Final Minutes TM II 2011

Biocides Technical Meeting
06 - 10 June 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 II 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 further changes.

2. Adoption of the minutes

COM posted in CIRCA version 1 of the minutes to which comments were sent by MS and several Applicants. The amended version of the minutes, version 2, was uploaded before the TM. After that **COM** received comments from **SE** and **FI** related to clarifing their position in one of the agenda items in the ENV session concerning the use of top coating as a risk mitigation method.

IND also sent out comments on Transfluthrin in which they also clarify their position in the discussion on the toxicological part. **COM** suggested including these comments since they were intended to clarify positions and the conclusions of the minutes were not affected.
No other comments to the ultimate version of the minutes were made during the TM. Therefore, with these mentioned additions the draft minutes were adopted. The minutes would be published on CIRCA after the TM.

Additionally, **COM** indicated that during the last TM there were some troubles with the recording and explained that the minutes of permethrin for the TOX session had to be reconstructed. As result two points needed to be clarified.

Derivation of AEL acute (item 1b.2 of the agenda)
UK commented that the value for the AEL_{acute} 0.15 mg/kg body weight per day for permethrin was more accurate than the one in the minutes (0.5). **IE** clarified the value proposed was from the summary studies published by JMPR and the value that was decided upon was from a study from the CAR. The understanding of **IE** was that the value 0.50 was ultimately agreed. **COM** added the data of the JMPR study was not available to the RMS, therefore the accepted value of 0.50 mg/kg bw/day came from a study where data were available. **COM** suggested to keep the value and asked **IE** to check again and come back to the TM if necessary.

Genotoxicity
SE commented on additional / inconclusive *in vitro* studies. Permethrin was also evaluated under the PPP by **IE**. Regarding the mouse micronucleus study the understanding of **IE** was to include in the CAR the findings of two additional MN studies from the PPP to make the genotoxicity section more robust. **COM** proposed to keep the wording in the minutes as it is now and the **RMS** to revise the studies and include more explanations. The RMS can start to prepare the draft final CAR, and if needed the dossier can be discussed again at the TM. The point is considered closed with the additional data that will be included.

3. Action List TM

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

   No information has been received by CEPE on where they are now on the development of the scenario.

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

   PL will revise and finalise the guidance document and forward to the CA meeting in September.

3. *Distribute list with tasks MS in EUSES training validation exercise and prepare the exercise.*

   COM informed that they are setting now the contract to repair some bugs in the current EUSES version. Thereafter the training validation exercise will be started.

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

   COM contacted **IND** on the progress on this action item. **IND** will provide some documents after the summer.

5. *Review of current efficacy guidance for PT 21 in TNsG on Product Evaluation document.*

   COM distributed the document for the first commenting round.

6. *Position paper on substance identity of isomeric mixtures.*

   COM will contact the relevant MS on the preparation of such a document. Once the document would be finalised it would be circulated for comments and included in the MOTA.

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

   COM is waiting for the document prepared by SE, this action item was discussed as agenda item 5f of the ENV Session (TM II 2011). This will come back in September

8. *Consult with the applicants for PT 13 in the Review Program to obtain more information on the parameters used in the ESD for PT 13.*

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

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

   COM received the document from **DE**. Information will be made available in the web page together with the ESD for PT 22.

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

    COM will consult with **DK** during the ENV session the status of the document.

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

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5. Next Technical Meetings

2011

TM III 3 – 7 October

TM IV 12 – 16 December

CA meetings: 5 - 8 July, 20 - 23 September and 6 - 9 December

TOXICOLOGY SESSION

1. SUBSTANCES in PT 08

1a. Cypermethrin (RMS: BE)

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1a. DDACarbonate (RMS: UK)

-

2. SUBSTANCES in PT 18

2a. Silicon dioxide – Degussa/Evonik (RMS: FR)

-

2b. D-phenothrin (RMS: IE)

-

2c. *Bacillus sphaericus* (RMS: IT)

-

3. SUBSTANCES in PT 19

3a. Lauric acid (RMS: DE)

-

4. SUBSTANCES in PT 23

4a. Al phosphide (RMS: DE)

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5. AOB

5a. Update HEEG:

5a.1 HEEG Workshop

COM informed on the HEEG workshop that took place in Paris, 3rd – 5th of May. The outcomes were as follows:
1. Assessment of rodenticides using the Chambers study – position finalised;

2. Assessment of inhalation exposure and when to consider a substance as volatile – discussion finalised, position paper in the drafting process;
3. Immersion of hands into liquids – discussion finalised, position paper in the drafting process;
4. Default parameter values for standard individuals – position paper in the drafting process; in order to coordinate with the values proposed by the Nordic Exposure Group the paper is pending until the publication of the final paper on "Existing Default Values in Exposure Assessment ";
5. PT6 exposure assessment: representative uses, combined exposure – concept paper in the drafting process;
6. PT 2 – IT approach in exposure assessment – concept paper in the drafting process;
7. How to facilitate a harmonised exposure assessment at product authorisation – proposal to create "Human Exposure Scenario Documents"; FR and DE indicated their interest to lead the work for PT 14 and IT for PT 2.
8. Brush painting of wood preservatives – discussion started;
9. Datasets; validation and support – a concept paper to follow;
10. Exposure IT tools – use and limitations of ConsExpo and BEAT;
11. GExFRAME – presentation of the tool and a discussion on possible uses;
12. Training on IT exposure tools – JRC is exploring the possibility to co-organise a training in the first two weeks of November 2011;
13. Connection between REACH, PPP and biocides – responsible with exposure to be identified;
14. Procedural matters of HEEG;
15. Cumulative and aggregate exposure – AT prepared a follow up paper that will be developed for TM.

COM asked the TM if the idea of drafting "Human Exposure Scenario Documents" for the use at the level of product authorisation is supported by the TM and clarified that the initial draft should be based on the assessments and exposure scenarios performed for the active substances. COM asked if such documents should be organised based on product types or on uses. COM asked if sufficient resources would be available.
UK, **DK** confirmed the usefulness of the approach and the interest to participate.

COM informed the TM that HEEG considered necessary a wider participation from the MSs and that it may be useful if each MS nominates a member to the group.

DK supported the training regarding ConsExpo and BEAT and asked how many participants per MS are envisaged. **COM** answered that one participant per MS is foreseen and if free places remain, they will be offered on a first come, first served basis.

5a.2 HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants) – Chambers study

DE presented the paper that mainly covers the exposure due to the manipulation of rodenticides formulated as grain baits or wax blocks and is based on the Chamber *et al* study. The paper covers the professional use. CEFIC is the owner of the study and if an Applicant is to base its assessment on this paper, a letter of access would be necessary. For the drafting of the paper the discussion of HEEG covered the dossiers of the Annex I included rodenticides, the Chambers study and the pilot Snowdon study. HEEG agreed to take the 75^{th} percentile as the data basis, instead of the arithmetic or of the geometric mean. DE expressed the confidence that the paper will also be helpful for the product authorisation of rodenticides.

UK, **NO** supported the approach and the paper.

CEFIC asked for a clarification on point 1.2.2, block baits, application phase. In the second paragraph a reference is made to a factor that was used by some MSs to cover for the weight of the bait. It is noted that in the paper such an approach is not advised and in the examples a supplementary factor is not used, but this is not completely clear. CEFIC asked for a clarification in the paper stating that such a factor should not be used. **DE** confirmed that CEFIC was right and agreed to introduce the clarification. Also the editorial comments received from **FR** and **UK** will be included.

TM has endorsed the paper.

Conclusion: the paper was endorsed by the TM; the agreed clarifications will be introduced by DE.

5b. MOTA and oral absorption

The TM agreed to the proposal of FR to add the following technical decision to MOTA:

In case according to experimental data the oral absorption rate exceeds 80% then the default value of 100% should be applied for the derivation of AELs and internal exposure levels *via* the oral route.

5c. Dietary risk assessment

FR presented the position paper (see room document) on performing dietary risk assessment (DRA) at the Annex I inclusion stage. **FR** proposed to perform a worst case scenario DRA for the representative uses. The assessment may be refined and if needed proceed with MRLs setting. **FR** suggested that DRAWG may give support to the RMS if needed. A number of points were discussed in relation to the position paper. The main issues were *when*, *what* and *how* to perform DRA. Though the TM unanimously agreed that in principle DRA should be performed before Annex I inclusion, the present feasibility was questioned. The DRAWG is developing guidances for the DRA. The guidance for animal husbandry can already be used; the first draft for the guidance of food exposure is expected for early 2012. **IE** considered the position paper as a policy proposal that needs to be discussed at the CA level. **UK** proposed to apply a reverse reference scenario when food contamination is plausible. **UK** presented the example of metafluthrin: the food lying on surfaces being contaminated by a plug in vaporiser had been assessed, and the number of sandwiches needed to be eaten to reach the AEL had been determined. **UK** said if risks are unacceptable the product may be labelled as "*do not use where food is likely to be contaminated*". **SE** supported to use the reverse reference scenario till the guidance becomes available. **DE** pointed out to consider the MRL setting procedure. MRLs are not set for private uses of biocides, but are important *for example.* for disinfectants used in the food industry. DRA is an integral part of the MRL setting procedure, i.e. MRLs are set based on the results of DRA. The MRL setting procedure involves other authorities (EMA, EFSA)), which will require additional time. To avoid running out of the timeframe at the product authorization level, **DE** warned, a solution should be found; the issue needs to be forwarded to the CA. **SE,** supported by **UK** requested to have a transitional period for applying the new guidance and to set a date when compliance will be compulsory. **IE** observed that a PAMRFG document is under way on when guidance becomes applicable. The scope of the position paper should be refined: more elaboration is needed to define for which uses DRA needs to be carried; and to establish scenarios outside of other legislative frameworks (Food Legislation). Also, all references to any specific a.s. need to be removed. Regarding d-phenothrin, **IE** stressed that the conclusion of the previous TM was that the use was not assessed in food and feed areas, but a safe use was found in other areas. It was clearly stated in the CAR that if food and feed areas are to be evaluated at the product authorisation stage

then a DRA may be required. **COM** emphasised that if DRA is not preformed at AnnexI inclusion for a certain use which may lead to food contamination it does not preclude nor support such a use. It has to be stated in the CAR, under elements to be taken into account at product authorisation, that the assessment needs to be carried out before authorizing such a use. Carrying out a DRA without a guidance document was not considered feasible. **IE** pointed out that the main products may have multiple uses in multiple areas which may not all be assessed at AnnexI level. **IE** wondered whether specific uses need to be assessed or left to product authorization; and what happens when uses are multiple, it may include a use in kitchens, which may not be specifically assessed in the CAR. The default parameters, *e.g.* size of the room, number of spraying, target organism (cockroach *vs* house fly), square meterage of surfaces etc.; the use of a tiered approach; and the consequences of not acceptable risks (risk management options and MRL setting) need to be agreed upon. **IND** supported performing a DRA at the Annex I inclusion stage and suggested finding a pragmatic approach to be able to carry out the DRA at this stage. **IND** proposed to group the a.s. where DRA is not needed, for which specific issues are present and emphasized not to go into too much detail which would render the assessment difficult to carry out. If the DRA needs to be performed for very specific uses, the Applicants will withdraw the relevant uses at Annex I. **DE** answered that DRAWG is looking at all the ways food can be contaminated through an intended use. Without going into detail **DE** does not see the usefulness of a guideline. The IND representative actively involved in the development of the DRA guidance has the opportunity to present the views of industry. **COM** proposed FR to reconsider whether the position paper should be forwarded to the CA. It is present practice that in principle DRA needs to be performed at AnnexI inclusion; DRAWG is working on the methodology for this.

Conclusion: FR to decide whether to rewords the position paper to be sent to the CA or withdraw it. If position paper is to go to CA, the references to any specific a.s. needs to be taken out and the scope, i.e. in which cases a DRA should be performed needs to be elaborated. The CA needs to be informed that postponing the DRA to product authorization may lead to running out of the available timeframe, because if MRL setting is required other bodies are to be involved (EMA, EFSA).

GENERAL SESSION

COM opened the general session welcoming the participants and inviting **MS** to raise any additional point for discussion they might have. **COM** informed the TM that they had and additional point on the mutual agreement **COM** had with Switzerland. The TM would be informed under A.O.B. item 7. No additional items were included for discussion. **COM** considered the agenda as endorsed.

1. Reporting on 39th and 40th CA meeting

COM reported on the outcome of both CA meetings.

2. Tracking System: Progress reports

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3. SUBSTANCES in PT 08

3a. Specification of copper compounds

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3b. Cypermethrin (RMS: BE)

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3c. DDACarbonate (RMS: UK)

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4. SUBSTANCES in PT 18

4a. Silicon dioxide – Degussa / Evonik (RMS: FR)

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4b. D-phenothrin (RMS: IE)

-

4c. Bacillus sphaericus (RMS: IT)

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5. SUBSTANCES in PT 19

5a. Lauric acid (RMS: DE)

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6. SUBSTANCES in PT 23

6a. Al phosphide (RMS: DE)

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7. AOB

7a. TM procedures

COM introduced the document prepared by **FI**, which included some proposals on procedures for the TM, namely, how to deal with bilateral consultations and how to proceed after the discussion had come to the TM. **COM** reviewed the original document and put in some modifications. **COM** agreed with **FI** to bring the document together with these modifications for discussion to the TM. **COM** opened the discussion on the document where the main proposal would be to introduce the content of this document in the MOTA in a chapter named "TM procedures" as questions and answers.

NO welcomed the document and highlighted that it was very important for the TM preparation that issues that were to be discuss were clearly indicated and that bilateral discussions were included in the RCOM table. **COM** agreed with **NO** that it was important to reflect the results of these bilateral consultations in the RCOM table. This would allow **MS** to be informed on any bilateral discussion on going between the **RMS** and the **MS** who made the comment. **SE** on the other hand was concerned about the fact that comments or issues highlighted as "to be discussed" were not finally discussed. **SE** asked if it would be possible, for the sake of clarity, to provide a room document to highlight what comments would be discussed. **SE** suggested a two week's deadline before the TM.

COM explained that during the process to prepare the TM and always in consultation with the **RMS**, **COM** identified comments that they would like to discuss at the meeting. Most of the time, this identification ended up only days before the TM. The same happened with the bilateral consultations, which often went on until the very last moment, even continued in the meeting itself. **COM** was not against providing this information, but this could only be done the day before the TM. On the other hand **COM** stated that at the beginning of the discussions, **COM** always clearly indicated which issues were going to be discuss, giving then the opportunity to **MSs** to raise any relevant issue that were not identified neither by the **COM** nor by the **RMS**.

DE agreed with **SE** and they indicated that they would also like to have the list of identified issues even if it was only the day before the TM. In their opinion RCOM tables are too long to deal with during the TM especially if one has to follow all the comments. **DE** also proposed to make available in CIRCA the list of open points sent by **RMS** to **COM** before the TM. Concerning the bilateral discussion during the commenting period, **DE** indicated also that for **RMS** it was sometimes very difficult to include bilateral discussions in the RCOM since they were quite lengthy.

COM clarified that in the document the **COM** was not asking for inclusion of the bilateral discussions in the document that it is uploaded for discussion during the meeting. The current procedure stated that the consolidated response tables should be uploaded in CIRCA 5 weeks before the TM. As previously mentioned bilateral consultation went on until the very last day,

thus this would not be feasible. But after that, the bilateral consultations should be reflected in the RCOM.

COM on the other hand, can not oblige **RMS** to send before the TM a list with pre-identified issues to be discussed. Then **COM** would rather prefer to stick to the way it is now, where identified issues/comments are stated at the beginning of the discussion. This allowed **MSs** to check which issues are being discussed and whether all their identified issues had been taken on board for discussion. **COM** assumes that identifying issues for discussion by MSs forms part of the preparation to the TM.

In order to close the discussion **COM** asked **FI** if the content of the document had been well covered during the discussion and if there were additional comments. **FI** did not have any additional comment.

COM then concluded that the document presented by **FI** and amended by **COM** will be incorporated to the MOTA as questions&answers in the way it is reflected in the document. **COM** closed the discussion by urging MSs to make clear before the TM which issues they would like to raise for discussion.

7b.General principles testing efficacy for preservatives

COM informed the **TM** that **DE** was currently working on a document on "the general principles for testing efficacy for preservatives". **DE** has sent the document to the **COM,** who suggested starting with an e-consultation since, there is an established group of effcqcy experts. **DE** has now circulated the document and is waiting for comments to revise the document. The amended document will be brought for discussion and endorsement to the next TM. **DE** reminded the TM that 8th July was the date set as the deadline and kindly ask for comments.

7c. Mutual agreement with Switzerland.

COM informed that in October 2010 the **EU** and **CH** agreed on mutual recognition of biocidal products. This implies that **CH** now counts as any other country in terms of mutual recognition and authorisations of biocidal products. Additionally **CH** can also be Rapporteur for Annex I inclusion. In the context of this agreement the **COM** has made the declaration that they will consult **CH** experts in the preparation of draft legislations and invite Swiss experts to the expert group meetings. For the **TM** the mutual agreement means that **CH** will have full member status. Therefore, comments made by **CH** during meetings, comments sent when a document is posted in CIRCA or comments to the draft CARs during the 90 days will be taken into account by the **RMS** as it is done with the comments from any other country.

ENVIRONMENT SESSION

COM opened the Environment Session by informing the **TM** concerning the ESDs for PT 2, 3 and 4 which were endorsed at the last CA meeting. The ESDs will be soon available in the biocides website (http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/).

COM also informed of two projects related with wood preservatives that had been finalised recently. The first one was on the revision of the ESD from the OECD. **COM** would like to table it for discussion at the next TM and after that it would go through the OECD formal adoption process. The second project related to the evaluation of the experience in the determination of the leaching rate for wood preservatives, where several MS took part as steering committee. The final report would be made available via CIRCA. COM informed the TM that a second leaching rate workshop is foreseen, date to be determined.

The agenda was endorsed.

1. SUBSTANCES in PT 08

1a. Cypermethrin (RMS: BE)

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1b. DDACarbonate (RMS: UK)

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2. SUBSTANCES in PT 18

2a. D-phenothrin (RMS: IE)

-

2b. Bacillus spaericus (RMS: IT)

-

3. SUBSTANCES in PT 19

3a. Lauric acid (RMS: DE)

-

4. SUBSTANCES in PT 23

4a. Al phosphide (RMS: DE)

-

5. AOB

5a. Groundwater assessment and Annex I inclusion

Discussion on the number of the 9 EU standard FOCUS Scenarios which should demonstrate no risk for Annex I inclusion.

Background: Within the Review Programme, the approach followed was that suggested under Directive 91/41/CE for PPP, where one FOCUS scenario showing a safe use of the a.s was considered enough for annex I listing. At national authorisation level member states can check for their own scenarios. The term “safe” means that the groundwater trigger value of 0.1 µg/L of the EU Groundwater Directive is not exceeded.

The question was discussed at two TM Biocides in 2010 (together with the harmonisation of FOCUS groundwater model PEARL for PT 18, insecticides used in stables and manure storage systems), but no final conclusion could be drawn. Several member states did not agree with the followed approach and would prefer to have more scenarios with a safe use in order to be listed in Annex I. Thus, the issue was brought to the **TM** for final discussion before sending the conclusions to the CA.

In order to get a realistic picture of the situation, **COM** asked the **TM** how many scenarios would be check within countries to grant the biocidal approval. **UK** indicated that at least 5 scenarios would be needed in their specific situation.

BE indicated that under the BPD it was stated that for Annex I inclusion at least one safe use should be found. **BE** proposed to follow still the PPP approach: for Annex I listing, one of the scenarios showing a safe use was enough, at national authorisation **RMS** were free to check their particular conditions.

DE described a similar situation to the one described in the **UK** where several scenarios are check-up. According to **DE**, the so called "Hamburg scenario" does not represent the German soils and therefore would not be sufficient. **DE** supported the need of more than one safe scenario for Annex I inclusion. On the other hand, **IE** indicated that they also looked at several scenarios that had been identified as relevant for the Irish agricultural environments. Nevertheless, for Annex I inclusion they were still of the opinion that the applicant should only show one safe use. **EL** supported **BE** and **IE**, one safe scenario is enough for annex I inclusion. According to **EL**, the nine FOCUS ground water scenarios represented a Tier 1 approach and did not represent an actual measurement of the groundwater leaching as monitoring would be. **EL** for national authorisation required the scenarios that are specific to the south zone to be below the trigger value since they were more relevant to the Greek's scenarios. **EL** also indicated that in the case that the scenario also felt down the trigger value this didn’t necessarily mean that the product could not be authorised at all. Lysimeter studies were then considered. FOCUS ground water modeling was not the only tool for decision at MS level. **ES** agreed with **EL** and added that the FOCUS ground

water scenarios were not originally designed for biocides, and this some times had made it difficult to implement the emission scenario documents.

UK wondered where this comment on only one safe use in the PPP program came from since most companies would normally withdraw the use of the pesticide if only one safe use is demonstrated in surface water. With regard to what had previously been done in the biocidal review program, **UK** stated that the fewer scenarios are needed for Annex I listing, the more additional work **MS** will have to do at national authorisation level for registration of the biocidal products. Five scenarios showing a safe use will lead to significantly less work. **DK** supports the general view of **UK** and **DE**.

SE stuck to the previous statement in which they agreed with only one safe use being enough for Annex I listing, but they would also like to indicate that it was up to the applicant to support their intended uses. In **SE** this would mean that for national authorisation two or three scenarios should show a safe use. **FR** support **DE** and **UK**. **CH** was also of the same opinion, and at least three scenarios should show a safe use of the a.s. for Annex I listing. The rationale behind was that if there was a large contamination of scenarios then it was clear that there would not be a safe use of the a.s.
NL on the other hand, stuck to their original conclusion, one safe scenario was enough.

COM referred to the TM again that information on the number of scenarios assessed at national level would be a good piece of information. The idea behind is that by knowing this Applicants would know which data was required for ground water risk assessment in terms of modelling.

EL indicated that applicants normally submit the whole package of scenarios covered by FOCUS. **BE** reminded the TM that the dead line for the submission of the fourth priority list was already over. Then pressure should not be placed on the applicant this would delay the whole process and this is not what we were trying to do. BE also stated, that it might be unfair not to keep the same rules.

The TM could not reach a final decision. Thus, **COM** concluded that the discussion would be covered in a paper and sent to the CA meeting so they could decide on the issue. **COM** agreed a 6 weeks period for submission of information on the number of scenarios needed at national authorisation level.

5b. Risk mitigation measures for PT 21

COM informed that no representatives from **CEPE** (European Council of producers and importers of paints, printing inks and artists' colours) could be available for discussion during the TM. However, **CEPE** provided the **COM** with a letter presenting the documents submitted and uploaded in CIRCA for consideration of the **MS**. They proposed to discuss these documents both at the **TM** and in the PT 21 e-consultation group so they could be used within the frame of the risk assessment of PT 21. Following issues were highlighted,

The ESD for antifoulings addressed the antifouling paint application and removal stages with relatively conservative assumptions. As more active substances are evaluated it becomes important to identify relevant Risk Mitigation Measures (RMM) and to quantify the effects of these RMM on environmental emissions as far as possible.

The **CEPE** antifouling working group has collaborated with **CESA** (Community of European Shipyard Associations) to identify relevant RMM applied in European shipyards and to quantify the effect of these measures on the reduction of the emissions of these substances to the environment.

In 2006 CESA prepared a document entitle: "statement on protective measures the measures applied to European shipyard relating to the application or removal of antifouling coatings". This document included the results of a survey conducted in the NL on the effect of specific RMM on the quantitative reduction of the emission to the environment during the application and removal of antifouling paints. The paper further described the best practice process to which this reduction relates within the shipyard. In 2010 **CESA** conducted a new survey across Europe, this document focusing on shipyard activities and pollution control to establish the extent to which these best practises have been adopted. The answers received constitute the 80 % of European shipyards activities. This document is entitle “Characterisation of antifouling emission scenario in European shipyard: a survey” on the basis of this information **CEPE** prepared a document: "RMM applicable during application and removal of antifouling paint".
This document defines the effects that specific risk mitigation measures have on the emission antifouling paints to the environment for consideration and use in the risk assessment. **CEPE** propose to discuss this documents both at TM and within the antifouling PT 21 e-consultation group with the view to use them as a basis to determine which mitigation measures are applicable and realistic in relation with the evaluation of active substances and authorisation of antifouling substances. **CEPE** hopes that this document will provide further clarity for competent authorities on the control measure already in place in the shipping industry. CEPE is ready to participate in any discussion or answer any questions on these documents.

COM suggested that since no representatives of CEPE were present to feed both documents in the topics to be discussed within the e-consultation group.

Concerning this PT 21 e-consultation group **UK**, informed the TM that the last email consultation sent to the e-group already covered some of the point for discussion included in the proposal of **CEPE**.

With regard to the **CESA** survey, **UK** noted that some of the values that were quoted from which the indexes were derived were just for one situation of a graving dock it doesn’t cover the most worst case initial situation of sleep ways and the other types of dry docks that are less enclosed that the graving. This is important to be considered when considering the relevance of that data to mitigation.

UK also questioned how representative **CESA** survey was. **CESA** claimed that with their survey they had covered 80% of the EU waters. However the results were based on the 66 responses received (out of ca. 300 members of the association) which roughly represented the 20% of CESA members. Furthermore, the Eurostat website stated that there were 19000 enterprises which perform maintenance and repair of ships in Europe. **UK** then wondered whether the profiles of those who had responded the survey could be used across EU.

COM asked the TM if there were any other comments regarding the documents. Nevertheless, these questions would have to be address in the e-consultation group and also later on when the discussion on antifoulings would come to the TM.**COM** informed that three antifoulings were scheduled for the next TM.

SE agreed with the **UK** on the representativeness of the survey. **SE** also pointed out that the do–it-yourself application was not even included in the survey. Neither was the answer frequencies of the yes and no of the answers of the CESA members incorporated in the frequencies result. For some of the maintenance and repair activities the frequencies of the facilities what they have replied it was not incorporated in the statistics. For some of them is not even more 50%.

COM suggested noting down all these reservations in the minutes and forwards them to **CEPE**.

UK added that they have included in the e-consultation document mitigation using the values in the **CEPE** document. **UK** proposed it is not accepted across the board. Instead, UK has proposed in the document a sort of classification scheme where they distinguish between enterprises which have the full range of mitigation techniques available and those who don't. They also included in the classification the amateurs' use where it is supposed that they do not have any kind of RMM available. The question is how this should be regulated. According to UK in order to answer this, industry should presumably be involved. Otherwise, in the opinion of the **UK,** that would be difficult to regulate without their help.

COM agreed with **UK** that how to regulate and how to include this best practices especially in the do it shelf situation would be crucial**.**

COM concluded the discussion**.**

5c. Proposal DE for "swimming scenario"

As agreed by TM IV-2010 DE has drafted a document outlining the direct release to surface water-scenario (i.e. swimming scenario) which is brought up at this TM II-2011 for commenting by other MS.

The "swimming scenario" was developed for the active substance Lauric Acid in PT19 (RMS: DE) by the German Federal Environment Agency together with the applicant for this active substance. The scenario can be found together with the complete calculations in the draft CAR for Lauric Acid. The aim of the document was to have the opinion of the MS about the applicability of the scenario in a general way as PT 19 and to discuss the specific scenario input data.

Proposal: swimming to take place once a day on 150 days per year as a maximum limit. This time is set as T_{1d} and $T_{emission}$.

Discussion: OMS (DK, IRL, UK, SE, BE, EL, ES) objected on the frequency of the application timing (1 to 3 times per day) and the period (days per year) proposed. Further, SE questioned the surplus value this scenario would give the environmental risk assessment, and that this should be avaluated before spending resources on developing a new scenario. The consequences, if an unacceptable use was identified in the swimming scenario, were also discussed. OMS (NL, ES) are of the opinion that the DE proposal is a hugh improvement from te tonnage approach and there is a need to get relevant information form North to South Europe. CEFIC questioned the relevance of this scenario and asked to be based on more statistics and scientific evidences and relevance of the real effects on man and the environment.

Conclusions: OMS thanks DE for preparing the proposal for an emission scenario taking into account direct releases to surface water when repellents (PT19) are applied to human skin.

MS support the development of the scenario and that there is a need to refine the defaults values. For this purpose MS would like to provide some statistics on the national situation.

DE has developed the scenario with the applicant and on making the calculations with data from PT 19 no risk was found in any of the two (2) scenarios considered. DE does not expect problems to occur. At present a new ESD for PT 19 goes beyond the review process for Annex I inclusion and the RMS will include a statement in the assessment report that direct releases to surface water should be assessed at product authorisation stage.

OMS are asked to send their comments, statistics and additional information to DE by August 15ht 2011.

5d. Outcome e-consultation bronopol

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5e. Outcome e-consultation environmental exposure assessment PT 07, 09 and 10 DE

DE presented the results of the e-consultation concerning the exposure assessment of PT 07, 09, and 10 carried out in March 2011.

The first question was about the annual precipitation which had to be taken into account for the derivation of a leaching rate for TIME 2.

On the question what the correct annual precipitation value was to be applied for emission estimation on biocides, most **MS** and **COM** were in favour of considering the value of 700 mm of annual precipitation. This would be consistent with the TGD and other assessment performed for PT 8. As for some **MS** this value does not represent the national situation, for the authorisation of biocidal products on national level other values would be appropriate.
Therefore, it was proposed to use 700 mm of annual precipitation for the assessment of a.s. for Annex I inclusion.

The second point for discussion concerned the soil compartment that was to be taken into account adjacent to a house. The question to be answer was whether there was the need for adapting the receiving soil volume to a higher value on masonry preservatives.

During the e-consultation no agreement could be reached since the different MS had a different view on the issue. **DE** summarised the answers and **COM** started the discussion.

BE was of the opinion that at least for PT 10 it was not possible to consider mixing, specially not close to a solid construction. **UK** stated that they were aware of the fact that the choice of the 50 x 50 cm distance was not scientifically supported, however for consistency reasons they would support this value until a valid scientific argument was found. **NL** would propose to stick to the values taken for PT 18 which means 10 x 50 cm.
BE agreed with **UK** and **NL** on the need to harmonize between PTs and suggest using the values already agreed for PT 8. The proposal was also supported by **FR** and the rest of **MS**.

DE did not fully agree with the decision of the **TM** since in their opinion the TGD could be use for all PTs and harmonizing with only one PT was not the ideal solution. However the decision would be followed.

COM closed the discussion. Values already agreed for the evaluation of the soil compartment for PT 8 will be used for PT 7, 9 and 10.

5f. Top coating
As agreed during TM I 2011, **UK** prepared the document presented for discussion. This document constituted the continuation of the discussion on top coating for wood preservatives initiated by **AT**. The document was peer-reviewed before the TM and as result, several amendments had been done incorporating the comments made by **MS**. **UK** clarified that they had not ignored any of the comments received. However, some differences in opinion were found in certain areas making their incorporation difficult, this comments had been pointed out and sent for discussion together with the amended document to the TM.

The **UK** suggested that the document here presented could be considered as the start of a living document; nevertheless, for the time being the **UK** didn't have results to go any further in the

development of the document. **UK** summarised the comments received. In brief, the document covered comments ranging from the use of top coating by amateurs and the need to regulate its use, to comments referring to the long term leaching rate.

Concerning the use of top coating by amateurs, the **UK** saw the enforcement in the amateur sector as a political decision. The use in the amateur sector had never being considered as appropriate previously. However, countries know their market best and perhaps this was a decision that could be taken at national level.

UK also pointed out the document was written for mitigation where the mitigation is recommended for the use of a top coat as a specific mitigation measure. It didn't considermitigation for practices which occurred as a matter of course when for example top coating would be applied following the application of a prime which included a biocidal wood preservative. This could maybe be considered for a further stage of the document.

COM thanked the **UK** for the document and stated that they also see the need to discuss the use of the top coating by amateurs. According to the **COM** this should be discussed either at the CA meeting or at the product authorisation group. **COM** also informed on the offer by **CEPE** to gather information concerning the topic, which could bring the document further away.

DK asked **UK** whether it was possible to rephrase some sentences in the first and in the second page. This could help to understand better some of the statements presented in the document. UK agreed to reconsider this paragraph and clarify the text if needed.

DK has another question, last sentence page two; it starts with "many MS are in agreement…." also clarification was needed. **UK** clarified that they only considered the top coating adequate for prefabricated items, items that are fabricated and then sold such as window frames, however they have tried not to skip any other option that is why the sentence had become so complex. **UK** would rephrase the sentence

COM asked the **TM** how to proceed with the document discussed here. In the view of the **COM** one of the options would be to discuss the document at **CA** level or product authorisation group regarding the use of top coating by amateurs.

Concerning the document the **UK** wondered what the opinion of the TM was about the use of top coating as risk mitigation or whether it would be used as part of the treatment regime following application in a prime.

DK stated that have strong reservations about the use of top coating by amateurs and that top coating could also be as part of the treatment system so they consider very important to have this use. According to **DK** in their county the use of top coating could be regulated by claiming that it can be used by amateurs in the proper way. For clarification, **COM** asked if **DK** would be in favour of using the top-coating by amateurs if it can be regulated. **DK** gave a positive answer to the question and added that it was the responsibility of the amateurs to do what they were told to do.

UK has an opposite view on this respect. According to UK this was a **MS** issue, since MS know their market best and knows what can or can't be assumed in this regard.

The **COM** asked if the issue regarding the use of top coatings by amateurs would be to leave the decision to national member states since they can see if it can be regulated. However, the **COM** was anyhow of the opinion that this should be sent to the product authorisation group rather than to the MS since the mutual recognition of this type of application process will be in place soon.

NL on the other hand supported the suggestion of **UK** that top coating for amateurs should be treated at national level due to the specificities of each country. **IE** supported the **UK** and **NL**.

NO supported the **COM** on their proposal to send the document for further discussion at CA or the product authorisation groupl. **NO** pointed out that the two thirds of the detached and semidetached houses in Norway were made of wood. It was a huge market and people maintain the houses themselves. Among other reasons people applied the top coating to enlarge the life of the wood but also for esthetical reasons. According to **NO**, top coating should therefore not be disregarded as a risk mitigation measure to be applied by amateurs.
COM stated that the position of the countries requiring this kind of risk mitigation measures was quite clear.

COM ask for any other comments on the document itself or on the long term leaching, whether this was a harmonised approach that could be used for the moment when it came to the evaluation of the efficacy of top coating until MS gather more experience.

CH asked what the consequences of considering the top coating use at national level would be for Annex I since without the application of the top coating there would not be any safe use. **CH** have the feeling that the approval of the top coating should not be left to national authorisation. **COM** clarified that the question under discussion was whether the application of the top coat could or should be regulated for the amateur market not the use of top coating for Annex I inclusion.

BE state concerning the amateurs use, that Applicants in Belgium are obliged to label the precaution measures, some times even at the top of the container next to the opening place. So when it is well labelled the chances that an amateur user read the warnings are quite high.

Concerning the long term leaching**, COM**, **NL** and **DE** as well, agreed on the suggested proposal by **UK** for the long term leaching

With regard to the comments submitted by **DK**, **UK** asked for some clarification on the comment made concerning method EN 927. UK and DK agreed to solve this point would on bilateral basis.

COM concluded that the meeting supported the content of the document, there will be some rephrasing done as suggested by **DK** and it will be decided by **COM** whether the document will be further discussed at the CA or Product authorisation level..

DK asked **UK** whether they were 100% sure that the components of the top coating should be evaluate under REACH, because the top coating ingredients can interact with the wood preservatives in a way. This will be solved bilaterally.

COM clarified that the question was also that the top coat was not authorised unless it contains a film preservative biocide, then we would indeed need to look to the top coat. We don't authorise the top coat and the leaching test that you may have with the top coat there may be interaction and some other compounds may come out due to this interaction. **COM** stated also that it was assumed that when the top coating is not produced in the EU or when it was imported there will be needed registration of the components under REACH. The use would have to be assessed by the registrant. **UK** stated that taking into account all the possible interactions would render the risk assessment extremely complicate. **COM** agreed on this extent and suggest as way forward contacting **CEPE** for a classification of top coating. **SE** asked how should the biocidal substances present in a top coating be assessed if the wood preservative needs a top coating and this top coat contains the same biocidal a.s. Additionally, SE posed the question about how this would work at national authorisation level and whether this should be assessed jointly or separately.

The **COM** could not answer the question for the time being.

UK came back to the first comment by **DK** (regarding page 1) and asked more clarification on the nature of the question and the changes to be done. **UK** wondered whether **DK** wanted only some rewording or on the contrary wanted some clarification on the content of the paragraph. **DK** wanted the sentence clarified and simplified

UK asked then if this implied that **DK** were happy not to accept top coating as risk mitigation measure to be accepted in Annex I inclusion. **UK** explained that the meaning of the sentence was that "if top coats are required for annex I inclusion as risk mitigation method, then the biocidal active is inappropriate for Annex I listing".
DK answer that they first need to have the sentence clarified in order to issue an opinion.
COM asked whether the comment related to both professional and amateur use, and it also seems to differentiate the kind of industrial use and also remedial treatments use. It also refers to the fact that if you have a top coating a wood preservative would not be necessary since the pest would not go into the wood for newly treated timber.
BE disagreed with this last statement since there would always be some species that could go into the wood once the top coating is applied. BE could agree for fungal attacks since the top coat would represent a physical barrier but not for insects. Furthermore during the service life of the top coating there would be a diminution of the protective effect of this top coat (e.g cracks). Thus for preventive purposes a wood preservatives would be applied most of the times. According to **EL** in that particular case, the top coating would not be a risk mitigation but part of the application regime.

COM stated that more clarification was needed in this part of the paper.

NL agreed with **BE**, top coating is a temporary risk mitigation for the initial fluxes. According to the **NL** there were no perfect top coats; otherwise we would not need wood preservatives. **COM** also agreed.

UK would reflect on this and see if they are able to deal with this issue, since from the discussion held, it was clear that clarification implied more that a simple rewording.

COM will revise the amended paper and will bring it to the CA meeting or to product authorisation group to discuss especially the item on amateur use. The paper will have to be probably updated/revised later on in light of further experience.
COM will contact CEPE to get more information. COM suggested one month for updating the paper. **COM** closed the discussion.