PII assessment would not distinguish between biotic and abiotic degradation in a water/sediment study. Level PII assessment will separate the degradation from partitioning process but it would not give information on the proportion of the abiotic or biotic degradation. If input parameters from a water/sediment study are selected, the assumption is that a true degradation rate covers abiotic and biotic degradation.

Conclusion
TM supported the Level PII FOCUS kinetics criteria in the PT21 Guidance. The issue on relaxation from monitoring data was not deeply discussed; however MSs agreed to relax those criteria in a very specific qualitative assessment of monitoring *vs* modeling data.

2. *Use of data from anaerobic water-sediment studies*

The draft GD currently proposes that the preference should be given to utilising information from aerobic marine test systems. The rationale behind this approach in the GD is that for the water compartment of MAMPEC scenario is assumed to have aerobic

conditions. Detail comments were received by **SE** proposing to use data from anaerobic systems as supporting data. **SE** referred to recent trilateral discussion in the use of degradation rate in the PEC suspended matter calculation on their own PT21 active substance. **SE** also referred to the on-going discussion on the sediment phase in reality that sediment phase will be quite complicated with a top layer of aerobic surface sediment interface with anaerobic sediment beneath; in addition **SE** added some geographical variation issues related to large anaerobic bottom water areas i.e. Baltic Sea or Norwegian fjords. **SE** also highlighted that they were aware of other biocides with higher degradation rate in anaerobic studies. **UK** remarked that the use of anaerobic data is to better reflect the behaviour in the sediment phase; the first tier sediment phase RA is based on suspended matter which is independent on the sediment phase DT50 and dependent on the water phase concentration and partitioning to suspended matter. UK pointed out that if a high tier sediment RA is performed, that would not be sensitive to the sediment DT50 and perhaps it would be useful to use anaerobic DT50 as more representative of deeper sediment layers.

Discussion

NL underlined that it was agreed that the PNEC sediment is reflecting the upper layer of the sediment where most of the biological activity partly aerobic and anaerobic in a deeper layer are expected, a situation that is reflected in the OECD 308. **NL** responded that strict anaerobic studies could reflect different microbial population, redox situations, and degradation pathways. **UK** agreed with **NL** considering that the standard OECD 308 includes a contribution from anaerobic degradation in those deep sediment layers, therefore there is not a need to use data from purely anaerobic studies. **UK** supported the position that a.s. that present much faster degradation rate in anaerobic studies could be maybe related to different redox or microbial population, therefore they are not really relevant for the kind of water body considered for biocides assessment.

Conclusion

In accordance with the discussions and decisions of the TM the proposal by **SE** is not included in the GD. **UK** will discuss it bilaterally and consult with **SE** experts to agree on the reworded text.

3. *Use of Kp or Koc triggers in selecting main degrading compartment in first tier kinetic assessments*

This point is connected with the discussion point (1), when using that Level PII from FOCUS kinetics where all system degradation rates should often be used and applied for the compartment where degradation most likely takes place. In the Guidance some Kp trigger values from the TNsG to aid in the selection of which compartment the degradation mostly taking place were used. A Kp suspended matter value of 2000 l/kg in TNsG, as well as in the Draft Information Requirements BIP 6.1, is reported. **IE** questioned whether Kp 2000 l/kg is appropriate to characterise if a substance is strongly absorbed to the sediment. A Kp of 2000 l/kg, assuming a Koc of suspended matter of 10%, then is equivalent to a Koc of 20,000 l/kg. **UK** agreed with **IE** in the adoption of a lower Koc triggers from the FOCUS surface water guidance based on Koc <100 l/kg (for selecting water as the main degrading compartment) and Koc >2000 l/kg (for selecting sediment as the main degrading compartment).

Discussion

FI and **NL** agreed to use Koc triggers from the FOCUS surface water guidance, **NL** remarked that this information should be selected if no other data are available and other

data should be scanned firstly. **NO** reported that their PT21 a.s. with a Koc >2000 l/kg where from the water/sediment study (with concentrations reported for the water and the sediment phase) quickly degrade in the water phase and will never reach the sediment compartment. **NO** stated that in the case reported above if the proposed triggers are followed this will bring to a wrong evaluation with an over-estimation of the concentration in the water phase. Additionally **NO** remarked that in the case of PT21 a constant exposure in water is always the first compartment for degradation. **UK** clarified that this Koc or Kp triggers are not the only one criteria used to identify the compartment where degradation should be assumed, and all available results from studies should be considered.

Conclusion

TM agreed on the adoption of the alternative triggers based on Koc <100 l/kg and Koc >2000 l/kg listed in the generic $FOCUS_{sw}$ GD with a clear reference to a proper use of them. **UK** will report clearly that other sources should firstly be explored in order to select the compartment where the biological degradation is assumed to take place.

Open point on the Draft GD "Selection of multiple simultaneous exposure routes for PT21 active substances":

1. *Possible revision of boat numbers and painting periods in line with the revised OECD EU marina*

In the draft GD the existing ESD numbers of 50 boats for professional M&R activities is maintained. The figure of 50 boats comes from the assumption that 10% of 500 boats in a marina are professionally treated, while with the revision of the ESD the number of boats assumed to be treated are reduced to 27.6. **IE** pointed out that the number of boats treated per painting period and the duration of the painting period are directly related. If the original ratio of the Tpaint/Nboat is applied to 27.6 boats the emission rate would be more or less equal to the original scenario that considered 50 boats. **UK** proposes to stick and maintain the existing ESD defaults.
UK highlighted another issue on the inconsistency between the calculation of emissions for commercial and pleasure craft scenarios. For commercial activities the total emission to SW is a peak daily emission value because the painting period for one of those large commercial ships is one day. While in the ESD for pleasure craft activities, the $Elocal_{water}$ value is averaged over the painting period of 183 days for 50 boats, with the assumption of a lower emission rate.

Discussion

NL asked clarification on the 10% assumption. **UK** clarified that the value is not related to the market share, but it is the percentage of boats repaired professionally in a marina. **IND** responded that for consistency to the revised OECD marina scenario the number of boats should be reduced to 27.6, while the duration of the painting period for pleasure craft (183 d) should not be modified, since the summer/spring painting is a seasonal activity. Therefore **IND** proposed to reduce the number of boats and left unchanged the duration of painting period. **IND** remarked that for the other point consistency should be foreseen in the calculation of emissions for commercial and pleasure craft. **IND** pointed out that in commercial ships treatment the emissions are much larger compared to pleasure crafts where the pick emissions are less significant than a treatment of one large commercial vessel. **UK** pointed out that keeping the average approach and reducing the number of boats but not the duration of the painting will have impact on the reduced result emissions.

Conclusion

MSs need to consult and come back to **UK** by 1st of July with their view. **UK** will define and send options to MSs to facilitate the decision.

2. *Proposed additional scenario for assessing realistic losses to soil from amateur activities*

This was a proposal from the **NL** for an additional scenario for assessing realistic losses to soil from amateur activities. The current draft GD recognizes for amateur M&R of pleasure craft that not all activities take place in the same area (e.g. boats taken home for maintenance or painted in the storage areas). An example was included in the draft GD that concentrates on the treatment of multiple boats is in a single storage area. **NL** commented that the scenario of amateur treatment of pleasure craft at home is missing. An additional adapted M&R scenario from EUSES is based on a vessel treated 11 times (which represent 10 years of application and removal on a private boat owner area). **UK** agreed to introduce this scenario but proposed to add a trigger. **UK** proposed to use this scenario only for the substances that pose a risk of accumulation, with a soil DT90 > 1 year.

Discussion
NL agreed with the **UK** trigger and proposed another trigger that if after a first single treatment the PEC/PNEC ratio is lower than 0.1 there is no risk at all after 10 years, for long term assessment. **UK** responded that the PEC/PNEC should be calculated first to consider this trigger. **UK** will include the trigger suggested by **NL**.

Conclusion
TM agreed on the additional adapted M&R scenario proposed by **NL** with the addition of the two triggers.

3. *Appropriateness of the MAF (multiple application factor approach) for simulating the fate of intact paint particles in soil*

SE commented on the appropriateness of the MAF approach, used to calculate accumulation of soil residues through entire treatment periods that would occur between different exposure M&R events. **SE** commented that MAF approach assumes that all the a.s. are available for degradation, and this may not be true for a.s. inside paint particles where the release may be rate limiting. **SE** proposed additional text; **UK** think that the addition of this proposed text would suggest that the MAF is no longer a conservative approach. **UK** commented that using the MAF approach in conjunction with the assumption that all active is biologically available is still likely to be a highly conservative assessment. **UK** considers that a more accurate simulation of the loss of active from paint particles would alter the duration of exposure. **UK** reported the bilateral discussion with **IND** where they did not agree on the under prediction of the MAF approach, as **SE** commented. In previous discussion TM agreed for the MAF approach. **UK** invited the TM decide on the additional text proposed by **SE**.

Discussion
FI agreed with the MAF approach already stated and supporting **UK** proposal for the use of a single soil PNEC value. **IND** commented that if the release rate from intact paint particles is lower, the degradation rates are lower. Therefore, as **UK** clear mentioned in the text, a counted balance of degradation argument is highlighted.

Conclusion

TM agreed on the **UK** proposal to leave the text as it is with no additional text inclusion, and the default position should be to compare peak PEC_{soil} from MAF approach with the single PNEC value.

4. Scale of use argumentation in the terrestrial risk assessment

IE commented on whether scale of use argumentation in terrestrial RA could be used. For the assessment of terrestrial exposure the determination of the surface of the receiving soil compartment is based on the 1 metre walking path around the pleasure craft that has been treated. Therefore the PEC_{soil} is represented by a relatively small area around the boat (typically 7.5 m length, 2.5 m width and 1 m walking path). **IE** proposed to take into consideration the limited scale of this exposure as risk mitigation measure. For the professional activities the ESD considered that the release is expected to be occurring on an area of compacted earth, **IE** questioned if an area of compacted earth used to remove paint from this boat on repeated basis is a really relevant. **UK** commented that this is a kind of issue that may be discussed in next CA related workshop on PT21. In general **UK** supported the comment from **IE** and considered useful to include the terrestrial RA but for PT21 assessment the main focus should be on the aquatic environment.

Discussion
NL commented that the issue on the scale of use argumentation in terrestrial risk assessment should be discussed at CA level. **CH** agreed.

Conclusion
UK will bring this pending point at the CA. Point closed.

Overall conclusion
The PT 21 Environmental Risk Assessment guidance documents were discussed and endorsed by the TM. **UK** will revise the proposed GDs in accordance with the discussion of the TM. No open issues remain except for the use of the limited scale of use/exposure to mitigate the risk to the terrestrial environment from PT 21 actives substances (discussion point 4 on the "Guidance on assessment of multiple simultaneous exposure routes for PT21 active substances"). **UK** will bring the issue to the next CA meeting with the request of having a CA position on that.

3.d Biocides higher tier guidance

COM introduced this agenda point and on the need of a dedicated workshop in parallel to the next TM meeting. The Workshop Agenda drafted by **IND** contains the discussion points to be included. **IND** thanked **NL**, **FR**, **DE**, **SE**, **DK** for the comments received**.** The Guidance was initiated by **IND** and other MSs were invited to participate. **COM** will consider as background overview information the Assessment Reports, in respect to mesocosms studies, considered up to now and evaluated for Annex I inclusion. 1st of July will be the deadline for sending comments on the Draft Agenda.

Discussion
TM supported the organization of the workshop. **NL** proposed as way forward to move on were that MSs will contribute writing different chapters of the Guidance. **NL** volunteered to take responsibility of the exposure chapter. **COM** asked the other MSs to take actions for the other discussion topics listed in the Agenda. **DK** will consult with their colleagues and come back to **COM** on the availability for the presentation in respect to AF. **DK**

asked to take into consideration the confidentiality issue in respect to the overview table on different a.s. dossier information, in reference to mesocosm studies. **COM** will verify how the data shall be presented concerning the confidentiality of dossier information. **DE** would like to contribute and will communicate to **COM** in which issue they will take action. **SE** supported the **NL** proposal but did not guarantee their writing contribution. **FR** expressed they will to contribute to the Guidance.

Conclusion
MSs should comment and complement the chapters or communicate their intention for involvement in the workshop by the 1st of July. The document will be drafted with the involvement of one or more MSs.
COM will search in the minutes of the TM and in the Assessment Reports in order to collect information on a.s. in Annex I in order to identify which substances have made use of microcosms studies in their assessments. Point closed.

3.e Study CEPE regional marina scenario

This agenda point was discussed at TM IV 2012 and TM I 2013. For TM II 2013 3 documents were uploaded to CIRCABC: the responses from CEPE to MSs comments received before TM I, comments from UK to the CEPE document, and the results of the e-consultation performed by SE. MSs were invited to look at the minutes of the previous meetings and meeting documents, including the comments sent by MSs for TM III 2012 (when the discussion did not take place).

Discussion
DK and **SE** discussed issues about the delimitation of Baltic Sea. **DK** and **SE** will further clarify this bilaterally.

Conclusion
MSs will send further comments to **CEPE** and **COM** by 1st July. **CEPE** will revise the documents and send it to **COM** by the 19th August, as MSs asked for more time to look at the revised document before TM discussion. At the next TM the revised document will be proposed for endorsement.

3.f Use of OECD guidance for PT 13 and 3.g Preliminary results on refinement of the Environmental Emission Scenario for metalworking fluids in PT 13

COM informed that these two agenda items (3f and 3g) would be discussed together and it would be an open session so that industry could also participate.

Background
The use of OECD guidance for PT 13 was first discussed during TMI 2013. **COM** informed that **IND** had contacted a consultant (Fraunhofer Institute) for being able to facilitate the refinements of an appropriate and realistic scenario for the assessment of environmental exposure for PT 13. Fraunhofer prepared a presentation on these refinements. **NL** had circulated an Excel file for the calculations for OECD ESD for metalworking fluids. **COM** also informed that at the OECD Task Force on biocides to be held the following week after the TM, **COM** would report on this specific ESD for PT 13 and the development of other ESDs on which the TM is working.

Discussion

Fraunhofer gave an overview of the results of the project of gathering information for the refinement of the ESD for metalworking fluids (mwf). Fraunhofer reported that there were two emission scenario documents about the application of mwf (EUBEES ESD and the OECD ESD). The applicability in Europe is questionable for both ESDs and this led to the formation of an mwf working group whose aim was to gather up-to-date information about the waste and treating of mwf in Europe. The project consisted on several parts, starting by the evaluation of the regulatory information, evaluating some information about the best available techniques and which techniques are commonly used by **IND**. A common evaluation of existing scenarios for mwf was performed and information from MSs representatives end-users and waste management companies was also gathered. The different pathways to use for mwf, such as the on-site waste treatment and the external waste management companies, were shown. At all points of these possible pathways there are directives implemented by MSs, such as the water framework directive or waste framework directive, which interact with the waste handling or use of mwf. These legislations mostly deal with the control of parameters, such as the biological oxygen demand, chemical oxygen demand or concentration of heavy metals. MWFs are considered to be hazardous wastes, so they cannot be lead directly to a river without an appropriate prior treatment. Fraunhofer did not find documents specific for mwf. However all documents affect mwf, since the biological oxygen demand or metal concentration are affected by the release of mwf.

The general comparison of the different ESDs reports that both ESD are based in old data, from 1990s, with limited data, based on assumptions, without any experimental data or reference. The EUBEES ESD represents the waste companies while the OECD ESD represents end-user companies from the USA. These different approaches lead to different releases of mwf. In the case of EUBEES ESD the release is of 200m^3/day while in the OECD the maximum is of 4 m^3/day.

Some examples of general plausibility check for the ESD were also shown. The EUBEES assumes that there are waste management companies represented in the ESD, but on the other hand only considers one biocide release and only one mwf found in the waste. The reality is that waste management companies recollect wastes for different companies, so there would be different kinds of mwf and different biocides. The OECD ESD recommends some waste treatment techniques, such as ultrafiltration or evaporation, although the efficiency of these techniques for all substances is not discussed. This efficiency depends on some physico-chemical parameters such as the molecular weight or the partition coefficient.

The survey responses were gathered from different MSs which gave information about the number of mwf used per site and the average sizes of companies. Replies from industries settled in **SE**, **UK** and the **NL** were received. A questionnaire was circulated to end-users and waste management companies. Seven replies were received from end-users, three replies from manufacturers or suppliers of mwf and four replies from waste management companies. Although the number of replies was not too high, there is a sign that something needs to be refined in the ESD, since it is very far from reality.

Some main results from the survey were that water-soluble mwf are in low tonnage and quantities, and in many cases mixed with emulsion mwf. Since the waste is treated together, both types of mwf can be represented in the same scenario. All companies that sent replies indicated that they sent the waste to a sewage treatment plant, so there does not seem to be direct release into the water. The emulsions are split, so they do not go to

the municipal sewage plants. The oil part and to some extent the biocide is removed before the sending to the treatment plants.

According to the data, there should be at least two scenarios, one for the on-site waste treatment and another for companies which refer to external waste treatment companies. On-site waste treatment is usually performed by large companies who can afford to have the ultrafiltration or evaporation processes, while smaller companies refer to external waste treatment. There was a high variability in the quantity of mwf that is used. In a large company, there would be a large STP with a high dilution factor. Therefore, it would be convenient to use the dilution factor, instead of the direct volume.

Emission scenario should be based on worst-case. Neither the EUBEES ESD nor the OECD ESD seem to be suitable for a reflection of the European situation. The main conclusion is that a refinement of the existing ESDs is needed. Fraunhofer suggested for the further proceeding to form a working group consisting of representatives of the authorities and **IND**. The aim should be to further analyze the pathways of mwf, to collect more data and to develop further solution on how to perform risk assessment for PT 13. Data recollected during this project could be used as a starting point for the working group. Fraunhofer suggested using a dilution factor of 100 for the step from the company to the sewage treatment plant instead of 10 suggested by the EUBEES ESD, and another factor of 100 for the step from the sewage treatment plan to the river, instead of 10 suggested by EUBEES ESD. These values should be applied for both on-site treatment and external waste treatment companies. These factors are still a worst-case estimate, since the survey they had found much larger factors up to 10000. **AT** had suggested some refinement of biocide concentration in the diluted mwf. Fraunhofer suggested as a refinement to use for on-site treatment 100% fraction of the mwf within the overall amount of emulsions which is treated with a specific substance but for external treatment would be conservative enough to use 30%.

COM stated that it would be preferable to finalize the ESD for TMIII in September, so that TM could see a final proposal on this ESD. **COM** reported that the narrow timeline was due to the handover from the Directive to the Regulation. Only a few MSs had sent the information although many other MSs at the last TM said they would have provided information. **COM** asked if MSs would be able to submit the information.
IND stated that more data are needed in order to finalize the ESD, especially from end-users, and that finishing it by September would be very demanding. **SE** thought that the current ESD are based in low amount of data. **SE** reported it would be overambitious to have it finalized by next TM, especially considering that MSs would be involved and asked if this issue was urgent to be finalized before transition to ECHA. **SE** said that a question they would like to be integrated in the ESD would be the use of different biocides in the mwf, since there does not seem to be any approach dealing with that issue. However, in the future, there will be mixtures of mwf which contain different types of biocides. **SE** reported that the suggestion of increasing the dilution factor would mean to allow higher concentrations of biocide on the mwf.

DK apologized for misunderstanding the request at last TM and asked if these questions were very important for MSs or it was more important to obtain data from **IND**. **DK** would be very willing to participate in the working group and reported that the evaluations cannot be postponed since they were for this year. **DK** asked that the dilution factor of 10 was common to be used in other ESDs. Therefore, other industrial uses should be taken into account. **FR** thanked **IND** and stated this was a good way to refine and have a realistic scenario. **FR** said there are not data from **FR** industry. **FR** would like to see the

data to check if there were representative of the **FR** industry and asked to be included in the working group. **NL** thanked IND for providing the document and agreed that the dataset is too small. Preparing an ESD would take more time, and the working group would take more than two months to come up with a completely revised ESD. **NL** supported **DK** and **SE** in the criticism of changing the dilution factor, which might be needed but only if it was supported by a strong basis with good distribution of companies, river, flow rates and effluents. **NL** also supported the initiative of creating a working group.

It was concluded that the timeline of September was not realistic. **COM** said **IND** still needs to gather information from stakeholders. **IND** replied they need more time to answer the questionnaire and to contact personally people. **COM** asked for a proposal of timeline. **NL** asked if the project is finished. **IND** replied that the project was planned until the TM since they did not know if the project would go further or not. The project was finished but it could be extended. **IND** stated that it could not be only task of industry to come to TM and propose ESD, but come to the TM and hear opinion of MSs. **COM** stated that the TM supported the creation of the working group that will start with an e-consultation. **COM** proposed **IND** to gather information with stakeholders and suggest a timeline. Meanwhile, MSs will indicate which the experts will join the working group on PT 13. **IND** will prepare the questions to be discussed in the consultation. **NL** asked if it would be also worth to ask MSs. **IND** reported that support by MSs would be needed at some extent, but concerning the statistical questions it would not be so important any more. **IND** replied that answers by single companies would be more important. **NL** said that mwf are supposed to be treated in waste plants, but the efficiency of these treatment plants is not known and asked to gather information on this. **IND** replied it is not so easy to define a standard treatment since it depends on the type of mixture and considered it not possible to define an efficiency that apply to all substances, since efficiency is dependent in some parameters. There might be possibilities to estimate efficiencies for some substances but it cannot be generalized.

COM asked who would be the contact for the e-consultation. **IND** suggested Michael Scholz, since he is the coordinator of the consortium.

NL added that most biocides would degrade in the system and degradation is not included in the ESD. **NL** received recently an application of a biocidal product for mwf, where both OECD and EUBEES predicted an unacceptable risk. However, the applicant submitted data demonstrating degradation within 24 hours, and therefore **NL** authorized the product with risk mitigation measures.

Conclusion

The TM agreed with the proposal of creating an e-consultation group. **IND** will gather the information, elaborate the questions and prepare the follow up. **COM** asked IND to proceed with the work and reported ECHA is much interested in developing and finalizing ESD.

3.h BIP, 6.4 - Block I (Hazard, effect-, exposure, and risk assessment)

The draft guidance was distributed to the TM for information before the meeting, the aim of the presentation was to explain the background of the guidance document and raise awareness on critical points before commenting starts. The following points identified by ECHA as needing further clarification where discussed:

- *Regional assessment (as in TGD, 2003): for biocides mainly/only local assessment is relevant – text from TGD **to be deleted** (pages 89 ff in Annex Ia or Ib)?*

According to **SE** the performance of a regional assessment is relevant for treated articles. The regional assessment should therefore remain in the guidance document.
Conclusion: The chapter on regional assessment will remain in the guidance document.

- *Assessment of waste stage (as in TGD 2003): for biocides not considered relevant – text from TGD **to be deleted?***

According to **SE** the assessment of waste stage is relevant for treated articles and should therefore remain in the guidance document.
Conclusion: The chapter on the assessment of waste stage will remain in the guidance document

- *Tonnage based approach: Should the tonnage based approach be adapted according to current REACH guidance, i.e. use of ERCs and spERCs? (pages 41 ff)*

DK stated that if ERCs (= environmental release categories) represent an improvement compared to the A&B tables with regard to user friendliness it may be beneficial to use them instead of the A&B tables. **ECHA** explained that ERCs provide standard default values for emission fractions whereas spERCs provide specific default values for specific industry sectors. It was proposed to send an overview on ERCs to the TM after the meeting and it should be considered and concluded during the commenting phase if the A&B tables should be replaced by ERCs. **SE** and **NO** stated that it is a positive development to harmonise the terminology between legislation.
Conclusion: an overview on ERCs will be provided together with the revised guidance and it will be evaluated by the MS during commenting if the A&B tables of the TGD should be replaced by ERCs.

- *How to deal with (ecotox.) testing strategy (in Part A or Part B => so far not included in Part B)?*

NO stated that they think it would be sufficient to have the testing strategy in the REACH guidance, since this prevents confusion when updates of the guidance document will have to be performed. In addition the REACH guidance is based on TGD but is more up to date. Concerning PBT assessment, **DK** asked if this is the same procedure as under REACH and if a reference to the REACH guidance is sufficient. In addition it was mentioned that it is difficult to find REACH guidance on the ECHA website, a link would therefore be helpful. **NL** also supports that strategies should be matched and streamlined. **ECHA** explained that some parts of the REACH guidance have already been included in the guidance document, if the MS find additional points that need further streamlining, they should be highlighted during the commenting phase. ECHA also referred to the sediment workshop which took place some months ago, the outcome should be reflected in the guidance document.
Conclusion: Only a reference to the respective REACH guidance will be included (this concerns also the PBT assessment). In order to find the REACH guidance more easily, links to the respective websites will be included.

- *MOTA issues on PT specific points on emission estimation: keep in the guidance document or include together with the ESDs at a common place? (pages 33 ff)*

DK stated that the decision on PTs (currently in MOTA) should be placed together with ESDs on one website; there was a general agreement by the TM.
Conclusion: MOTA issues on PT specific points on emission estimation will be placed as separate document on the ECHA website where in future the ESDs per PT are provided.

- *Emissions during service-life of long-life articles: to be deleted (refers only to waste stage) or reference to treated articles to be included (pages 45 ff)*

SE asked if the guidance on treated articles will be a separate guidance document or part of this guidance document. **DE** stated that it is also used for the assessment of paints and should therefore remain in this guidance document (and not only in the guidance on treated articles). **SE** also prefers to keep the chapter since paints can be considered as treated articles as well. Placing it in different guidance documents may be confusing.
Conclusion: The chapter will be kept in the guidance document. However, it will be flagged and it should be decided during the commenting if the chapter should remain in the guidance or not.

- *Risk characterisation for petroleum substances: not considered relevant for biocides,* ***text from TGD to be deleted?***

No comment was received, it was proposed by **ECHA** to follow the same procedure as for the previous point.
Conclusion: see previous point.

Additional comments:
PBT assessment: **NL** stated that in the table of content of the guidance document there is currently only a placeholder for the PBT assessment. Will there by only a reference to REACH or additional text? In addition the PBT assessment should be under "hazard assessment" not "risk assessment". **ECHA** replied that only a reference to Annex XIII of REACH is foreseen and that a chapter on hazard assessment will be included in the guidance document. **NL** further stated that the REACH chapter 11 (extended PBT guidance) should be considered with care since this may not be fully applicable to biocides. **ECHA** needs to check. **NO** asked if the PBT assessment of biocides a.s. will be performed by the ECHA PBT Working Group, and if this evaluation would have to be finalised before the inclusion of the a.s. in the list of approved active substances and if the routines in the PBT Working Group are already agreed. **ECHA** stated that this was initially discussed in the last BPC meeting and that there are discussions on-going at ECHA to streamline procedure with RAC (for C&L) and the PBT Working Group.
SE asked where the efficacy assessment is provided. **ECHA** replied that there will be specific scientific guidance on efficacy. The presented guidance document only refers to environmental risk assessment for active substances.
FI asked for further clarification on different guidance documents for risk assessment and evaluation provided in the proposed new guidance structure in the presentation. **ECHA** clarified that the proposed guidance structure is similar to the guidance currently available: the TGD only refers to risk assessment whereas the TNsG covers evaluation.

Proposed follow-up after TM II:
The proposed timelines (i.e. commenting over summer and discussion of the guidance at TM III) were considered as being too ambitious viewing the workload the Members States are currently facing. Therefore it was proposed to discuss the guidance not at TM III but only at TM IV. A revised schedule should be provided to JRC.

Revised schedule (15 July 2013): The guidance - revised based on the comments received during TM II - will be distributed to MS for commenting in the first week of August, deadline for providing comments is 4 October 2013. If any urgent issues come up during the commenting, they can be raised already during TM III.

Any further question or request should be addressed to ECHA.

3.i PT6-10 city scenario

Background
This agenda item was an open session for industry. **COM** reported that the document had been prepared by **NL**. The discussion on this item started in TMII 2012 and continued in TMIV 2012. The final version of the document was uploaded on CIRCABC for discussion and preferably for endorsement.

NL stated that the city scenario presented was a modification of the existing city scenario in order to estimate the emission from preserved surfaces leaching from paints, coatings. The addition to the existing city scenario is that it compensates for the objects that were recently applied, since leaching is very fresh from recently painted objects. The scenario was first introduced at TMII 2012 and a second discussion took place at TMIV 2012. It was decided that a suburban scenario was not necessary and therefore, it should be focused on urban exposure. There have been some agreements on surfaces and volumes, for instance in volumes of plaster in a wall.

Discussion
COM asked MSs for the support on the revised document. **DK** suggested that the service life could be added, since it was based on not so many data, and therefore for the service life, all the situations were not covered. **DK** stated that there are many kinds of plasters and perhaps 25 years was not appropriate for all plasters. **DK** asked to insert a sentence stating that there could be other cases or other types of plasters with different service lives. Regarding the amount that is used, for the joint fillers the area is 0.45 m^2. However, the sealant was not used around windows and doors but used between houses and terraces. **DK** asked if it was stated the amount of sealant around windows and doors for a standard house and wondered if it would be the same number.

NL replied that for the data of the volume of joint sealants it was not understood that it considered the joint filler between the houses. **NL** also wondered that if the volume of joint sealants around the windows was smaller, it would be a worst-case. **NL** stated that the volume was rather small and they did not expect any risk.

DK stated that they did not have that information and asked **NL** to provide it in order to make the calculations for a standard house. **UK** said that the proposal suggested that all the waste goes via an STP and asked how this would match the agenda item of DE on the direct route from ground water to service water. **NL** said that they did not know either and added that DE had some suggestions for roof membranes which could be incorporated in the city scenario. **NL** reported that the city scenario was initially developed with STP as a main compartment, since the bridge-over-pond scenario already exists to cover the direct emission to the water phase, which is absolutely the worst-case. **NL** stated that city scenario was especially important for the STP and not for the surface water. **DE** stated that this was not a problem, since the emission amount can be calculated, and further there is the STP or direct rain water pathway. **UK** replied that the document would need to be amended to consider both routes. **UK** asked if the default scenario works with the proposal from **DE** of going direct to service water or for an urban area where there it would go to an STP. **NL** replied that the scenario was for the STP, but it was possible to incorporate the DE suggestion, although the opinion of NL was that STP was more important. **DE** stated that it is in the city where there is the mixed sewer system or separate sewer system, and both have emissions leached by rain water. Therefore, it should not be a problem to use both. **CH** supported UK to add a sentence mentioning that in areas where there can be

a high percentage of direct or separate uses, it is possible to perform the calculations suggested by DE. **ECHA** reported that in the frame of the revision of the OECD ESD for PT8 it was included for the ground water scenario the weather side factor, since it does not rain in all sites of the house, but mainly in two parts of the house and data were got from a research institute showing that not all sites of the house are exposed. This issue was shortly discussed in the Leaching Workshop on Wednesday 12th June. ECHA asked if this situation was considered for this scenario. **NL** doubted about the correction since the heavy showers come from different directions and this scenario would be a worst-case.
COM thanked NL for preparing the documents and other MSs for their contributions.

Conclusion
The document could not be endorsed since the **NL** will need to add different statements suggested by **DK**, **UK** and **DE**. **NL** will reword and re-elaborate some calculations in order to verify the questions that **DK** pointed out. **NL** will submit the document for endorsement at next TM in September.

3.l Leaching to groundwater from paint, coatings and plaster

Background
NL introduced the document that represented the final version of the proposal for how to calculate the concentration of active substance leaching from films, wood and masonry preservatives into groundwater using FOCUS PEARL. NL proposed a methodology where the constant leaching fraction is calculated using PEARL by defining the non-leaching "wall" that degrades totally into the active substance. The first version of this document was presented at TM II 2012 and TM IV 2012.

Discussion
UK asked **NL** to elaborate the correction factors to compensate for the PEARL limitation, and which would be the differences of this refinement with the one used for PT8 in ESD. **NL** responded that the correction factors were based on a use application once every 5 years, as the PEARL allows only once every 3 years. **UK** expected that the correction factors would work for the service life, but this would lead to underestimation for the first years, and overestimation for the last years. UK proposed a side-by-side comparison of the new methodology versus the existing one for PT 8. **UK** has some data from industry for the comparison of 10 and 300 degradation events/year and is willing to share the data with **NL**. **DE** would appreciate to see the comparison. **NL** agreed to consult bilaterally and perform the comparison.

DK asked for the correction factors to be detailed, to include the cases when you do not have a paint or plaster. **NL** responded that the correction depends on the service life of the product. The paint is viewed as the worst case, if in the paint assessment a risk is not identified, you would not expect risk from silicone, or other materials. **NL** agreed to add further clarification in the document on the correction factors.

DE remarked that for the house the density unit should be kg/Hectare, and will send this comments in written.
DE asked why leaching is not expected for substances for Koc >500 and DT_{50} <21, was this decision considered reasonable, was it ever questioned? **NL** specified that the decision regarding Koc and DT_{50} was made about 10 years ago. **NO** remembered that this decision was never questioned, and needs to check if it was included as such in the TNsG on data requirements for BPR. **NL** will try to trace back the background of the decision, as it might have been related to the pesticide field, prior PEARL. **UK** agreed.

COM pointed out the issue of inconsistency between this document with the OECD ESD for PT8 in respect to the number of houses. At OECD level, the number of houses has been revised from 35 to 16. **NL** responded that they took the number of houses from the 2003 ESD version. **DE** mentioned that the 35 houses/Hectare is the density of houses in UK and 45 % of houses were expected to be wooden houses. However, **DE** agreed with the usage of the number of 16 houses. **NO** remarked that the wooden houses in Scandinavia make up for 100% for holiday houses, and above 90 % for all of the houses.
COM replied that the number of houses (16) came from an European survey, rather than a national one. **COM** will send to **NL** the reference to this survey.

Conclusion
NL will consult bilaterally with **UK** on the comparison of this methodology with the existing one for PT. **NL** will add further clarification in respect to the correction factors. **DE** should send their comment in written to NL.
The point will come back to TM for further discussion.

3.m Assessment of direct emission to surface water in PT 7 and 10

Background
The paper discussed direct active substance discharge to surface water under 2 emission pathways: direct emission due to storm water and separate sewer systems with direct discharge of rainwater.
The "bypass of STP" scenario covers the situations of the direct emission to surface water due to storm water. DE asked MSs whether they know if EUSES Fstp water is set to 1 as according to TGD. In this case the dilution is set for 2000 m^3.
The second scenario is when the rainwater is collected separately from the wastewater; the rainwater is in most cases discharged directly to surface water bodies. When they analysed statistical data from Germany, they found appropriate to reduce the effluent discharge rate for this scenario from 2000 m^3/day to 600 m^3/day (equivalent to 60 L/capita/day for a population of 10,000 inhabitants).

Discussion
MSs welcomed the document and found it appropriate for Annex I inclusion. MSs proposed to include the case of PT 6 and PT 8 (especially relevant for the case of noise barrier) in the document. **DE** clarified that this approach is important for the cities and that the infiltration was not included in this scenario. DE informed the TM that they are preparing a document for the PT 9 rainwater infiltration in soil and they will present it later on (chapter 3n).

UK agreed with the proposed value of 60 L/day/capita proposed by DE.

FR asked if the amount of the substance released to the river is not more important than the dilution factor to the river. **UK** agreed with **FR** that dose is important. **SE** also wondered what would be the faith of the rain water and how to incorporate this into the scenario, if is it a single point of release until the river as worse case, or multiple retention points.

In **DE** they are also using other retention points prior to the river discharge, but in this document they meant for the scenarios to be as simple as possible, and considered a

realistic worst case scenario would not have retention points. DE asked if MSs consider reasonable to change the dilution factor of 10 to other value.

NL asked to include in the document the reference to city scenario, **DE** took note on this.

COM confirmed that when you chose to bypass STP in EUSES the Fstp is set to 1, according to TGD.

COM remarked that probably most a.s would not pass the risk assessment when they would be release to surface water. COM asked MSs if they envisage RMM, as in case of disinfectants (e.g. for a.s that degrades rapidly to use the ESD for PT 5).
NL said that in the neighbourhood to the sewer system there are some implemented restrictions, as for example you cannot wash the cars in the street, maybe some restrictions can be applied for biocides as well. RMM might be for example to prevent spilling to sewer during application.

Conclusion
TM agreed that the scenario is appropriate for Annex I inclusion, and to include PT 6 and 8 in the document. Infiltration issue for PT 9 will be covered by DE in a separate document.
For changes of the dilution factor MSs will send their comments and supporting data to **DE** by the 2nd September.
The point will come back to TM for further discussion.

3.n Use scenarios for PT9 roof membranes

Background
DE informed about the document they had prepared, which was going to be first discussed during the TM. **DE** reported that they are finalizing a draft CAR in PT9 for an active substance which is added to the plastic with which roof membranes are manufactured. The roof membrane is the material to be assessed. It was agreed for PT9 that generally the tonnage approach would be used, but for specific uses use-based approach might be justified. **DE** was of the opinion that roof membranes are a specific use, since they are in direct contact with rain water, which is collected for each house and discharged to the sewage system. Therefore, **DE** thought about a new use-based approach in addition to the tonnage approach, and especially the direct emission to soil which is not included in the tonnage approach. **DE** developed one scenario "direct emission to soil". **DE** also informed that especially commercial buildings in cities are predominately flat-roof buildings, which frequently use roof membranes, and **DE** had developed a specific scenario which reflects this situation, which would be the second scenario.

The first scenario is direct emission to soil. In this scenario, **DE** followed the ESD PT8 for a house scenario. Currently, **DE** did not get leaching data for PT9 substances and therefore the cumulative quantity which is released from 1 m^2 of roof has to be calculated. The emission factor from ESD of plastic additives could be used, although it was necessary to know the weight of 1 m^2 of roof membranes. An internet search was carried out and a worst-case value of 3 kg/m^2 was obtained. With this value it was possible to calculate the cumulative quantity which is leached off a square meter. Afterwards, to calculate the cumulative quantity leached off a house, the area from the façade could not be used. There were data of roof surface from PT10, but for roof membranes **DE** considered better to use the area of the flat roof. The values of OECD were used to calculate the roof area and they

came up with a value of 131 m^2. The emission was therefore calculated applying the service life, which can be obtained from the ESD of plastic additives.

The default value for the soil volume was not applicable since rain water does not run down the façade, but is collected and trickled away on the ground in a controlled way. **DE** searched for more information and found out that in Germany there are several infiltration techniques applied, from surface infiltration to hollow infiltration. It was decided that as worst-case, the hollow infiltration would be used since in the surface infiltration the water spreads in more surface. It is known from German practice that for the dimension of the hollow it is estimated that 10% of the connected sealed area is used for good permeable soil. If the cleaning capacity of suburban surface soil is poor, the depth of the surface soil should be at least 20 cm. With these values, **DE** came up with a volume of soil for the hollow of 2.8 m^2.

Discussion

1st scenario

FR thanked DE for the preparation of the document and asked on the question 6 which was not a time-weighted average concentration but a steady-state concentration, which was correct but they questioned the term used. **FR** agreed to use the steady-state concentration. The other comment was about the roof surface, which was derived from the default value of ESD PT 18. In this ESD PT 18, the value had been refined for the surface of commercial buildings and modified to 609 m^2. **FR** asked if this value had to be refined according to the change in the ESD PT 18. **DE** replied that the value used by them was derived from OECD values for flat roof and house. **FR** stated that the previous value of 300 m^2 was used for commercial buildings. **FR** asked to change the value in MOTA for PT 18 and adapt it to the current 609 m^2. The number of commercial buildings had also been refined to 300, and before it was 1000. **DE** stated that they used the area of commercial building in the second scenario, but in the first scenario **DE** used the small OECD house which is also used for PT 8 with a façade of 125 m^2 and a height of 2.5 m. **DE** stated that the surface area for commercial buildings had been reduced since the whole area would not be sprayed. **DE** thought that the value for roof membrane should not be changed since the dimensions of the house have not been changed and therefore the roof surface neither should and this would refer to the second scenario.

DK reported that the roof area for the normal house does not include an overhang (of approximately 0.5 m) and asked if this should be considered. **DK** stated that is common to have a channel which transports the water from the roof that may be a retention system. **DE** replied that the rain water stayed there for a short time and then trickled down. **NL** thanked DE and asked some questions about the amount of leaching. It was stated that 3.2% leaches during service life. However, for other PTs it was decided to apply 100% leaching over the service life by default, unless leaching data are available. **NL** would like to change the value to 100%.

UK pointed out that the hollow infiltration systems do not operate in the UK, and wondered which kind of organisms are living in the soil or infiltration pits and asked if it was a relevant environment for the risk assessment. **DE** stated that it was the same discussion as for PT 8 and reported that whether there was not water standing, the general people would use the surface as a garden and they would like to have grass on it.

The other possibility presented by **DE** would be the surface infiltration, where the area would be much bigger, but in this case the water would flood the garden. The volume got with the hollows is very small and stated it would be a good compromise. **UK** asked

whether in other MSs it is common to have the hollow pits. **DK** replied that the usual thing is to have the roof, the gutter, and usually there is not a soil area since it would be a problem to lead the high amount of water into the soil. **DE** stated they could collect written comments and reported that it is very important to think about ground water. **DE** commented that the next step would be the calculations when rain water goes directly to ground water. **COM** stated that MSs could look at their national situation and send comments and proposals to DE on this scenario. Therefore, DE could elaborate more on the calculations for direct emission to soil by leaching. **DE** reminded that 100% leaching had been used for the city scenario and for the special case of PT9, 100% had been considered in the tonnage approach. **DE** suggested writing it in the scenario and having a further discussion, which may lead to a reduction of the value. **COM** suggested submitting comments to DE by 1st September.

2nd scenario

DE reported that the 2nd scenario was developed to reflect the situation that commercial buildings in cities are predominantly flat-roof houses which mostly use roof membranes. The approach was based on PT 18. **DE** calculated the cumulate quantity leached of a single roof, similar to the 1st scenario but using the appropriate roof area for commercial buildings (3280 m^2), which is defined in ESD PT 18. For PT 18 it was agreed that 300 commercial houses are connected. As a first start, it could be said that all these building have a roof membrane, although this factor could be reduced if there were data.

DK stated that the scenario seemed appropriated, but they did not have reflected about it since DK did not have any substance with that used. **NL** reported that the fraction of treated houses was very low. It had been decided that in the city scenario all the houses should be included. **DE** replied that in a first scenario the factor should be 100%, but when there would be more information available it could be lowered. This was an example for their substance, where the information showed that 30% flat houses in the EU used the roof membrane. Therefore, it was decided that they could reduce the factor for their substance. **NL** stated that this value depends on the compounds, since if the applicant does not submit enough data, the default value of 100% should be used as decided in the city scenario.

DE proposed to use in this scenario a market share of 100% as a first step, and when more information is available the value could be reduced. **COM** asked **DE** to include in the text further explanation on the reduction of the market share factor.

SE added that in the paper it is stated that about 5% of the flat roof contains an active substance, which means that 95% of the membrane does not contain an active substance. SE raised the attention that this is a use of treated articles. The roof membranes will be imported to the EU and a product authorization step will not be carried out, which means to perform a risk assessment about an application in treated articles where the efficacy is not certain. In the future, there will be a need to look at effectiveness in the use of treated articles or in the approval of the active substance. Otherwise, there will be active substances in the market used in treated articles, where the efficacy is not assured. **DE** replied that the number of 5% was specific for their substance and in other roof membranes there will be other percentages of active substances. **DE** added that it was important the use-based scenario for those active substances which are not covered by the tonnage-approach.

Conclusion

COM concluded that it was a very good start for the revision of this scenario. **COM** proposed other MSs to submit their comment by 2nd September and **DE** would re-elaborate the use scenario for roof membranes.

3.o Preparatory activities for WGs

Based on the presentation the following points were discussed:
DK asked, related to the IUCLID 5.5 file shown in the CAR structure, where annotations will be included in the future. **ECHA** replied that the annotations will be included (for dossiers submitted as IUCLID file) directly in the respective IUCLID template, there is a special field foreseen. For dossiers not submitted as IUCLID 5.5 file, the annotations will remain in the study summary templates. **DK** further asked if the studies as such will be included. **ECHA** replied that the studies will be attached to the respective IUCLID study template; means a IUCLID file covers in the future the former Doc III and Doc IV level.
DE asked if in the future only one discussion per CAR is foreseen in the Working Groups (WG). **ECHA** said that it is not possible to do it otherwise due to the legal deadlines provided in the BPR. Consequently, there will be only one WG-discussion per CAR and, if needed, an ad-hoc follow up. It is recommended that if already during the evaluation phase issues come up, they should be brought to a WG before the committee phase has even start.
SE asked if the WGs are meeting back to back and why the efficacy and the phys-chem/analytic WGs are meeting electronically. **ECHA** replied the meeting structure (back to back) will be the same as currently in the TMs. At the beginning all WGs will meet physically, but since the major discussions take place for Human Health (HH) and Environment (ENV), those will continue for the time being as physical meetings, whereas the other two WGs may continue by virtual meetings later. Further procedures will be discussed during TM IV in Helsinki in November.
PL asked if the WG meetings for phys-chem/analytic are formal requirements and if the meeting has to take place even if there is nothing to discuss. **ECHA** replied that if there is no point to be discussed there is no need to set-up a meeting.
DE has concerns that following the proposed timelines, there will be no time to discuss those points which are currently covered under AOB, e.g. work on ESDs or single scenarios. **ECHA** stated that this point is taken and that also **ECHA** considers the discussions on ESDs and emission scenarios as very important. How to proceed will be discussed internally at **ECHA** and feedback will be provided at the next TM.
Any further question or request should be addressed to **ECHA**.

TMII2013-item1-Draft-Agenda-version4.doc

07/06/2013

Draft AGENDA

Biocides Technical Meeting II 2013

Place of meeting: Palace Grand Hotel, Varese, Italy

Date: 10th – 14th June 2013

START: 10th June 2013 at 14:00 hrs
FINISH: 14th June 2013 at 16:00 hrs

NOTE: the present agenda includes a tentative schedule. Please note that items might be slightly shifted due to the length of the previous discussions.

INTRODUCTION

START: 10th June 2013 at 14:00 hrs
FINISH: 10th June 2013 at 14:30 hrs

1. Approval of the agenda
(TMII2013-item1-Draft-Agenda-version1; TMII2013-item1-Draft-Agenda-version2; TMII2013-item1-Draft-Agenda-version3_with schedule; TMII2013-item1-Draft-Agenda-version4_with schedule;)

2. Adoption of the minutes
(TMII2013-item2-Draft minutes TMI 2013_version1.doc;
TMII2013-item2-Draft minutes TMI 2013_version2.doc;
TMII2013_item 2_TMI2013 Draft Minutes_version 1_SE comments;
TMII2013_item 2_TMI2013 Draft Minutes_version 1_NO comments;
TMII2013_item 2_TMI2013 Draft Minutes_version 1 - BE comments;
TMII2013_item 2_TMI2013 Draft Minutes_version 1 COMMENTS NL;
TMII2013_item 2_TMI2013 Draft Minutes_version_FI comments;
TMII 2013_Item2_TMI2013 Draft minutes version 1 - UK comments;
TMII2013_item 2_TMI2013 Draft Minutes_version 1_DK_comments;
TMII2013_item 2_TMI2013 Draft Minutes_version 1_DE comments;
TMII2013_item 2_TMI2013 Draft Minutes_version 1_FR comments)

3. Action List TM
(TMII2013-item3-Action List TM.doc)

4. Members of the Technical Meeting
(TMII2013-item4-tm-members.doc)

5. Next Technical Meetings and CA meetings
(TMII2013-item5- timeline TM process)

TM III	16-20 September 2013
TM IV	25-29 November 2013 (Helsinki)

CA III	10 - 12 July 2013
CA IV	25 - 27 September 2013
CA V	11 - 13 December 2013

TOXICOLOGY SESSION

START: 10th June 2013 at 14:30 hrs
FINISH: 10th June 2013 at 18:00 hrs

1. GENERAL ISSUES

2. SUBSTANCES

(The documents for this agenda item are distributed via the confidential CIRCABC site for the evaluation reports; the main discussion document will be the consolidated commenting table.)

2.1 First discussion for the following substances

2.1e Icaridin PT 19 (RMS: DK)

2.1b BKC PT 8 (RMS: IT)
(TMII2012_Tox_Item2.1b, 2.1c - DDAC _ BKC PT8 _ EQC_rev)

2.1c DDAC PT 8 (RMS: IT)
(TMII2012_Tox_Item2.1b, 2.1c - DDAC _ BKC PT8 _ EQC_rev)

START: 11th June 2013 at 9:00 hrs
FINISH: 11th June 2013 at 13:00 hrs

2.1a Tolyfluanid PT 21 (RMS: FI)

2.1d Silver zinc zeolite PT 2, 4, 7, 9 (RMS: SE)
(TMII2013_Tox_item2.1d - Tox discussion pointsTM II-13;
TMII2013_Tox_item2.1d - Tox appendices)

3. AOB

3a. HEEG: Opinion On Default Human Factors For Use In Exposure Assessments – For discussion
(Document prepared by UK. Item chaired by ECHA)
(TMII2013_Tox_item3a - Existing default values and recommendations for exposure assessment_Nordic project final;
TMII2013_Tox_item3a - HUMAN FACTORS - HEEG OPINION PAPER)

3b. DRAWG: Dietary risk assessment for PT6 biocidal products – For discussion
(Document to be presented by DE)
(TMII2013_Tox_item3c - Anschreiben_DRAWG_Opinion_Dietary_Exposure_BfR_130521;
TMII2013_Tox_item3c - DRAWG Opinion_Dietary Exposure - PT6 Worst Case)

START: 11th June 2013 at 14:00 hrs
FINISH: 11th June 2013 at 18:00 hrs

3.f Preparatory activities for WGs – For Info
(ECHA to inform)
(TMII2013_tox, Item3f_Env,Item3o - ECHA presentation WG)

3.d Guidance on local risk assessment: Risk Characterisation for local effects including sensitization – For discussion and endorsement
(Discussion chaired by ECHA)
(TMII2013_Tox _ item 3.d - DRAFT_LRA_final;
TMII2013_Tox _ item 3.d - DRAFT_LRA_final_revised)

3.e BIP 6.4 HH- Block I (Hazard, effect-, exposure, and risk assessment) – For discussion (and endorsement)
(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products. Discussion chaired by ECHA)
(TMII_2013_Item_3e_TOX_B_note; TMII2013_Item3e_TOX_B_RCOMs;
TMII_2013_TOX_Item_3e - Documents for discussion)

3.c. Establishing protective measures for the professional use of biocides – For discussion
(Document to be presented by DE)
(TMII2013_Tox_item3c - Establishing_protective_measures_for_the_professional_use_of_biocides_FB4;
TMII2013_Tox_item3c - UK COMMENTS)

GENERAL SESSION

START: 12th June 2013 at 09:00 hrs
FINISH: 12th June 2013 at 13.00 hrs

1. GENERAL ISSUES

1.1 Reporting on the 51st CA meeting – For information

1.2. Tracking System: Progress reports – For information
(TMII2013-Gen-item2-Progress report existing.pdf
TMII2013-Gen-item2-Progress report new.pdf)

1.3 Information on the handover of Biocides Review Program activities from JRC to ECHA - For information
(JRC to inform)

1.4 TM SOP version 5 – For endorsement
(TMII2013_GEN_item 1.4 - SOP_TM_BPD_FIFTH_VERSION_2013(track changes))

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

3.1 First discussion for the following substances

2.1a Tolyfluanid PT 21 (RMS: FI)

2.1b BKC PT 8 (RMS: IT)
(TMII2013_ENV, GEN_Item 2.1b - ADDENDUM C12-16-BKC_PT8_EQC;
TMII2012_Gen_Item2.1c - C12-16BKC_EQC PT8 _GEN Sess discussion)

2.1c DDAC PT 8 (RMS: IT)
(TMII2013_ENV, GEN_Item 2.1c - ADDENDUM DDAC_PT8_EQC;
TMII2012_Gen_Item2.1c - DDAC_EQC PT8 _GEN Sess discussion)

3a. Guidance on Efficacy of PT 8 - For endorsement
(Document prepared by FR)

START: 12th June 2013 at 14:00 hrs
FINISH: 12th June 2013 at 17.30 hrs

3. AOB

3b. Guidance on Efficacy of PT 22 - For endorsement
(Document prepared by FR)

(TMII 2013-GEN_item 3b-Efficacy guidance PT22;
TMII2013-GEN _item3b-RCOM Table consolidated_Efficacy Guidance PT22)

3.c Reference values in ground water for rodenticides: 0.01 µg/l analytical level – For discussion
(Discussion requested by FR)
(TMII2013_GEN_item3c_References Values in ground water for rodenticides)

3d. Guidance on Efficacy of PT 21 - For discussion
(Documents prepared by CEPE
TMII2013_GEN_Item3d - TNsG Efficacy Annex PT 21 - Revised in track changes
TMII2013_GEN_Item3d - TNsG Efficacy Annex PT 21 - Replies to MS comments
TMI2013-Final minutes of workshop on PT 21 efficacy_DE_AT_SE_comments.doc
TMII2013_GEN_Item3d - DE Proposal for the definition of antifouling product efficacy
TMII2013_GEN_Item3d - BE comments on the Proposal for the agreement on defining antifouling product efficacy;
TMII2013_GEN_Item3d - NL comments)

3.e Workshop on the efficacy of repellents within PT19 – For information
(JRC to inform on UK behalf)
(TMII2013_Gen_item3e_Efficacy workshop on PT19 repellents

SPECIAL SESSION

START: 12th June 2013 at 09:00 hrs
FINISH: 12th June 2013 at 17.30 hrs

WORKSHOP ON SUBSTANCES OF CONCERN

The purpose of the workshop is to discuss and reach a consensus the issues that were not resolved during TMIV 2012, included in the checklist document prepared by Sweden and the compiled document prepared by the United Kingdom and facilitate further development of the guidance document on the substances of concern.

Agenda

9:00 Welcome and introductions (JRC)
9:15 Presentation on proposed approach for identification and evaluation of SoCs (UK)
9:45 Presentation on issues still to be resolved (UK)
10:00 Identification of SoCs and SE CA checklist (SE)
(a) Which substances/co-formulants should be considered SoCs?
(b) At which level should they be present in the biocidal product to be considered SoCs?
(c) How should they be evaluated? Which band do they belong to?
11:00 Coffee break
11:30 Identification of SoCs and SE CA checklist continued (Chair)
12:30 Lunch
13:30 Search for information on SoCs (Chair):
(a) Applicant's duties
(b) CA's duties
(c) What about (QSAR), category or analogue approach to predict toxicological hazards for SoCs?
15:00 Coffee break
15:30 Additivity principle of the CLP Regulation – should it be applied to identify SoCs (Chair)?
16:30 Combined risk assessment of SoCs and active substances – should it be applied to band C SoCs and active substances or is it too demanding at this stage (Chair)?
17:00 Summary, conclusions and way forward (Chair and JRC)
17:30 Close (JRC)

SPECIAL SESSION

START: 12th June 2013 at 09:00 hrs
FINISH: 12th June 2013 at 17.30 hrs

2nd WORKSHOP ON LEACHING FROM WOOD PRESERVATIVES

This second workshop aims to discuss the experience of Members States and Industry regarding the environmental exposure assessment of wood preservatives acquired during the product authorisation over the past years. Other discussion topics will be on data requirements and evaluation of leaching studies, risk mitigation measures and emission scenario documents.

Draft Agenda

1. **Request of leaching studies**

"Background presentation – Evaluation and Experience from the EU Review Program" (Virginia Rodriguez-Unamuno, ECHA) 30 min.
"Overview of test guidelines for wood preservatives – limitations and problems encountered during product authorisation" (Morten Klamer, DTI, DK) 15 min.
Open issues to be discussed:
Core data, selection of specific test guidelines, laboratory studies versus field studies, minimum requirements, top coating, substances of concern, read across.

2. **Evaluation of the leaching studies and data processing**

"Experiences by Denmark" (Anne Munch Christensen, Danish EPA, DK) 15 min.
Open issues to be discussed:
Leaching (flux) rate calculation (tiered approach); application of assessment factors; acceptability of varying test designs (field studies).

3. **Top coat as risk mitigation measure**

"Influence of the top coat on leaching behaviour of active substances" (Susanne Hardt, KLIF, NO) 15 min.
Open issues to be discussed:
Risk mitigation measures (RMM) for amateur use; specifications on top coat; restrictions to the composition of the top coat.

4. **How to deal with environmental risks identified during product authorisation?**

"Experiences during the process of mutual recognition" (N.N., UBA, DE) 15 min.
Open questions to be discussed:
Risks identified in Time 1 (30d); in-situ application; cumulative risk assessment.

5. **Further open points**

Application of the revised OECD ESD on PT 08; exposure assessment of temporary wood preservatives
"PEC in soils and surface water resulting from leaching" (Barry Muijs, CTGB, NL) 15 min.
Transferability of results to other PT's; AOB.

ENVIRONMENT SESSION

START: 13th June 2013 at 09:00 hrs
FINISH: 13th June 2013 at 13.00 hrs

1. GENERAL ISSUES

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

2.1 First discussion for the following substances

2.1b BKC PT 8 (RMS: IT)
(TMII2013_ENV, GEN_Item 2.1b - ADDENDUM C12-16-BKC_PT8_EQC;
TMII2012_Env_Item2.1b - BKC PT8 RMS_ENV_fate;
TMII2013-ENV-Item2.1.b-BKC-ecotox-open points)

2.1c DDAC PT 8 (RMS: IT)
(TMII2013_ENV, GEN_Item 2.1c - ADDENDUM DDAC_PT8_EQC;
TMII2012_Env_Item2.1c - DDAC PT8 RMS_ENV_fate;
TMII2013-ENV-Item2.1.c-DDAC-ecotox-open points)

2.1d Silver zinc zeolite PT 2, 4, 7, 9 (RMS: SE)
(TMII2013_Env_item2.1d - environment discussion pointsTM II-13)

START: 13th June 2013 at 14:00 hrs
FINISH: 13th June 2013 at 18.00 hrs

2.1a Tolyfluanid PT 21 (RMS: FI)

3. AOB

3.a Consolidated PT 21 technical agreements – For endorsement
(Document prepared by UK)
(TMII2013_Env_Item 3a - UK Consolidated PT21 Technical agreements)

3.b PT 21 Environmental Risk Assessment guidance documents For discussion
(Document prepared by UK)
(TMII2013_ENV_Item 3b - PT21 Environmental Risk Assessment guidance documents)

3.d Biocides higher tier guidance – For information
(Document prepared by IND)

3.e Study CEPE regional marina scenario – For information
(JRC to present the advancements on behalf of IND

TMII2013_Env_item3e-Regional_Marina_Scenario_Comments_UK
TMII2013_Env_item3e-Regional_Marina_Scenario_SE_e-consultation
TMII2013_Env_Regional_Marina_Scenario_CEPE_responses_March13)

START: 14th June 2013 at 09:00 hrs
FINISH: 14th June 2013 at 12.30 hrs

3.f Use of OECD guidance for PT 13 – For discussion
(Discussion requested by SI in the frame of MIT)
(TMII2013_Env_item3f - PT 13 ENV ESD - TMI 2013 - TEGEWA paper 11032013)

3.g Preliminary results on refinement of the Environmental Emission Scenario for metalworking fluids in PT 13 – For info
(IND to present)
(TMII2013_ENV_Item 3g - draft report-sponsored project on gathering of information;
TMII2013_Env_item3g - Report TM II 21052013)

3.i PT6-10 city scenario – For endorsement
(Discussion requested by NL)
(TMII2013_ENV_Item 3i - The city scenario draft-final)

3.l Leaching to groundwater from paint, coatings and plaster – For discussion
(Discussion requested by NL)
(TMII2013_ENV_Item 3l - Leaching_to_groundwater_PT06_10 draft-final)

START: 13th June 2013 at 13:30 hrs
FINISH: 14th June 2013 at 16.00 hrs

3.m Assessment of direct emission to surface water in PT 7 and 10 – For discussion
(Discussion requested by DE)
(TMII2013_ENV_Item3m - Direct emission to surface water)

3.n Use scenarios for PT9 roof membranes – For discussion
(Discussion requested by DE)
(TMII2013_ENV_Item 3n - Use scenarios for PT9 roof membranes)

3.o Preparatory activities for WGs – For Info
(ECHA to inform)
(TMII2013_tox, Item3f_Env,Item3o - ECHA presentation WG)

3.h BIP, 6.4 - Block I (Hazard, effect-, exposure, and risk assessment) – For discussion
(Technical guidance document in support of the Regulation 528/2012 2012 concerning the making available on the market and use of biocidal products. Discussion chaired by ECHA)
(TMII2013_tox_Item3h - ECHA presentation – Guidance;
TMII2013_Env_Item3h - Appendices)