Final Minutes TM II 2010

Biocides Technical Meeting
14 - 18 June 2010

INTRODUCTION

The meeting was chaired by E. van de Plassche and for specific items on the agenda by J. Janossy, P. Piscoi, V. Rodriguez Unamuno, S. Pakalin and L. van der Wal (DG JRC), and C. Kusendila (DG ENV). E. van de Plassche welcomed the participants to the TM II 2010. 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

COM informed that the agenda items 1a from the TOX Session and 3a from the GEN Session were moved to TM II 2010.

The agenda was endorsed without any further changes.

2. Adoption of the minutes

COM informed that some comments received from DK on the second version of the draft minutes of TM I 2010, were not included. It was agreed to include these comments. No other comments were received on the draft minutes of TM I 2010.

3. Action List TM

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

   The first version is expected from CEPE in the first half of 2010.

2. *Environmental risk assessment PT 06.*

   Reactions were sent by MS to PL. The item was discussed under the ENV Session under agenda item 5c.

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

   COM stated the exercise is under preparation.

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 *Draft guidance document on field studies and distribute to COM and involved MS.*

COM stated that **IND** had informed them a first draft would be distributed after the summer.

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

   COM stated that **CEPE** had informed them a first draft would be distributed after the summer.

6. *Finalise guidance document on risk characterization for local effects.*

   COM stated the document was finalised and published on the biocides web-site of JRC-IHCP.

7. *Send comments to COM on document distributed as room document on substance identity of isomeric mixtures.*

   COM stated that comments on this document were received for the CA discussion on metofluthrin from **DE**, **SE** and **NL**. Based on this a document to be discussed at the TM will be prepared on substance identity of isomeric mixtures. **COM** will contact the relevant MS on the preparation of such a document.

8. *Add contact points to RCOM.*

   COM stated a table filled in by the RMS before the First Draft CAR is uploaded on CIRCA for the 90 days commenting period, is now inserted in the RCOM.

9. *Send comments to DK on document on "problems related to ESD for PT 6, 10 and others".*

   COM stated some MS had send in comments. **DK** will inform **COM** if this issue needs to be discussed again at the TM.

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

COM asked to inform by e-mail on any changes.

5. Next Technical Meetings

2010

TM III	4 – 8 October	CA	21-24 September
TM IV	22 – 26 November	CA	14-17 December

TOXICOLOGY SESSION

1. SUBSTANCES in PT 08

1a. Diamine (RMS: PT)

See agenda item 1a of Introduction.

2. SUBSTANCES in PT18

2a. *Bacillus thuringiensis SA3A* (RMS: IT)

-

2b. Dichlorvos (RMS: IT)

-

2c. Chlothianidin (RMS: DE)

-

3. SUBSTANCE in PT19

3a. MNDA (RMS: ES)

-

4. SUBSTANCES in PT21

4a. Tralopyril (RMS: UK)

-

5. Use of developmental studies in risk characterization

FR introduced the position paper on the use of development studies. Considering the comments the following text was agreed to be included in the MOTA:

1. Should developmental studies be used for AEL derivation if their NOAEL is the lowest available?

When valid developmental studies are available, all relevant critical effects should be evaluated together with other observations from other studies. If the NOAEL derived from relevant effects in a valid developmental toxicity study is lower than those from short-term RDT studies, and this cannot be explained by dose spacing, the NOAEL from the developmental toxicity study should be used for the derivation of the AEL value. This will apply to the global population (thus protecting both pregnant and non-pregnant women).

Developmental studies are often the only studies to use gavage dosing with the aim of determining a NOAEL. This can give rise to Cmax related effects, such as certain clinical signs, that might not be relevant to dermal exposures where a spike of absorption is not normally seen.
It should be noted that due to their inherent limitations, developmental studies cannot be considered as surrogates for other repeated-dose toxicity studies when these are missing or invalid.

2. Can maternal effects be regarded as critical effects for characterising medium- and long-term risks? If so, is it necessary to apply duration extrapolation factor?
Maternal effects can be regarded as critical effects for deriving medium- and long-term AELs if they are deemed relevant in comparison with other critical effects observed in other valid repeated dose toxicity studies.
Usual assessment factors and duration extrapolation factors (as recommended in the chapter 4.1 of the TNsG on annex I inclusion) should then be applied, unless scientific rationale is presented for adapting them to the specific situation. Deviating from the default factors will need to be justified e.g. by explaining why an effect is specific to the pregnancy period.

3. Can developmental effects (i.e. embryotoxic or foetotoxic effects) be regarded as critical effects for characterising medium- and long-term risks?
When the lowest relevant NOAEL is based on developmental effects, this may be used for deriving medium- and long-term AELs on a case-by-case basis. This will depend on the type of effect and its relevance for humans. Duration extrapolation factor might not be needed if the effect is specific to the developmental-time window investigated.

4. In case where a RC is based on a maternal effect, should the intra-species factor remain at 10 or should it be reduced for taking into account the higher sensitivity of the pregnant subpopulation?
There is no evidence that pregnant women are always more sensitive than the rest of the population. The AEL derived from maternal effects will cover the whole population, and the intra-species factor is 10 unless there are specific reasons to deviate from this.

Regarding the last question, i.e. "Can RMMs be taken into account in reducing the risk arising from a developmental effect to an acceptable level?" it was decided not to be included into MOTA since it is not specific to developmental toxicity.

Conclusion: The **TM** agreed to include the 4 items in the MOTA.

6. Survey of DNT studies for pyrethroids

COM introduced the document and acknowledged the role of NL in summarising the issue covering the current status of science and the assessed substances under the Review Program. **COM** stated the document was considered to be confidential as it contains data on individual active substances. **NL** presented the document. The overall conclusion was that, in general, for pyrethoids the AELs are based on neurotoxic effects (except for some of the long-term AELs). The evaluations indicated that possible DNT effects induced by pyrethroids are covered by the AELs set on neurotoxicity in the acute neurotoxicity and medium-term studies since DNT effects from acceptable OECD TG 426 performed

studies are taking place at higher LOAELs than other neurotoxicological effects[1]. The DNT effects are also covered by the AELs set for long-term exposure (based on neurotoxic or other critical endpoints. As neurotoxic effects are critical effects after acute or medium-term exposure and the available data indicate that DNT effects are induced at higher LOAELs, it is unlikely that, in the absence of DNT studies, the potential DNT effects are not covered by AELs set on neurotoxic effects observed in acute and medium-term studies. The data also indicate that an additional assessment factor for species sensitivity is not required. It was concluded that additional DNT studies according to OECD TG 426, if such a study is not present, is not necessary. **COM** proposed to use the document presented by NL as basis for the assessment of this category of substances. This was agreed and the decision will be reflected in the MOTA.

7. Draft Guidance Dietary Risk Assessment

DE presented the main principles of the draft guideline on the dietary risk assessment (DRA) in case of livestock exposure. The DRAWG guidance only deals with external exposure of animals using a tiered, stepwise approach. If the exposure is estimated to be above a trigger value the active substance and/or the biocidal product will be sent to EMA to evaluate the internal exposure and if necessary to set a maximum residue level. **DE** informed the TM that the draft TGD will be finalized by DRAWG at its meeting in Berlin in July for approval by the CA-Meeting in September 2010. Further comments on the draft TGD were invited by end of June 2010.

8. Evaluation Manual Product Authorisation

See separate minutes for this agenda item.

9. AOB

9a. Update HEEG

COM introduced the document prepared by DE in collaboration with HEEG. **DE** presented the paper. **NO** commented that the figures referred in the document for paste bait are relevant for paste bait deployed using prefilled cartridges only, whereas the same figures as for wax blocks should be used for paste formulations with a different exposure patterns, as agreed at TMIII06. **DE** responded that this information would be included in the document. Discussion took place regarding the interpretation of MSs in relation to the number of manipulations for application of bait and for cleaning of bait stations. It was considered that 20% of the exposure frequencies of daily use will be used to include the clean-up phase (as decided at TMIII06). **IND** represented by CEFIC expressed their wish to contribute at the paper through written comments. These will be sent to HEEG.

Conclusion: CEFIC will submit comments to the paper. The revised form will be presented to the TM.

[1] **SE** submitted a paper to TMII10 stating that **SE** does not agree with this statement as a general conclusion for pyrethroids. In case the sensitivity of young animals cannot be deduced from a DNT study (for instance if the study is considered compromised by the use of a strain/species in which no clinical signs of neurotoxicity have been observed in any oral studies performed at comparable dose levels) **SE** does not agree with the conclusion that an AEL set for neurotoxicity in adult animals covers possible DNT effects in young animals.

9b. Harmonisation of exposure assessment for PT 11 and 12
(TMII2010-TOX-item 9b-Harmonisation exposure assessment biociden PT 11-12_NL.doc)

NL introduced the document. **FI** proposed that on CIRCA a dedicated space could be made available where on voluntary basis a RMS could upload their exposure assessment before these are send to the Commission for the start of the 90 days commenting period. These assessments could then be consulted by other RMS and assisting them in preparing their evaluation. This proposal was accepted.

GENERAL SESSION

1. Report 36th and 37th CA meeting

COM reported on the 36th and 37th CA meeting.

2. Tracking System: Progress reports

-

3. SUBSTANCES in PT 08

3a. Diamine (RMS: PT)

-

4. SUBSTANCES in PT18

4a. *Bacillus thuringiensis SA3A* (RMS: IT)

-

4b. Dichlorvos (RMS: IT)

-

4c. Chlothianidin (RMS: DE)

-

5. SUBSTANCE in PT19

5a. MNDA (RMS: ES)

-

6. SUBSTANCES in PT21

6a. Tralopyril (RMS: UK)

-

7. Update MOTA

COM informed that a version of the MOTA including the agreements from the ENV Session will be made available before the next TM.

8. Evaluation of efficacy tests for PT 18

NL introduced the revised guidance document. **NL** stated that comments were received before this TM from **DE**. All these comments will be incorporated except for a comment on the combined use in PT 18 and 19 on page 50. The following comments were made:

- **CH** (page 6) stated that information on the composition of the biocidal product or as a minimum the content of the active substance(s) in the biocidal product shall be available. CH will send a text proposal to NL.
- **AT** questioned why the control of termites was split into PT 08 and 18. **DE** explained that use of preventive and curative treatment of wood is considered as PT 08 while the use of bait stations as a barrier treatment or the use of biocidal products added directly to the soil to protect for example electrical wires is considered as PT 18.
- **CZ** stated that they still had comments which they would like to send in writing to NL. This is rather late in the process and **NL** stated they were not sure if **NL** has the recourses to review all these comments. Moreover, the TM was not able to look at the comments from CZ, since these were not provided before the meeting.

Conclusion:
COM concluded that NL will revise the document based on the comments made at the meeting. The revised document will be tabled for the agenda of the CA meeting for endorsement.

9. Evaluation Manual Product Authorisation

See separate minutes for this agenda item.

10. AOB

10a. Formation e-consultation group on efficacy

UK proposed the establishment of an efficacy e-consultation group. All interested MSs will notify COM and A. Low of the UK (andrew.low@hse.gsi.gov.uk).

ENVIRONMENT SESSION

1. SUBSTANCES in PT18

1a. Emission estimation for insecticides for households and professional uses: targeted applications

COM introduced the proposal submitted for the meeting (TMII2010-ENV-item1a-Proposal surface area targeted applications.doc). Thereafter, **IND** introduced their proposal (TMII2010-ENV-item1a-Proposal surface area targeted applications_comments industry.pdf.zip). **DE** stated that the input parameter in the IND proposal of a band-width of 0.10 m (as explained in the crack and crevice proposal for domestic households) is probably based on experience. Also values of 0.05 and 0.20 m have been used by Applicants in the past according to **DE**. In addition **DE** stated that in the IND proposal here only 1 room is used in fact, whereas the wet clean rooms in a domestic house consist of 2 rooms (bathroom and kitchen). **IND** stated that the calculations may be refined considering that indeed 2 and not 1 room is wet cleaned. **FR** proposed to change the COM proposal and correct the barrier treatment for the wet cleaned zone. The wet cleaned zone is 38.5 m^2 for a domestic house, being according to ConsExpo parmeters indeed the bathroom and the kitchen. The correction factor would then be approximately 0.30 as derived in the IND proposal. The same correction factor would then be used for the commercial building. **FR** proposed however to not correct for the wet cleaned zone in the spot treatment. **BE**, **DE** and **IND** agreed to the proposal from FR.

COM concluded that the proposal from FR will be used. This leads to the following scenarios:

- Targeted applications for which default values are available: i) spot treatment or crack and crevice treatment, and ii) barrier treatment;
- Default value for spot or crack and crevice treatment for a domestic house is 2 m^2 as stated in the ESD. The default value for barrier treatment for a domestic house is 20 m^2 based on a proposal from France[2]; in the PT 18 Workshop;
- The same relation between the treated and total surface for the commercial building as for the domestic house is used. This leads to 9.3 m^2 and 93 m^2 for spot treatment or crack and crevice treatment and barrier treatment, respectively.
- These values for barrier treatment are corrected for the wet cleaned zone. The wet cleaned zone for a domestic house is 38.5 m^2, equal to the surface of the kitchen and bathroom (ConsExpo). This leads to a correction factor of 38.5 / 131 = 0.294. The same factor will be used for commercial buildings. This leads to the following default values for barrier treatment: 5.9 m^2 for a domestic house, and 27 m^2 for commercial buildings. No correction is applied for spot application.
- COM will prepare a document to be endorsed at the CA meeting in which the revised default values are. This will be a revised document of the one discussed at TM I 2010 (TMI2010-ENV-item4a_Proposal COM on PT 18 scenario.doc).

[2] The proposal was motivated at the PT Workshop as follows: "A chemical barrier is not applied on the entire surface of the building but must be set up in such way that each crawling insect has to cross it during its moving. This treated surface (around the doors, the windows, the kitchen devices) is estimated to be 15 – 20 m^2 for a house of 130 m^2 according to Prisse, G. (2002). Dératisation - Désinsectisation - Désinfection. Le Guide de l'applicateur. Deuil la Barre, France, PC MEDIA."

1b. *Bacillus thuringiensis SA3A* (RMS: IT)

-

1c. Dichlorvos (RMS: IT)

-

1d. Chlothianidin (RMS: DE)

-

1e. Diflubenzuron (RMS: SE)

-

1f. *lambda* Cyhalothrin (RMS: SE)

-

2. SUBSTANCE in PT19

2a. MNDA (RMS: ES)

-

3. SUBSTANCES in PT21

3a. Sediment risk assessment for antifouling products

COM and **UK** introduced the agenda item. First the UK document was discussed (TMII2010-ENV-item3a-Sediment risk assessment antifouling products.doc). **SE** stated with respect to a refinement of the PECsuspended matter they consider suspended matter and sediment are two different compartments. As only one PNEC is derived at the moment which should cover both suspended matter and sediment no refinement is possible. **NO, DK** and **FI** agreed. **UK** stated that ideally indeed two different PNECs are available. **IND** stated that if this is the case, there should have been more time to respond by delivering additional data to allow the derivation of these different PNECs. **UK** clarified, following a question from **FI**, that a tier 2 assessment (using bulk sediment concentrations applying MAMPEC) is followed only if there are unacceptable risk to sediment dwellers and acceptable risks to filter feeders (using suspended matter concentrations) in the tier 1 assessment. It was suggested by **SE** that a tier 2 assessment is probably not the correct term as this would not be a refinement. **NO** stated that at the moment it is indeed not possible to derive a PNEC for both suspended matter and

sediment due to lack of data. Although for degrading substances the differences between PECsuspended matter and PECsediment are high, **NO** advocated to calculate both suspended matter and sediment concentrations and carry out the evaluation. It may be the case that the risk assessment for sediment/suspended matter is not that critical as the risk assessment might anyhow be driven by the water phase. **COM** remarked that, certainly for boosters, the water phase will most likely drive the assessment.

Then the CEPE documents were discussed. The following was concluded for the points listed in the document "TMII2010-ENV-item 3a-Response to MS Questions Annex-II November 2009 Final_CEPE.doc":
Point 1 (Sweden: comment on preference to use PEC_susp.matter instead of PEC_sediemnt): no further comments were raised;
Point 2: (Norway: comment on values and preferences for SPM, POC, DOC and settings in MAMPEC): **IND** clarified that the settings for SPM and POC in some of the default scenarios transcription errors rather than bugs. This can be overcome by manually overwriting the settings for these parameters. While there are some errors in the default scenarios, the OECD-EU scenarios are correct.
Point 3 (Sweden, Norway: comments on handling of sedimentation and settling of suspended matter): **IND** clarified that the depth of the mixed layer for the OECD shipping lane (Table 3 in the document) has to be changed to 0.1 m. **IND** in addition explained that the settings for the default scenarios cannot be changed as these scenarios use different settings compared to the OECD scenarios. Also, the net sedimentation velocity is the outcome of a calculation applying other parameters and can therefore not be harmonised between the OECD and default scenarios.
Point 4 (Questions on depth of mixed sediment layer): The currect MAMPEC default sediment depths of 10-20 cm are based on sediment depths of the North Sea. It was discussed to alternatively use a mixed sediment layer of 6 cm (based on the extensive data-set in the study of Teal et al. of 2008) in the calculation of the PECsediment and whether to use this as a refinement option or not. It was preliminarily decided to use the value of 6 cm sediment depth for all scenarios. This is open to written comments 2 months after the meeting.
Point 5 (Comments on degradation of compounds adsorbed to SPM) and point 6 (Comments on diffusive sediment-water transport): **SE** thanked IND for their clarification.

Then the other CEPE paper (TMII2010-ENV-item 3a-MAMPEC rate constants for degradation of organic carbon in sediment final_CEPE.doc) was discussed. Following a question by **NO**, **IND** explained that in Figure 1 there is almost no difference between the different rate constants considering the concentrations on a dry weight basis as the organic carbon is only approximately 2% of the total weight of the sediment. It was agreed to keep the default value for the degradation rate constant of 0 day^{-1}.

Conclusions:

- the evaluation for the sediment compartment will be based on the PECsuspended matter and PECsediment which both have to be compared with the PNECsediment;
- the depth of the mixed sediment layer in marine systems is preliminary set at 6 cm. MS shall send in comments to COM by August 18;
- the rate constant for degradation of organic carbon in sediment to be used is 0 day^{-1}; and the PECs should be expressed on a dry weight basis, not an organic carbon basis;
- COM and UK will consult on how to proceed with the document developed by the UK.

3b. Tralopyril (RMS: UK)

-

4. Evaluation Manual Product Authorisation

See separate minutes for this agenda item.

5. AOB

5a. Project "Efficiency and practicability of risk mitigation measures for biocidal products"

DE introduced the paper and stated the end report will be made available to the meeting. A workshop is envisaged to take place by the end of the year.

5b. Environmental risk assessment formaldehyde releasers for PT 13

COM stated the agenda item is open although the document prepared by **PL** is considered confidential as individual active substances are mentioned. However, the issue raised by **PL** is a generic issue. PL introduced the document. **COM** asked if the rapporteurs for PT 13 dossiers can confirm the statement in the document that applying the ESD for PT 13 will lead to an unacceptable risk due to the high value of the parameter "treated volume of metalworking fluid" (40 m^3/day for water soluble and 200 m^3/day for emusifiable MWF). **UK** stated that for such high volumes release will not take place in the **UK** as these volumes are valid for large metal working facilities where the treated volume has to be regarded as chemical waste. For smaller metal working facilities a license for the discharge of the treated volume is required. This license will contain conditions on the volume but also on the concentration of the active substance. Consequently, **UK** will first use the ESD in a tier 1 assessment and assess the risk more qualitatively in a tire 2 applying this information. **COM** stated this would be in line with their proposal made at a previous TM. **SI** stated they had monitoring data available for their dossier and used these instead of the ESD. **DE** stated its concerns on different approaches followed by the RMS for PT 13. **DE** asked if IND could provide more information.

Conclusion: IND will consult with the applicants for PT 13 in the Review Program to obtain more information on the parameters used in the ESD for this PT.

5c. Harmonisation of ESD for PT 06

PL introduced the document. First the general issues raised in the document were discussed (page 1-3 of TMII2010-ENV-item 5c-Harmonisation ESD PT 06_PL.doc):

1. in-can preservatives used in cosmetics: **COM** will consult internally on whether these fall under the scope of the BPD.
2. evaluation of waste stage for in-can preservatives: it was agreed that no harmonised approach exists at the moment on the evaluation of the waste stage. On a case-by-case basis the evaluation of the waste stage can be added by the RMS.

3. cumulative exposure assessment for in-can preservatives: **PL** stated no method is available at the moment on how to carry out a cumulative exposure assessment. **DK** stated a cumulative exposure assessment for PT 06 is necessary due to the many different uses. **BE** asked which action to take if a risk is identified following the cumulative exposure assessment. **DE** informed that a project has been started on cumulative exposure assessment focussing on terminology and an overview of the methods available. The end report will be available approximately by end of August. **DK** proposed to send some of their ideas to PL. **DK** stated that care should be taken to not make cumulative exposure assessment too complex for PT 06. **SE** stated that a cumulative exposure assessment is needed and that uncertainty on how to deal with the result should not prevent starting carrying out such assessments. **COM** decided to first await the outcome of the project mentioned by DE.
4. evaluation of each specific sub-category versus evaluation using the tonnage approach: **PL** asked if an evaluation of each sub-category is needed, **DK** agreed this is a difficult issue, for example what end product is going to be tested: solvent based or water based as it is know that the formulation has a great influence on the leaching behaviour.

For the other, more specific, questions raised in the document (page 3 to 33) MS were requested to send comments to PL by August 18.

5d. Harmonisation of the application of the FOCUS groundwater model PEARL

DE introduced the document which contains a proposal for a harmonised approach for groundwater assessment using FOCUS PEARL. Following a question from **FI**, **DE** stated that the soil depth of 5 cm for grassland is taken from the ESD for PT 18, being aware that this is not in line with the value recommended by the TGD of 10 cm.

Two general questions mentioned in the document were discussed:

1. PEARL versus PELMO: **DK** stated that EFSA recommends to use both models for very mobile substances. **UK** stated that the relevant FOCUS group is revising both models at the moment. **UK**, **DE** and **FI** recommended to use only PEARL for all substances.
2. Do all FOCUS scenarios have to lead to acceptable risks? **FI** stated that all scenarios should lead to a safe use. **SE** disagreed stating that only one safe scenario is sufficient. **COM** referred to the evaluation of PT 08 (house scenario) where active substances were included on Annex I where not all scenarios lead to a safe use. **UK** stated that pesticides are being included on Annex I when some scenarios are failing. **UK** would argue that the majority of the scenarios have to show that the use is safe. **UK** stated that the areas treated with manure, which contains a biocide, is most likely less than the areas treated with pesticides. **DE** agreed with the UK stating that for pesticides risk mitigation for specific soil sites is feasible whereas it is doubtful if for example a label claim for a biocidal product stating that the manure after application of the biocidal product cannot be spread on specific soils for which risks have been identified is an effective RMM for biocides.

SI stated that the difference between pesticides and biocides is that manure will be applied to land when rain is expected for the latter, while this is not the case for the former. **SE** pointed to the model MACRO which can be used for groundwater assessment for soils

with cracks, like clay soils. It was decided that this model can be used at the national level, but not on a routine basis in the evaluation of active substances.

Conclusion: written comments to be send to DE by August 18 on the parameter setting for the groundwater assessment using FOCUS PEARL and on the four questions on page 3 of the document. DE especially asked for comments on the application data for grassland and arable land and on the selection of crop types where for arable land two options are indicated. A revised document will be discussed at the next TM. DE offered to prepare a guidance document containing screenshots of PEARL on where to enter the data for the different parameters. The latter was highly appreciated by the meeting.

5e. Baltic Sea Risk Assessment Methodology PT 21

This document was submitted by SE for information.

5f. Leaching rate PT 21

This document was dealt with under agenda item 3a.