Biocides Technical Meeting

03 - 07 October 2011

INTRODUCTION

The meeting was chaired by E. van de Plassche and for specific items on the agenda by A. Payá Pérez, J. Janossy, P. Piscoi, V. Rodriguez Unamuno, S. Pakalin, B. Raffael and L. van der Wal. E. van de Plassche welcomed the participants to TM III 2011. Representatives from the MS, NO, CH, and Industry were present at the TM. For specific items of the agenda, the interested companies were invited to attend.

1. Approval of the agenda

The agenda was adopted without any changes.

2. Adoption of the minutes

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

3. Action List TM

This agenda item was not discussed.

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

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5. Next Technical Meetings

2011

TM IV	12 – 16 December

CA meetings: 6 - 9 December

2012

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

CA I	28 February – 3 March
CA II	22 – 26 May
CA III	3 – 7 July
CA IV	18 – 22 September
CA V	11 – 15 December

TOXICOLOGY SESSION

1. SUBSTANCES in PT 08

1a. Corn cob (RMS: EL)

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2. SUBSTANCES in PT 18

2a. Triflumuron (RMS: IT)

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2b. Cyfluthrin (RMS: DE)

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2c. Pyriproxyfen (RMS: NL)

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3. SUBSTANCES in PT 02, 11 and 12

3a. Sodium bromide (RMS: NL)

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4. SUBSTANCES in PT 21

Several general issues related to PT 21 were discussed first.

Reference values based on frequency and duration of antifouling application (Copper pyrithione DocIIA comments 42,43; DCOIT DocI comment 5, DocIIB comments- 2, 7)

The use of reference values was discussed: **DE** and **NL** were supporting long-term exposure whereas **UK**, **IE** and **IND** supported medium-term exposure. **DE** and **NL** based their arguments on various survey data from shipyards (DE study and study presented in Cybutrin DocIIB, Table 3.2-1). **UK** and **IE** referred to the guidance given in the TNsG, 2002 and claimed that long-term exposure would be for antifoulings as a whole product type but not for a particular antifouling product containing a specific active. Therefore, they argued, an AEL mid-term is considered more appropriate for a particular active.
DE, supported by **FR**, proposed that similarly to pest control operators the type of active should not count and the exposure should be considered as chronic. **UK** and **IE** disagreed, in these countries pest control is considered as medium-term exposure.
The use of peer-reviewed guidance values and new data was discussed. **NO** and **SE** pointed out that the 2002 and 2007 versions of the TNsG gives different values for time duration and frequency of use. **NO** noted that it is also true for other PTs, such as PT8. The date from which the new version of the guidance come into force was also raised. The first assessments were made according to the TNsG 2002, before the new version became available. **FR** and **IE** raised that the use of different guidance documents questionedthe harmonization process; it may happen that the active is evaluated according to the TNsG, 2002 whereas for the products the new values of the

TNsG, 2007 will apply. Also, it may lead to differences among a.s. under review *versus*. new submissions.

PT pointed out that if the validity of the revision is questioned, it needs to be justified. **DE** explained the revision process: TNO had prepared the new database based on a questionnaire to IND but IND hadnot taken the opportunity to comment on it.

HEEG was asked to compare the data given in the old and revised version of the TNsG. HEEG should also propose a time-line when the revised version should be applied. Until the opinion of the HEEG is received and endorsed by the TM the TNsG 2002 applies, i.e. medium-term exposure and a mean duration of 180 minutes for spraying. Use of 184 minutes in the current dossier was acceptable.

Refinement of exposure during application and removal of paint by the Links study (DCOIT DocIIB 3, 4)

The use of the Links study was discussed and it was a common position that HEEG should peer-review the study. **NO** regarded the study as well performed, containing a rather extensive dataset and including measurements for both potential and actual body exposure using a whole body method rather than patch sampling, as well as potential and actual hand exposure for most workers **UK** mentioned difficulties in relying on the study: the roll application data does not cover brush applications and is limited to experienced professionals; the lower exposure data for spraying compared to the TNsG may be due to measuring in unconfined spaces; and the removal of paint scenario seems to lack data on what the concentration of active was in the paint originally on the ship.

NO clarified that the exposure data from the rolling application was used as refinement *only* for professionals. The main difference between the Consumer product painting model 4 (TNsG 2002) and the Links study is that the former gives data for amateur users with much higher actual hand exposure values. non-professional were using household gloves whereas professionals used appropriate chemical protective gloves. Regarding the spraying scenario, workers were spraying in uncomfortable positions especially during application to the stern of the ship and overhead spraying occurred regularly. Relatively high exposures are expected under these conditions. As for paint stripping, the amount of copper oxide in the old paint was given in the study, thus the a.s. can be converted to paint equivalent. the average value was used to convert the a.s. to the paint equivalent value. The ESD value was used to obtain the fraction of a.s. that was expected in the old paint layer compared to the new paint layer. **SE** supported the comments of NO; and the Links study was also only used for professionals.

SE compared the data with the TNsG data and concluded that the Links study is of higher quality. **FI** commented that the background data will be needed for the HEEG revision. **NO** stressed that there is no data for the paint stripping scenario in the TNsG, other CARs used the spray painting model 3 for deriving the exposure, which is not really appropriate.

COM asked for more involvement in the HEEG, which is working on voluntary basis. An opinion of HEEG, to be developed in collaboration with the RMSs for PT21 is planned for 2012-TMI. Until the opinion is encdorsed by the TM the present approaches should be kept in the CARs and shall be revised after if necessary.

Paint stripping (remaining fractions of a.s. in removed paint layers; leach rate) (DCOIT DocIIB comment 9 and Appendix 1)

There is ongoing discussion at the environmental session on converting the leaching rate per cm^2 to leaching rate per g of paint. UK understood environmental assessments for removal of antifouling were based on the OECD 2004 ESD; UK would not want to see a mismatch between environmental and human health exposure assessments unless the difference was supported by adequate data and reasoning. It was agreed that the decision on the leaching rate will rely on the outcome of the discussion at the environmental session.

The remaining fractions of a.s. in removed paint layers was discussed. There were three propositions based on the ESD document, as its interpretation was ambiguous. Out of the three propositions at the Exposure Workshop in Oslo, in 2009 the worst case scenario of 25% was chosen. **IND** proposed to harmonize the value with the 10% used for the environmental evaluation. Yet, **SE** and **NO** disagreed arguing that the 10% remaining fraction of the a.s. is a mass balance meaning that 90% have been leached out during the lifetime of the boat, and is not equivalent to the concentration of active sunbstance in the remaining paint layer, as the layer gets thinner during use. Moreover, the worst case scenario for the environment is not the worst case related to the human health assessment. Considering self-polishing paints, **NO** was concerned that the 25% is actually not even the worst case scenario.

It was agreed to discuss trilaterally among **SE, NO** and **IND** the remaining fraction of a.s. in removed paint layers. The result of the discussion will be presented at the next TM.

The relevance of a by-stander scenario (Copper pyrithione DocIIB 37, 38; Cybutryne DocIIB 34)

The RMS for Copper pyrithione, SE, pointed out that in their case, the by-stander scenario had been suggested by the Applicant, for persons not supposed to be involved in the spray application.

As far as Cybutryne was concerned, NL was of the opinion that access of unauthorised personal to professional shipyards was unlikely, hence they excluded such a by-stander exposure scenario, NL accepted the UK suggestion that dock/boat yards workers entering an area where paint is applied need to be warned to keep away from treatment areas, by a product label statement which states that ‘Unprotected persons should be kept out of treatment areas’. NO also favoured the UK label proposal aswell. NO commented that a bystander scenario is included in the CAR on DCOIT. NO would prefer keeing the scenario as it gives some useful information, but would not insist on keeping it. FR and PT also supported the label statement approach, but added that all people in restricted areas should have the same level of protection.

The TM agreed that a label statement was sufficient to tackle this issue without any need to build a specifically by-stander exposure.

Use of gloves by non-professionals (Copper pyrithione DocIIB comments 42, 43):

COM informed the TM that though the issue was already discussed at the CA, there was no firm conclusion thus it still remains open, and will be followed-up later. **COM** stressed that it became a CA issue and will not be discussed at the TM. **UK** supported that the wearing of gloves is a social, economic question that needs a political decision. **UK** emphasized that the issue relates to a whole PT, not just one particular active. To ease the decision process **UK** proposed that dossiers include two assessments, with and without wearing the gloves, for all PT21 CARs having non-professional applications. This way, the dossiers will have all the calculations allowing the CA Meeting to make an informed decision. The proposal was accepted.

4a. Copper pyrithione (RMS: SE)

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4b. DCOIT (RMS: NO)

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4c. Cybutryine (RMS: NL)

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5. SUBSTANCES in PT 01

5a. Glutaraldehyde (RMS: FI)

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6. SUBSTANCES in PT 12

6a. Ammonium bromide (RMS: SE)

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7. AOB

7a. Update on HEEG

7a.1 Training on ConsExpo and BEAT – York 9 to – 10 November 2011

COM informed the TM that places are still available and invited the MSs to participate. After mid October the free places were to be given to the MSs that showed an interest and have already subscribed with one participant, on a first come first served basis.

7a.2 Concept Paper on the development of Human Exposure Scenario Documents (HESDs)

DE presented a Concept Paper on the development of Human Exposure Scenario Documents (HESDs). The MSs were given one month to reply to the following questions for the finalisation of this concept paper.

Q1: Will the work be done by expert groups or by HEEG?
Q2: What would be the level of decision (HEEG, TM, COM) needed in relation to such documents?
Q3: Will the leaders and participants in different working groups be agreed at TM?

COM is to summarise the replies and prepare with the help of HEEG the final paper.

7b. Update on DRAWG

COM updated the TM on behalf of the DE chair of DRAWG as follows:

The draft guidance on livestock exposure is being withheld from public consultation until the EMA draft guidance on MRL setting is finalised. The EMA draft has been finalised in the working group and is currently in internal consultation within EMA. So both documents should soon be released for public consultation.

The DRAWG has been working on a second guidance document focusing on the carry-over of biocidal active substances into foods. For the following application scenarios, methods for exposure estimation have already been developed:

- *Disinfection of surfaces and machinery in the food industry*
    - It is standard practice in the food industry that surfaces and machinery are rinsed after each disinfection. The Applicant must show that rinsing effectively removes most residues. To do this, residues of the active substance will be determined in the rinsing water and on the rinsed surfaces. A similar approach will be taken for biocides used in aseptic packaging of foods.
- *Disinfection of surfaces in private kitchens*
    - Exposure of the consumer is assessed using a simple calculation with standard values for the area of daily food preparation, application rate of the biocide and body weight. Refinement of the calculation is possible through submission of additional data, e.g. on the transfer of the active substance from the surface to the food. A similar approach is proposed for insecticides used in domestic environments.
- *In-can preservatives in dishwashing detergents*
    - Exposure is assessed using a formula and default values taken from guidance developed by the industry project HERA.
- *Preserved wood for use as stakes for ranking plants, e.g. in vineyards*
    - This scenario was identified to have no relevance with respect to residues in foods. No dietary risk assessment is required.
- *Storage protection of processed foods*
    - Residue trials with representative foods are required. This is analogous to the requirements in the assessment of plant protection products.

For the following application scenarios, methods for exposure estimation are currently being developed:

- *Insecticides in the food industry*
    - Insecticides for use in the food industry carry label restrictions precluding food contact. It can be assumed that these label restrictions will be adhered to, and therefore an exposure assessment is not proposed.
- *Teat dips for dairy cows*
    - The evaluation starts with a basic calculation representing very worst-case conditions. If residues in milk are too high, residue studies are required.
- *Surface biocides in food contact materials*
    - A calculation is used employing standard values for daily food consumption and contact area of food and treated packaging and experimental data on the migration of active substance from the packaging to the food. This is analogous to the assessment under the food contact material legislation. Please note that it is not yet clear whether this use will be within the scope of the biocide regulation.

In addition, DRAWG is currently discussing whether hydrolysis studies may be required in some instances.

GENERAL SESSION

1. Reporting on the last CA meeting

COM reported on the outcome of the CA meeting.

2. Tracking System: Progress reports

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3. SUBSTANCES in PT 14

3a. Corn cob (RMS: EL)

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4. SUBSTANCES in PT 18

4a. Permethrin (RMS: IE)

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4b. Triflumuron (RMS: IT)

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4c. Cyfluthrin (RMS: DE)

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4d. Pyriproxyfen (RMS: NL)

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5. SUBSTANCES in PT 02, 11 and 12

5a. Sodium bromide (RMS: NL)

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6. SUBSTANCES in PT 21

6a. Copper pyrithione (RMS: SE)

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6b. DCOIT (RMS: NO)

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6c. Cybutryine (RMS: NL)

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7. SUBSTANCES in PT 01

7a. Glutaraldehyde (RMS: FI)

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8. SUBSTANCES in PT 12

8a. Ammonium bromide (RMS: SE)

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9. AOB

9a. General principles testing efficacy preservatives

DE presented the document on principles for testing the efficacy of preservatives. The document was commented upon by the other MS and is now ready for endorsement at CA level followed by public consultation. **FR** stated they still have some comments. DE stated they will take those comments into account before sending it to the CA meeting. It was stated by several MS that after this document on general principles guidance on individual PTs is required.

Conclusion: DE to update document and send to CA meeting.

9b. Update on changes of JRC-IHCP web-site biocides

COM presented a short note which is aimed at informing the TM (Technical Meetings) and CA (Competent Authorities) of the changes on the 'Biocides' web content previously hosted by the former European Chemicals Bureau web site at http://ecb.jrc.it/biocides/ and http://ecb.jrc.ec.europa.eu/biocides.

The note "TMIII2011-GEN_item9b-Note ECB- ESIS change of Website.doc" is uploaded on CIRCA.

9c. Evaluation of shelf life for biocidal products

DK introduced the document on the evaluation of the shelf life for biocidal products. A general discussion took place on the questions raised in the document. **NL** clarified that in the crop life manual, a change of more than 10 % is not allowed. After the storage period, it has to be shown that the degradation level is below 10 %. **NO** pointed out that the 10 % trigger value is maybe the only value we have at the moment; we have to decide on something to use in the wood preservative product dossiers. **NO** will use 10% in the first place. The TM considered the need to have guidance on the evaluation of these types of tests. **NL** mentioned that there is no specific guidance available for biocidal products, e.g. PT21 products and in-can preservatives and raised the question whether specific guidance should be developed. The existing FAO guidance and the GIFAP (Croplife International) technical monograph no. 17 were developed primarily for plant protection products. **COM** mentioned this could probably be achieved under the scope of the Evaluation Manual for PA. COM will consult with NL if this is possible. **IND** offered to assist in the development of such guidance.

ENVIRONMENT SESSION

1. SUBSTANCES in PT 14

1a. Corn cob (RMS: EL)

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2. SUBSTANCES in PT 18

2a. Triflumuron (RMS: IT)

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2b. Cyfluthrin (RMS: DE)

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2c. Pyriproxyfen (RMS: NL)

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3. SUBSTANCES in PT 02, 11 and 12

3a. Sodium bromide (RMS: NL)

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4. SUBSTANCES in PT 21

Wider environment discussion

COM reported that the CA meeting concluded that defining the wider environment scenario as the minimum level of protection for antifoulants may be a way forward. **NL** asked whether sedimentation areas are included in the MAMPEC surrounding area. **COM** clarified that in MAMPEC no sedimentation is taken into account in the surrounding area. **UK** clarified that the UK paper on surrounding areas only looks at the dilution factor for the aquatic environment. For marina the dilution factor is 100 and for commercial harbour 10. For suspended matter the same dilution will apply. **NL** could accept using the wider environment scenario for commercial harbours but not for marinas. NL also suggested that a freshwater marina should be developed. NL argued that it is important to come to a harmonised way to deal with this. **COM** stressed that we have to look for a way forward for a.s. which do not pass the marina scenario, and reported that the CA meeting saw the advantage of using the wider environment scenario both for marina and harbour. **UK** stated that risks in marinas should be dealt with at PA. Applicants have to get information on the relevant scenarios for PA soon, therefore new scenarios should be developed quite quickly. CEPE is working on developing regional marina scenarios. **IND** stated that the development of new products is expensive and markets are not too big. In some countries there are especially sensitive areas, which have to be dealt with at PA. However, mutual recognition will be difficult if everything related to the marina scenario is deferred to PA. **DK** supported IND and wanted to deal with the matter now by developing regional scenarios. **FI** accepted the wider environment scenario, but is sceptic to the high dilution factors for marina in MAMPEC. **COM** suggested that the e-consultation group could look into it. **UK** clarified that the dilution factor in the TGD is in line with the factor used for the marina in MAMPEC. **IE** agreed that this matter should not be deferred to PA. For Annex I inclusion, **NO** accepted using the wider environment with the dimensions outlined in MAMPEC. Mutual recognition will not work if industry does not have available scenarios before PA. We have to agree on regional scenarios. **CEPE** is conducting a survey on marina characteristics in EU. This will be discussed at TM, possibly in March 2012. **NL** agreed with using the wider environment for harbour but not for marina. **COM** concluded that the majority of the TM accepted the "wider environment", and additionally that the development of new scenarios is ongoing and this task should be finalised as soon as possible.

COM: it was decided to accept the use of the wider environment scenario with the dimensions as defined in MAMPEC vs 2.5 for Annex I inclusion

4a. Outcome of PT 21 e-consultation group

UK paper

1. Selection of kinetic input parameters

Background: Originally the UK produced a discussion paper that was sent around in February 2011. Comments were received from many MS and IND representatives. To reflect the broad range of use the **UK** has collated the answers received and amended the original discussion document. This document is proposed now as the draft guidance for the selection of input kinetic parameters. The draft guidance starts on page 3 of the cited document. **UK** picked out several topics that need to be discussed at the TM namely, aqueous phototransformation, use of average DT50 values, trigger values for performing sediment dweller risk assessment and the correction factor for biodegradation in open sea areas. The guidance document was written taking these points into account. However, **UK** felt that it was worthy to discuss them more in depth.

1. Aqueous photolysis

There were very conflicting views ranging from comments suggesting that we should never use photolysis to comments that suggested the use of photolysis as a degradation process in all scenarios. In order to reconcile these differences, the **UK** CA has treated photolysis within a tiered approach. Photolysis is excluded from MAMPEC calculations at the simple first tier, but can be included in refined higher tier assessments for all scenarios provided that quantum yield data, which are necessary to run the advanced photolytic degradation routines of MAMPEC are available. **NO** agreed with not including photolysis in tier one, but they have some reservations with tier two. **NO**could not see that photolysis would be as relevant process in harbors as in the open sea or in the shipping lane. **SE** clarified that when you use this advanced photolysis module you have depth variation in how much light penetrates the variouslayers of the water and you have a core describing how much sun light is penetrating the water, depending on the turbidity of the water, leading to lower photolysis in harbour environments. **SE** thinks that this MAMPEC advanced photolysis module should be used when possible. **COM** added that if this was the case then it would not lead to more contribution of photolysis in marinas as compared to open sea

2. Use of average DT50 or worst case value

The original discussion paper omitted any consideration of whether it would be appropriate to use average input parameters or worst case values for running MAMPEC simulations and this issue was raised during the commenting round. The guidance proposes that the vulnerability of the exposure assessments should be primarily within the description of the scenarios rather than the individual substance parameters. So the worst case of the scenarios is based on how you define those environments. On that basis, UK concluded that it is appropriate to use the geometric mean DT50 when you have acceptable results from more than one test system. **UK** considered this approach as consistent with other environmental compartment modelling like the FOCUS ground water scenarios or FOCUS surface water scenarios. **COM** supported the used of the geometric mean. **IE** also supported the use of the geometric mean and agreed with the comments make by UK. **NL** also supported **UK**, and thanked **UK** for reminding how the approach was taken for other models such as PEARL. **NO** agreed in principle with **UK.** However, **NO** pointed out the fact that biodegradation might be dependent on the concentration as it was seen in the substances **NO** was assessing. **NO**considered that it would be appropriate to leave this point flexible in order to be able to consider for instance a case were the average value might not be the most appropriate (inhibition at higher concentrations). **UK** agreed with **NO** and proposed to revise the guidance on input parameters to reflect these cases were average values would not be the most appropriate (e.g. concentration and also pH dependency). **FI** and **SE** also agreed with **UK** in the use of the geometric mean. Additionally **SE** supported the suggestion of **NL** on the need to investigate the mechanistic reason why we had great variations in DT50. If we see a great variation regarding the results from degradation studies; a discussion on the possible reason (s) is needed. **NL** was also of the opinion that more guidance is needed to help deciding when the average geometric value could be used and when it could not be used. **COM** concluded that the proposal of **UK** concerning the use of the geometric mean is accepted provided that comments made by **NO** and supported by other MS are added.

Point 3: Trigger values for performing a sediment dweller risk assessment

One of the difficult parts of the guidance was how to evaluate water-sediment studies to derive separate degradation rates for water and sediment. One of the experts comments **UK** received highlighted the particular situation where, the residues in the water sediment study remain in the water phase and there was not significant partitioning to the sediment. That cause a problem for them, because they wouldn't be able to refine the sediment DT50 based on the guidance. **UK** wondered whether we could think about situation when there is got an acceptable data base of water-sediment studies and there it is shown that no significant partitioning of the a.s or the metabolites occurrs to the sediment phase either. Do we exclude them for specific consideration within the risk assessment? At the moment MAMPEC will calculate PECsupended matter and PEC sediment B, what about the situation if you have a reliable data set from water-sediment studies showing no significant partitioning of the a.s. or metabolites to the sediment. **UK** wondered if the trigger value of 10% could be used. If we don't exceed 10 % then we don't have to do the sediment risk assessment. **NO** asked **UK** whether the proposal implied that no risk assessment has to be done for the a.s. if information from the water sediment study indicates that the a.s. was not detected in the sediment. Does it mean that you don't have to perform the a.s. RA for sediment or is this only relevant for the metabolites **NO** stated that because you didn't find something in the sediment it didn't mean that it did not partition this way, it can be tightly adsorbed. **NO** thought that the starting point was that the a.s. was so water soluble that it didn't partition. **NL** asked some more clarification on the point raised by **NO**. According to **NL** if the appropriate extraction method was used, identification of the a.s (if this partitioned to the sediment) would be possible. **COM** clarified that the way **COM** interpreted the proposal by **UK** was that you don't find significant partition for both a.s. and metabolites. **UK** confirmed that the proposal on the trigger value would apply equally for a.s and metabolites. The rationale was that if you have an acceptable data base of water-sediment studies they define the fate processes in the aquatic environment. So if you didn't find any significant partitioning to the sediment then there is no need to do a RA on sediment. The proposal is just a simplification in maybe rare cases. Perhaps more for metabolites but maybe some a.s. will also avoid having to do this quantitative formal risk assessment. **NL** can agree in principle with posing a trigger for this but they didn't know what this value trigger would be at this moment. **UK** suggested a 10%. However, according to **NL** the occurrence of the a.s./metabolites at a given time should be defined in the water-sediment study (e.g. detected at any time, at a certain time). Koc or Kow trigger values would also be an option. There were various options. But they agreed with the view that if the substance/metabolites seemed not to partition to sediment to certain extent the sediment RA can be waived.

COM suggests including the phrase "at any time" to the trigger value and leave the value as UK suggested 10% both for parent and metabolites.

FI gave an example of a substance where they had not done risk assessment for sediment becausethe a.s. was rapidly degrading and no partitioning to sediment was observed. However, the risk assessment of the metabolites which did partition to the sediment was performed. **FI** wondered if this approach could be considered acceptable. **COM** confirmed that this approach was acceptable and concludes this discussion point. **SE**posed an additional question concerning point 3. According to **SE** the TM was assuming antifoulings which are partitioning into the sediment and if we looked into harbors, we would find paint flakes in the sediment.Leaching from these flakes is an issue we are going to discuss today. Even a totally soluble substance may enter the sediment via these paint flakes and leach out from these. **SE** wondered whether this would change this proposal. **UK** supposed that this would not exclude the exposure of metabolites because by definition they had to be assessed. Obviously the risk posed by paint particles was a big challenge. **UK** would perhaps come with a second paper. There were difficulties assessing not only the exposure from paint flakes but the effects that they might cause. **UK** asked the TM if any MS could come with any idea on how to solve the issue. **COM** stated that considering the number of MS having taken part in the discussion of the assessment of the paint flakes presented for latter discussion, this is a difficult matter and a big challenge. We might come back to this later.

Point 4: correction factor for biodegradation in open sea areas

The original paper concentrates on selecting kinetic input parameters for water and sediment phases. The various OECD scenarios from MAMPEC coverscoastal and open sea environments where rates of biodegradation may differ due to differences in degrading populations of microorganisms nutrient levels, organic matter/suspended particles etc. A number of MS wondered if it would be useful to include a correction factor to try to capture the slower degradation in open sea environments. This approache was taken in of one of the PT 21 CARs based on the TGD. For the in-service shipping lane/open sea scenarios a correction factor of 3 could be used, compared to the coastal scenarios, so the degradation rate would be reduced by a factor 3 copared to the marina or coastal environment. So the uncorrected rate would cover the marina and the commercial harbour and the corrected rate would cover the shipping lane/open sea scenario. **FI** would like to clarify if this correction factor only refers to biodegradation meaning that if you had a substance that degrades hydrolytically then you keepthe same rate constant. **UK** thanked **FI** for the comment and confirms that this indeed is the case. They will correct the guidance to clarify this point. **CH** stated that this correction factor could greatly depend on the molecule and chemical structure and ask for clarification on how this factor 3 was derived. **UK** clarified that this value is taken from the TGD chapter 4.2.3. There is a table for potential degradation rates and distant marine locations and from that it could be concluded that the TGD suggested that a correction factor of 3 was appropriate based on the default mineralization half-lives. **UK** suggested that maybe **NO** can add more support since it was their idea. NO explained that they applied it because it was in the TGD and stated that microorganism density in the distant marine environments was lower than in the estuaries. It seemed logical to **NO** to do this because biodegradation studies they used in their risk assessment were performed with water from estuaries and not fromdistant areas. **COM** added for clarification that the applicability of this correction factor would depend indeed on the type of information available. If relevant seawater information was available **COM** supposed that the correction factor would not be necessary. **UK** added to the discussion that it was a good correction to do because there was a scientific basis behind it. It is unlikely that, applying this correction factor would lead to a problem in the shipping lane scenario. So it was unlikely to have a regulatory impact for annex I. But it was important that we include it now. **SE** supported the proposal and confirmed that they have used a similar approach with one of the metabolites with MAMPEC when trying to calculate a degradation rate. COM closed the discussion on the outcome of the PT 21 e-consultation group. COM concluded that using the correction factor of 3 to correct for biodegradation in remote areas is agreed (as long as DT50 values were derived from studies using coastal waters) and suggested to amend the paper with the results of this discussion and used this paper as the basis for the selection of the kinetic input parameters for MAMPEC.

2. Refinement of the new build, maintenance or repair exposure assessment

This was the second paper presented by the **UK** and looked for options for refinement for new building, maintenance and repair exposure assessment. This discussion paper, as it was previously mentioned, was the result of the technical discussions back in June 2010. The discussion paper drafted by the **UK** was divided in two main parts. The first part considered options for refining the quantitative exposure assessment. **UK** looked at the approaches that **UK** used in its own CAR and also on approaches other MS had used in their CARs which were available at the time. In the second part of the paper really looked to rather trying to refine quantitatively, it was investigated to whether we could introduce risk mitigation options as a way of mitigating the risk posed by these application and removal scenarios. So in the paper that it was presented at the TM **UK** had tried to summarize the comments received on both parts of the document. Having reviewed the various approaches there were approaches based on the CEPE mass balance leaching rate method trying to reflect the release rate of bioavailable a.s. from paint particles that would be released from paint droples of flakes, either following application or removal activities. The idea of a $T_{DepleteParticle}$value, could be a transparent way of refinement in the exposure assessment. Late comments were received from the NL which are not included in the document. Briefly NL wondered whether there was an option to ask industry providing data on the the parameter $T_{DepleteParticle}$. At the time of drafting the paper, **UK** could not conclude on a value however, it was the intention to give MS an idea of the level of refinement that would be feasible. All the MS were keen on explore options for risk mitigation but **UK** opens the floor for the discussion on the $T_{DepleteParticle}$ particle of whether this was an approach worthy to develop further. **COM** thanked UK for the introduction.

SE pointed out the fact that there were lots of types of paints and this could complicate derivation of $T_{DepleteParticle}$. **NO** acknowledged that this proposal would be the closest to the real situation however, they recognized the difficulty in developing a harmonized approach. Leaching behaviour of a.s. could differ greatly. In line what they had previously said concerning the paper from **UK** they would rather focus on risk mitigation measures instead of this $T_{DepleteParticle}$approach. **FI** thanked UK for the work done in elaborating this paper. Concerning the $T_{DepleteParticle}$, they find it difficult to implement it within the risk assessment and would propose as **NO,** to focus on risk mitigation measures. **COM** agreed with the **UK** that the parameter could be useful but how the parameter could be used depending on the characteristics of the particle itself and the environment surrounding, might be very difficult approach to harmonize. No further discussion was held concerning $T_{DepleteParticle}$ It was agreed that this approach was too difficult and that risk mitigation measures should be applied. This was agreed.

UK proceeded with the second part of the document. The second part of the document introduced some mitigation options. Valuable comments from several MS were received. **CEPE** also commented on the issue, all comments were reflected in the paper. In particular one of the key points was the possible crossover of what we are doing at the TM and what other EU and national legislations were doing. Several practices were mentioned. A BREF document for shipyards is now available This again reflects best practice that it was listed and described well in the CESA and CEPE papers which were discussed at TM II 2011. The paper tries to investigate how RMM should be implemented when they were well controlled by other pieces of legislation. **NL** has come with a clear statement that they have applied strict control measurements in their own yards. They were content with achieving their own levels of environmental protection Perhaps in the EU legislation under other pieces of legislation other MS have a responsibility to achieve similar levels of control. On page 6 of the document, **UK** had put some question together to be discussed at the TM: "the experts of the COM to consider really the scope of the BPD. Looking to the arena of this TM to determine the extent to which this RMM can be introduced in this area again bringing back which areas might fall back in the control of other pieces of legislation like IPPC". **COM** admitted that there was still some work to do concerning RMM. What would be the scope of the BPD and what can be done under other pieces of legislation looking to the IPPC, maybe other pieces of legislation? Code of good practice to be developed or implement a code of good practices that was already included in one of the documents provided at previous meetings. That it also something that we could refer to when we address risk mitigation for new building and maintenance and repair scenarios. **COM** concluded that they still have to do some homework and come back to the TM on this issue.

UK added that the best practice guidance would be a very simple task because we had an enormous amount of information from the CESA survey and the existing best practice guidance. The decision to be made is how this would be implented, perhaps to which extent the emission can be reduced by this RMM. Perhaps some more detailed investigation on the CESA survey is needed and try also to try to quantify what level of environmental emission reduction can be achieved when applying the best practice at shipyards could be a way forward. **COM** would indeed advocate for having some certainty that the measure that is put in place might at the end reduce the risk. Having said that, COM would consult with colleagues in Brussels and then COM would come back on this issue in writing. **UK** just for clarification asked COM that, given the time scale, if this was the kind of thing that was going to be left for product authorization level in the same way that maybe we would leave the development of scenarios to product authorization level. They are thinking about the time scale especially regarding the new substances UK is working on. **COM** would suggest that this shall not hamper the inclusion of annex I process. **COM** believed that along the lines with the original scenarios for marinas, that this was something where we could work on in parallel to the annex I inclusion. So , **COM** suggests indeed going on with the evaluations for Annex I inclusion and regarding the new building and M&R scenarios, go for RMM as the proper way instead of refining technically the risk assessment. Then in the mean time we can work on something appropriate that can be relevant for product authorization. **SE** wondered if we can drew up in parallel with the discussion of the previous days the presence of or non-presence of an STP outside the paper mill which was something we were allowed to have as special requirement for proposing annex I inclusion. It would be the same situation. **COM** asks whether SE could clarify on the issue and the relation what the previous discussions at the TM where we were discussing the situation of paper mils with and without STP. For COM this was a different situation. Here we are talking about the maintenance and repair situation where the only way to avoid risk will be putting RMM in place. **NL** agreed with **COM** that was a different situation because all marinas especially for pleasure yachts would paint their own ships. **SE** clarified that they were referring to big facilities where they paint large ships. For the emissions from that facility should be possible to have some treatment facility. **SE** asked if that was not the point of CEPE was trying to make. **NO** stated that the implementation of RMM at commercial shipyards was a little bit more complex than having an STP for the treatment of papermills. Also when we had evaluated wood preservative we had the same situation in the treatments site, but there it was relatively simple: we just required establishing a roof and hard standing surfaces.But the situation in a shipyard is much more complicated and RMM are more expensive to implement. **UK** will go back into some details of the original document, where one of the ideas was that we could use the information from the recently produced CESA survey. The idea was to try to classify boatyards, shipyards into different classes on the basis of the different levels of environment al RMM measures which are implemented.As **NO** pointed out, the situation is more complicated than just establishing a connection to an STP. **UK** clarified that there are many best practice measures which can be implemented and that was the basis for the suggestion to classify the different shipyards. Maybe it should be recommended that only certain products can be used in certain ship yards. But maybe it is worthy to go back to the CESA survey. For example, some boat yards might only with difficulty achieve the high level of emission reduction, while from the survey you can see that there are at least some measures which are routinely applied in all boat yards across EU. Some shipyards would consequently not be able to achieve the same level of reduction in exposure as others.That was the background for the proposal of UK. **COM** thinks that for this we should work closely with IND to see if such a system works. **IND** first commented about the CESA survey, **IND** thinks that it was a very good survey and that the result of this survey was representative and should not be disregarded. Therefore, it was important to consider this document and to extract whatever possible because it covered a significant fraction of the shipyard industry and was the result of a close cooperation between the biocide industry and downstream users. About the possibility to establish or to regulate the shipyards with respect to IPPC it was stated that this was very important for them because it would be difficult to for example establish a classification scheme of shipyards and then restrict some products to some classes of shipyards if the risk assessment associated with application and removal was not accurately done. Because actually the risks which were identified were related to a situation where all emissions from these operations become immediately available from paint particles or droplets the whole amount of emitted a.s. and was immediately dissolved in the water column. So obviously it was not a realistic scenario within this context. This was the reason why a refinement of the risk assessment regarding leaching from particles was important. If RMM have to be applied they agree with this approach. But in this case it seems to be difficult, without refinement of the risk assessment to put some restriction on the product related to the classification of the boatyard.**COM** agreed that this was an important point.

COM closed the discussion on this point and suggested that **COM** would come back to the TM on the question raised by the UK in the paper discussed and that **COM** consult with the e-consultation group and IND how we can take this further.

Cumulative assessment

This was the last paper discussed by the **UK**, it was sent around for comments in august 2011. Unfortunately **UK** could not prepare a briefing document to present at this TM due to the late receipt of comments. **UK** summarized the comments received and highlighted some key issues worthy to discuss at the TM, derived from this e-consultation. Overall there was a very good general agreement reached on the use of MAMPEC model for simulating multiple and simultaneous exposure and also as a higher tier refinement option over the simple first tier method of the application of maintenance and repair exposure assessments described in the ESD on PT 21. There was also general agreement over the structure of the surface water scenarios that the **UK** selected. **UK** proposed one cumulative scenario for commercial shipping, one for professional pleasure crafts and one for amateur's pleasure crafts activities. And in general, the two worst case examples which were included in the original discussion document were well understood and broadly accepted by all the experts. The final general agreement was over the use of the Multiple Application Factor (MAF) approach for determining soil exposure. In the interest of saving time at the TM, **UK** pointed out that there were several general issues that **UK** was happy to resolve either unilaterally or bilaterally with MS. All these points would be addressed in the revised version of the document. This might come out as a guidance document similarly to the one produced by **UK** for the input kinetic parameters for MAMPEC previously discussed at the TM. **UK** identified four issues that need to be discussed further by the TM in order to move on the development of the guidance.

Point 1: Cumulative assessment for the wider environment.

Now that TM had pretty much agreed that the wider environment scenario can be used for annex I inclusion purposes **UK** would like to take the chance of discussing cumulative exposure on those environments. The draft paper was written on the basis that we were assessing risk within the commercial harbour or within the marina. Obviously after the **SE** proposal on the wider environment,the **UK** paper and the discussions during this TM perhaps we can move to the wider

environment. UK would like to get an agreement on whether it is valid, as we decided to adopt the position of the wider environment scenario, to just apply the cumulative assessment scenarios developed in the paper by UK to those existing surrounding scenarios in MAMPEC. The technical issues to consider here was that when **UK** was developing the cumulative scenario for within marinas or within commercial harbours environments, **UK** found that the largest risk of multiple and simultaneous exposures would come either from in service plus application or in service plus removal activities.**UK** did not think that we had to consider in service-leaching and losses via an STP at the same time. However, a number of MS commented that if we move to considering the risk in the wider environment then we have to consider accumulative risk assessment from an STP. **UK** asked whether there was an agreement to consider the route via an STP for the wider environment scenario. If we can agree on this, **UK** will try to come with proposals on how to deal with it. **COM** asked **UK** if this would mean kind of regional background concentration from sources leading to an STP that is the river flowing just into the marina and that would then feed into the wider environment. **UK** guessed that the two options are: one to just to assume that your STP discharges directly into your harbour or marina; that would be very easy to implement in MAMPEC because, you could just add that daily load directly to the other daily load from in service or removal or application losses. The other options as pointed out by COM was the separate estimation of exposure via STP and try to work out a background concentration present in the wider environment and add that . COM wondered whether it was really significant in comparison to other contributions you have. **NL** reminded that there was the scenario also the river coming into the marina although it is a small one. **NL**remarked that we are already going very worst case the way we were going.**NL** would suggest not including the STP route **COM** agreed with the **NL** and would recommend not to include it. **UK** pointed out that the suggestion of considering this exposure route was coming from more than one member. In the interest of neutrality **UK** had to take the majority view, but would acknowledge comments from the TM.
No MS reacted what was interpreted by **COM** as an agreement in that sense, as most MS have express their will to include this route.**UK**would investigate further and see how it can be dealt with in the cumulative assessment and then see what comes out. UK added that these two options would be anyhow included in the draft CAR of Tralopyril which would be discussed at the following TM.

Point 2: There was a technical comment about the commercial harbour and the need to protect it considering both removal and also application and in service losses. For the moment the combined scenario UK proposed for the commercial harbor combined in- service losses and losses during application only. So there was not additional simultaneous emission due to removal. Our rationale in putting these scenarios together was that **UK**wanted them to be simple, transparent and realistic. And on that basis **UK** figured that considering combined daily emissions due to application losses are conservative. Adding application losses to the in-service losses on a daily basis would be sufficiently conservative and protective. And therefore, **UK** didn't add additional removal losses. But some MSs point out that in theory you can have a situation in a commercial harbour or even a marina that people are both applying the paint and removing the paint from their boats.So it was a possibility UK hadn't included in the rationale. **UK** considered that adding the losses during application to in-service losses was sufficiently precautionary, but they are happy to hear more comments or suggestions on this point. **NO** stated that putting the daily load into MAMPEC and thereby assuming a continuous daily load everyday is more conservative than the ESD. **NO** agrees not to add losses due to removal as well. Taking the worst case of daily application and in-service life losses would be sufficient. **NO** didn’t think you have to look both at application and removal. **DE** was very much in line with **NO** in that point. However, **DE** would like to point out that it is because of the daily emission from application that this was also conservative. Because in case we would adjust the application scenario latter it should not be forgotten that this removal was not taken into account just because it was conservative at that point of time. If **UK** could clarify on that it would be highly appreciated.

COM concluded that explaining the reasoning for accepting this as being sufficiently conservative relating to the daily situation of having application and in-service losses this proposal of **UK** is accepted.

IND just to note on the CEPE comments on this paper confirmed that a recently released MAMPEC 3.0 version is available. This version allows the application and the removal and the in-service activities to be considered separately as well as combined on an average annual bases if that is the choice. MAMPEC then calculates the effects of all of those activities but it does that on an annual average basis rather than continuous daily emission. IND supported the use of MAMPEC 3.0 in terms of cumulative assessment. MAMPEC 3.0 is available and freely downloadable. UK added that MAMPEC 3.0 that was a version probably worth looking at.

Point 3: Refinement options
The paper did not really cover refinement options. The document focused mainly on developing the first tier combined multiple exposure scenarios that we can agree on. However, the main conclusion was that MS wanted refinement options included in the revised paper. We can take the following approach.The ESD proposes typical or worst case following a tiered approach. **IND** suggested version 3.0 of MAMPEC for this purpose. The other possible refinement option would be to go into detail into the CESA survey information. **COM** asked for opinion on this aspect. From the **COM** perspective the best option was to leave it without further refinement in the first instance and see what the outcome of the cumulative assessment - as decided by this TM – would be in our evaluations. Looking to the previous discussions COM could foresee that it could easily be moved to risk mitigation. **IE** we could accept in principle the feature list of this document with the possibility of refinement options. **UK** pointed out that they would try to explore these options as much as possible in the Tralopyril CAR.

Point 4: soil exposure assessment
Most MS agreed to the Multiple Application Factor (MAF) approach. TM had agreed for the purposes of annex I to assessthe risk in the aquatic wider environment. FI accepted also the use of wider areas in marinas and harbours, but was concerned about the much higher dilution in marinas than in harbours. COM also stated that it is strange Perhaps it comes into question the value of assessing the risks in the directly impacted soil. And whether we retained the formal soil risk assessment for completeness, but in following the line for aquatic risk assessment for substance that showed an exceedance for annex I inclusion maybe it is not an issue. **UK**could not imagine a situation when we would encounter no risk for the aquatic scenarios but we were not allowing the a.s. for the risk to the terrestrial organisms. **UK** considered that the demonstrating that antifoulings are safe for the aquatic environment was already quite a challenge. The question was why investing a lot of time in the soil compartment when we will never use it to make a regulatory decision. But UK is happy to include it anyhow. **FI** pointed out that a soil risk assessment has only to be done for pleasure crafts and that no risk mitigarion measures have been agreed regarding this use. **COM** explained that when the ESD was put together the idea was to have a simple risk assessment scheme for soil and then go for risk mitigation measures **NL** thinks that the same approach as taken for the wood preservatives should be taken. **COM** would suggest then to leave it as a first tier at it is suggested in the paper by the **UK**.

MAMPEC

Several issues connected to the MAMPEC calculations were discussed.

Which version of MAMPEC should be used?
COM suggests using vs. 2.5. **UK mentions that there was a b**ug in vs. 2.0 regarding the withs of marina mouth. This should be added to MOTA.

It was agreed that v 2.5 will be used.

Should any additional scenarios be used?
COM: National scenarios not necessary. Fish net scenario has to be developed if use foreseen. NO: CEPE has indicated that there is a bug in version 2.5. COM will ask CEPE to clarify this bug in the MOTA.

General discussion on how to enter Koc into MAMPEC for calculations of PECsedimentand PECsuspended matter

Several approaches when dealing with Koc could be found in the different assessments of antifouling paints. The question of how to deal with concentration dependency of the KOC value was highlighted by several MS as an important input parameter in MAMPEC. **SE** was of the opinion that it was appropriate to adjust Koc value when calculating PECs as these are so low. They had three options on how to proceed. 1) MAMPEC model should do this adjustment of the Koc value, dependent on which concentration is modelled. However, SE recognised the difficulty of this proposal. This correction is done automatically by many PPP models. **2) SE** suggested alternativately to look into the OECD protocol 106. Some times measurements are performed at lower concentrations than this reference concentration of 1 mg/L. Look at the raw data from the study and how the Kd on Koc is plotted at the different concentrations. Then you simply pick the Koc that is measured at the lowest concentration. 3) **SE** indicated for the third option that MS could consultate the RCOM table for CuPT for further information (comment 268 CuPT RCOM). **NO** suggested at first tier to apply the highest Koc value at the lowest test concentration. In the LoEP preferrably one value should be stated. **FI** appreciated the detailed reasoning by SE made in CuPT risk assessment regarding Koc-values but was of the opinion that this issue should be kept simple in the risk assessments. .It was decided that SE shall make a guidance with IND on this issue **SE** suggested that maybe the simplest thing to do would be to adjust the value manually.
The measured Koc value at 1mg/L has to be extrapolated to a lower concentration. **UK** supported **SE**. **UK** stated that this was not only relevant for PT 21 but for other PTs. How we interpret the absorption data in linear models was indeed important. Caution should be taken about extrapolating down over several orders of magnitude from the tested concentration Non-linearity continues to the ng-level. The use of the experimental Koc value determined at the lowest concentration is perhaps the most favoured option from the UK point of view. When MAMPEC was developed it was developed on the assumption of linearity. The manual contained various stages of the development and the validation or the reality check performed to see that the models in MAMPEC were realistic. That was on the basis of linear absorption on the model. So it is possible that other parameters in the model would correct for the assumption of linearity. **NL** stated that some guidance is needed on how to use this data and asked what would be the limitations MS would have to deal with when extrapolating data. **SE** agreed with the NL that a guidance on how to use this Koc values. SE would happy to contribute.

PEClocal, dissolved for marine compartments

$\text{PEC}_{\text{dissolved}}$ calculations should be harmonized for all PT 21 a.s. Currently, in some dossiers different approaches are used, both based on the TGD equation and also on MAMPEC. **NO** stated that this discussion is much related which what the TM previously discussed. It was the understanding of **NO** that it was agreed that **MS** would use MAMPEC vs 2.5 for the calculations. **UK** clarified that, however there could be a slight mismatch when you got exposure via an STP entering the surface water, because you would not then use MAMPEC calculations and you would have to revert to the TGD equations. Also during the e-consultation there were some comments on whether we should refine the application and M&R with MAMPEC and whether it would be useful to keep the simple first tier calculations in the CAR or not. The question is whether you want a TGD first tier followed by refinement in MAMPEC and there the advantage of the tiered approach was that it allowed you to see the level of refinement that MAMEC was giving. There was an approach by the **NL** to not use the average concentration from MAMPEC but to use 95%. The proposal of **UK** would be to decide whether TM wants to use first the TGD calculations and then MAMPEC for refinement or whether TM would prefer to go for MAMPEC directly using a refined PEC dissolved value. The proposal to be discussed according to **UK** should be first tier calculation according to TGD followed by MAMPEC calculation using a percentile of your PEC. **FI** understood that the agreement was to use first the first tier (TGD equations) and then the second tier would be MAMPEC. **NO** confirmed that this was also their understanding. **COM** concluded on this point that as first tier the TGD equation (Load divided by /volume) will be used and then for the second tier calculations MAMPEC will be used.

Leaching rate correction factor of 2.9

The leaching rate correction factor 2.9, agreed in the leaching workshop, has not been consistently applied within PT 21 dossiers. From **COM** point of view this is an agreed factor. **COM** could not see why this factor should not be applied unless of course there were evidences or field studies from where you can infer that the factor is not valid for your individual active. That was a case where you can deviate. **UK** was concerned about the proposal of **COM** of using the leaching rate correction factor as default value. Some Applicants who have produced very good leaching rate data demonstrating that this 2.9 factor is not longer valid, won't aplly this correction factor. And other Applicants not having provided data would benefit applying this 2.9 factor. **UK** suggested that the additional information should include a leaching test. Another point raised by **UK** was that, the 2.9 correction factor is to correct the CEPE mass balance leaching emission. Without the 2.9, 90% losses were assumed. When you applied this 2.9 factor you can consider that you are only losing 30% during service life. That might be valid when we talk about risk in marinas where boats are essentially static. Considering 90% lossess might be an overestimation in this situation. Now that we have decided to consider the wider environment scenario it maybe not longer valid to also take into account the correction factor. Additionally UK pointed out that another disadvantage of using the correction factor and thereby reducing the in-service leaching down to 30% was that if we followed the proposals for a cumulative or multiple simultaneous exposure assessment the factor for the amount of active remaining in the old paint is either 30% or maybe refining this 10%. If we refine then to 10% we lose 30% in-service and 10% on removal of the spent paint. Actually 60% of the a.s. never enters the environment what it is probably too beneficial. If we apply this factor with no additional information potentially 60% will never enter the environment. **FI** agreed with **UK**, in their dossier the factor was applied without any additional data or justification, so **FI** did not accept the factor. **NL** prepared the CAR at the time the correction factor was not established. **NL** agreed with using the factor only if there is supporting data available. **NO** was also of the same opinion as the **UK**, that Applicants should not be punished for submitting good leaching data. The correction factor should not be applied unless supportive data is presented. **IND** clarified that the correction factor did not only account for an overestimation of the leaching rate by the mass balance calculation method but also accounts for the difference between leaching in steady conditions and leaching in dynamic conditions. The leaching rate is higher when the ship is moving than when the ship is anchored in the harbour. Therefore, within this context, when using the correction factor with the leaching rate calculated by the mass balance method, ca. 30% is lost in the marina or harbour when ship is at berth, 10% is lost on removal of spent paint and the remaining 60% would come out into water mainly outside the harbour or marina, when ship is moving. **NO** added that if now the wider envirionment scenario was going to be considered the ships were indeed moving. So it might be that considering the 2.9 in this case would be wrong. COM concluded that in order to use the correction factor 2.9 some justification is needed.

COM closed the discussion on the general issues on antifoulings paints.

4b. Copper pyrithione (RMS: SE)

-

4c. DCOIT (RMS: NO)

-

4d. Cybutryine (RMS: NL)

-

5. SUBSTANCES in PT 01

5a. Glutaraldehyde (RMS: FI)

-

6. SUBSTANCES in PT 12

6a. Ammonium bromide (RMS: SE)

-

7. AOB

7a. Outcome consultation PT 11 rapid reacting chemicals in cooling water systems

COM thanks NL for carrying out this e-consultation which addresses many open issues of the discussion we will have on sodium and ammonium bromides. This consultation is subdivided in two parts, part A on the risk evaluation for the terrestrial compartment and part B on the risk evaluation for the aquatic compartment.

NL introduced the e-consultation saying that the questions are addressing not only fast reacting substances but also other substances in cooling water systems. However, slowly reacting substances in the terrestrial environment will be assessed as normally done in the risk assessment. For rapidly reacting substances we first need to know if the reach the surface of the soil. The first question is how to assess the spray drift to soil and to know to which area for water cooling systems and if TM accept the evaporation values.

COM structured the discussion following the open issues raised by NL.

A. the risk evaluation for the terrestrial compartment

A1. Is the emission route to soil from spray drift of cooling water with rapid reacting chemicals: a. negligible for small open recirculating cooling systems, and b. relevant for large open recirculating and once through cooling systems?

On this first issue TM discussed two questions:

- Does the TM accept to use AREAdepos of 75000 m2 for once through, large and small recirculating cooling systems.

DE has made some rough estimation resulting in a deposition are of 60,000 m2 for a 100 m of cooling tower. NL: ask if this is relevant for once through, large and small re-circulating cooling systems or only for smalls? DE: has no information to reply to NL question.

TM accept to use 75000 m2.

- Does the TM accept Fevap+drift default 0.01, with refinement to 0.0005 or 0.0001 (which one?) if mitigation measures are set in place.

ES: Spain supports the drift factor of 0.0005, the use of drift eliminators is mandatory in Spain. DE found the value of 0.0001 in BREF which should be taken into account. Refinement should be always justified, nee to assure that drift eliminators are installed, FR regulation impose a fraction of 0,0001. Refinement can be always possible. CH: Would like to know about the mitigation that justifies the other values. NL: FR and ES are using mitigation methods. For the RA 0.01 values can be lower when mitigation measures are in place. FR: it is a system that reduces the evaporation of water, and the water comes down in the system instead that to the air. There is less evaporation in the system.

NL ask if ion ES and FR are legal requirements is because they have a systems that reduce the drift and this can be different from MS. ES propose to use the higher value and for PA each country can use their value. NL in MS are IPPC regulations that introduces mitigation measures that allows to reduce the values.

For annex 1 inclusion we will go for 0.0001 if IPPC measures are in place. CH has problems with the mitigation measures and would like to require more information on this. NL proposed to introduce more text to explain how IPPC Directive is applied.

For Annex I inclusion: TM accepts the Fevap+ drift default 0.01, with refinement to 0.0001 if mitigation measures are set in place. NL will add an explanation in the document on the mitigation measures proposed by the IPPC Directive.

At the Product Authorisation each country should use the value stipulated by their national law.

A2. Should we request for soil tests and/or surface eco-toxicity tests in case of use in large open re-circulating and once through cooling systems?

TM considers that the tiered approach proposed by NL is acceptable.

A3. Can we use assessment factors used for PNECsoil (expressed as mg/kg wet weight soil also for deriving PNECsoil (expressed as on mg/m2 soil)?

NL ask if discussion on not rapidly degradable substance should take place. FIN: not clear what means rapidly degradable substance, is degradation occurring in seconds or minutes, on which time? COM: a definition on rapidly degrading substances is not available.

TM: agrees with NL proposal that for rapidly degrading substances with soil exposure via spray-drift PNECterrestrial is derived based on mg a.s./m2. The risk assessment of substances that do not rapidly degrade should be based on PNECsoil (mg/kg soil ww and dw).

A4. Is it possible to include mitigation measures? If yes, do you have suggestions?

NL: If there is a risk it is possible to include mitigation measures, drift eliminators can be introduced, NL will add some more text. In some countries like in ES it is mandatory to have mitigation measures like drift eliminators which will reduce the emissions to soil.
COM: asked MS to send NL other possible mitigation measures used in their countries and NL proposed to RMS to add in their CARs that mitigation measures could be required at Product Authorisation stage.

B. Evaluation of the aquatic compartment

B1. Is the direct emission route to surface water in treated cooling water: a. negligible for small open re-circulating cooling systems and b. relevant for use in once-through cooling systems and large open re-circulating cooling systems resulting in exposure of aquatic organisms?

NL: we have 3 types of systems, small open re-circulating cooling systems, once-through cooling systems and large open re-circulating cooling systems. We discuss what sort of dilution factors should apply. Should we use STP or not? TM discussed which is the maximum dilution that can be applied and it is agreed that 1000 should be the maximum one. On the other side TM discussed if the dilution factor could go below 2 or 5? ES introduced the data gathered in Spanish rivers, in particular the Tajo river. In ES in summer flow rate is very small and factor 50 can not be applicable. ES propose that the dilution factor 10 could be acceptable. NL: Are cut off values for dilution factors? We could suggest a factor 10. ES can try to find more information on south rivers. NL: We should assure that installations are in likely places to occur. FR: in FR large plants are submitted to authorization, and it is done site by site. Each plant knows the conditions of its effluent releases as the dilution, therefore minimum dilution of 10 can be assumed.

Questions discussed by the TM:

1. Can the TM accept to use the five levels of river flow rates 0.2, 2, 15, 100 and 1000 m3/s in the risk assessment?

Taking the proposal of 10 dilution factor of ES on board this requires recalculation of the 2 m^3/s river. NL will adapt the table. This will result in a change of the 2 m3/s river to a lower flow rate.

TM agrees

2. Can the TM agree on the dilution factors as proposed in the table above?

Chair: dilution factors can not be lower than 10 and the maximum dilution factor is 1000.

TM agrees on the following dilution factors from cooling system to surface:

	Dilution factors **ESD closed cooling system***	**ESD small cooling system***	**ESD large cooling system****	**ESD once through****
Discharge (m3/s)	*1.11E-07*	*5.56E-04*	*3.47E-02*	*6.67*
TGD river 0.2 m^3/s	1000	350	Not applicable***	Not applicable
rivers 0,5 m^3/s	1000	1000	10	Not applicable
rivers 15 m^3/s	1000	1000	200	Not applicable
rivers 100 m^3/s	1000	1000	1000	10
rivers 1000 m^3/s	1000	1000	1000	50

* Closed and small cooling systems have the option to restrict emissions via the STP

** Only option for restriction is the increase minimum flow rate of the receiving water

*** A dilution factor <10 is not considered realistic, nor acceptable and therefore not part of the risk assessment. Large cooling systems and once through cooling systems will not release treated cooling water to rivers with a too low flow rate, resulting in a dilution factor of <10.

3. Can the TM agree that dilution factors below 10 or 50 (which one) are not realistic and that this type of emission should be excluded from the calculations?

After discussion *TM agreed for rivers with 100 m^3/s in once through cooling system a dilution factor of 10*.

4. Can the TM agree that dilution factor of 1000 is the highest dilution factor acceptable for direct emissions?

TM Conclusion: dilution factor of 1000 is the highest dilution factor acceptable for direct emissions.

5. What dilution factor is required for emissions to (stagnant) large lakes?

IND asked MS to consider for annex I inclusion the worst case scenario and at product authorization the national values should be considered.

TM Conclusion: NL will develop a national approach. Other MS are invited to communicate with NL on other national practices.

B2. In some Member States emissions to surface water from cooling water systems are regulated. Should we take these approaches into account for our risk assessment? If yes, can you provide information on these approaches in your Member State, for harmonization purposes?

Further harmonization is considered preferable, but still under development. UK: no MS specific issues for Annex I inclusion. In UK no need to do more at product authorisation. In other MS that do not have the controls the risk assessment may be useful as NL proposed.

B3. The PNEC for these reactive substances is based on acute data with a large assessment factor of 1000. In most cases the PNEC will be below detection limit. Knowing the working mechanism of these reactive substances, is it possible to use the LOQ or a standard used in regulations in stead?

NL: DE and NL do not agree with the text proposed by NL. The main problem is that we do not have measurable concentrations, especially for rapid degradable substances.

TM Conclusion: MS does not agree with the text proposed by NL. NL will include in the document the discussion made by DE and UK.

B4. Is it possible to include mitigation measures? If yes, do you have suggestions?

NL: FIN has communicated mitigation measures. But there are many options for each system and location with different mitigation measures to prevent discharges. **FIN:** No more specific information as communicated in the written comments. **NL:** proposes as stated in the document. Only generic scenario is possible in the risk assessment for Annex I inclusion. **CH:** Which frequency is expected, daily, monthly? **NL**: large systems are 2 per year in smaller systems may be each month.

Conclusion: NL will revise the document which will include the discussion and will inform COM on the timing for finalization.

7b. Input to draft guidance on the use of topcoat for PT 08 products

DK introduced the document **DK** has produced regarding draft guidance for the use of top coating products for PT 08. **DK** has finished almost all product authorisations for wood preservatives and produced this document with some suggestions on how to deal with leaching studies. The majority of the leaching studies for the product authorisations that **DK** received were performed with a top coat in place. **DK** proposed to apply a factor of 10 to the leaching rate, this factor would cover those cases where **IND** wants any type of topcoat applied to their wood preservative, meaning other top coats than the one applied in the leaching study, and is also used to cover the uncertainty of how well amateurs apply the top coat. **NL** asked if **DK** could inform the **TM** on the background of the factors 5 and 10 used in the document, on what a "stable" topcoat is, and on the definition of **DK** for TIME2. **DK** responded that the proposal would apply to the laboratory leaching test and the semi-field leaching test and that the factor 5 would be applied in those cases where a "stable" topcoat would be applied. The "stable test" (EN927-2) describes the whole system, not only the topcoat. It is among others a visual test, physical parameters are tested, and resistance to UV-light, etc. **NL** then asked if such a test should be a requirement for product authorisation. **DK** responded that in many cases this test had already been performed by **IND** and could be provided. **NL** commented that it might indeed be the case that a "stable" topcoat would be used initially, however that a cheaper, less efficient top coat could be used in the future which would result in higher leaching and thus higher emissions. **DK** argued that in many cases a guarantee of up to 15 years is given for treated wood including a top coat. **NO** commented that **NO** was not familiar with the "stable" top coat test but that if it is a practical and feasible test to perform it could be used as a requirement for product authorisation, however **NO** would like to see paint manufacturers, who do have experience in the performance of such tests, involved. **NO** furthermore questioned the basis for the factor 10, **NO** stated that amateurs might be as good in applying topcoats as professionals and that there is no system in place in **NO** for qualifying as a professional painter as it is in for instance **DE**. **NO** favoured to use the leaching rate with topcoat for one year (study duration) in case a risk is identified for the uncoated samples and then revert back to a long-time leaching rate without top coat as it has been done in the dichlofluanide asesesement. **COM** explained some of the criticism on the **UK** approach (i.e. a sudden change in leaching behaviour in time). **DK** reacted that 10-15 different top coats are normally used, based on information by **IND**, therefore basing the leaching on tests using one specific top coat only would be unrealistic.

SE commented that there is a lack of technical experience in **SE**; however, **SE** was of the opinion that the factors proposed by **DK** are a bit high, although **SE** did not have a basis for that opinion. **COM** informed that during the CA-meeting it was discussed that the outcome of results of more leaching tests and the use of top coats would be necessary before deciding on a definitive approach for top coats. However, there is a need for a way forward to deal with current product authorisations. **NO** commented that in their assessments a maximum reduction in leaching rate by top coats of a factor 10 was observed for one a.s. and only a factor of 2 for another a.s... Therefore **NO** thinks that applying a factor of 10 would not be realistic since the factor 10 would only level out the reduction of leaching. **UK** agreed with the comment by **NO**, and remarked that in the **DK** scheme there is no requirement for **IND** to justify the choice of top coat. **UK** would like to see a minimum requirement for the use of a top coat. **UK** additionally mentioned that **UK** has a lot of data and proposed to share these data with other MS in order to see if the factors proposed by **DK** are right or that an average factor can be deduced from the available leaching test data.. **DK** reacted that among the products assessed by **DK** a maximum reduction of leaching rate of a factor 70 was observed, and that the reduction seemed to depend on the active substance as well as on the top coat. **UK** wondered if then a factor 10 would be enough if leaching tests would be performed using a 70 times reduction with top coat while in reality a top coat might be used which reduces leaching by only a small factor.

COM put forward that a lead would be necessary for such a comparison of leaching data and the effect of top coats. **NL** supported **UK** in comparing the available data and proposed **COM** to bring all the data together. **NL** additionally remarked that there is insecurity about the time frame of TIME2. **NO** commented that **NO** will investigate if they have resources to coordinate such a project **COM** highlighted the main discussed issues and closed the discussion.

Conclusions:

- Further discussion is needed on the time frame for TIME 2
- Minimum requirements for a top coat need to be identified
- Further information regarding the "stable" top coat test (i.e. EN927-2) is needed, IND should be asked if this test is carried out on a regular basis and suitable to be included in the assessment.
- Further justification of the proposed factors 10 and 5 is needed, where a project to analyse available data is proposed.

NO will investigate if **NO** has possible resources to coordinate the collection of leaching rates. If so, than **NO** will send out a template to be filled in by the other MS with information regarding the leaching tests and the top coats used.