

Biocides Technical Meeting

04 - 08 October 2010

INTRODUCTION

The meeting was chaired by A. Payá Pérez and for specific items on the agenda by J. Janossy, P. Piscoi, V. Rodriguez Unamuno, S. Pakalin and L. van der Wal and P. Barret (DG ENV). A. Payá Pérez welcomed the participants to the TM III 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 on the postponement of the discussion on Diamine in PT 08 for the TOX and GEN Session. **PT** apologised for the inconvenience of not sending the updated documents which will be done immediately after TM. The discussion on diamine will be scheduled for TM IV 2010. **AT** requested to table a room document entitled "Questionnaire concerning top coating of wood preservatives" under the ENV Session under AOB. The agenda was adopted without any further changes.

2. Adoption of the minutes

SE asked to mention their disagreement with respect to the conclusions of agenda item 6 of the TOX Session (Survey of DNT studies for pyrethroids) and to include the comments they sent previously. **UK** clarified a point of discussion with **FR** on agenda item 4a5a of the TOX Session for the exposure of children touching wet paint. **FR** agreed to accept this change in the minutes. **FI** asked to introduce their comments on agenda item 3b of the ENV Session. The minutes were adopted with these changes.

3. Action List after TM III

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

The item was discussed at TM II 2010 under the ENV Session under agenda item 5c. MS were requested to send comments to PL by August 18. Reactions were sent by MS to PL. **PL** informed on progress and further information will be provided at TM IV 2010.

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 *Draft guidance document on field studies and distribute to COM and involved MS.*

IND will inform COM on the progress on this action item.

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

IND will inform COM on the progress on this action item.

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

At TMII **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.

7. *Open a dedicated space on CIRCA where on voluntary basis exposure assessments prepared by the RMS are uploaded, before these are sent to the Commission for the start of the 90 days commenting period.*

Action to be started

8. *Inform COM and UK on participation in e-consultation group on efficacy.*

COM will inform the TM after the meeting.

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

COM will inform the TM after the meeting.

10. *Start e-consultation on tier 2 risk assessment for the sediment compartment and refinement of M&R and new build ESD scenario.*

At TM IV 2010 **UK** will inform on the progress of the e-consultation.

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

IND will inform COM on the progress on this action item.

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

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5. Next Technical Meetings

2010

TMIV	22-26 November	CA	14 - 17 December
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2011

TM I	14 – 18 March
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TM II	6 – 10 June
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TM III	3 – 7 October
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TM IV 12 – 16 December

CA meetings: 14 - 18 February, 3 - 6 May, 5 - 8 July, 20 - 23 September and 6 - 9
December

TOXICOLOGY SESSION

1. SUBSTANCES in PT 08**1a. Chlorfenapyr (RMS: PT)**

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1b. Diamine (RMS: PT)

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2. SUBSTANCES in PT 14**2a. Combined Assessment Report Brodifacoum (RMS: IT)**

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2b. Combined Assessment Report Bromadiolone (RMS: SE)

-

2c. Corn cob (RMS: EL)

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3. SUBSTANCES in PT 18**3a. Silicon dioxide – amorphous - Rentokil (RMS: FR)**

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3b. Silicon dioxide – amorphous - Applicant Evonik Degussa GmbH (RMS: FR)

-

3c. Bifenthrin (RMS: FR)

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3d. Margosa extract (RMS: DE)

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4. SUBSTANCES in PT19

4a. Cis-tricos-9-ene (RMS: AT)

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5. SUBSTANCES in PT 02

5a. Hydrochloric acid (RMS: LV)

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6. AOB

6a. Update HEEG

6a.1. Harmonising the number of manipulations in the assessment of rodenticides.

At the TM II 2010 this paper has been discussed and CEFIC asked for a period of consultation.

Following the written round of comments it has been accepted that the 20% representing the cleaning of the baits is included in the daily number of manipulations for operators.

NO commented that the document currently developed by HEEG on the averaging of the exposure, based on a study by Chambers *et al*, should also take into account the new HEEG paper.

Conclusion: the opinion was endorsed by the TM.

6a.2. Exposure model for washing out of a brush

UK introduced the paper by saying that when washing the brush, the operator is exposed to the biocidal substance. The model is intended to be used for non–water–based paints and is built on an idea used by FI in on of their dossiers. The intention of **UK** supported by the work of HEEG was to formalise the model and make it available in MOTA for a consistent use by the other MSs. **UK** recognised that the model is a theoretical one and invited **MS** to undertake validation work if resources are available.

DK was of the opinion that since the model was developed for non–water–based paints, the value of 2% for the dermal absorption is too low. **UK** clarified that the value of 2% is a chosen theoretical value for an active substance that is applied by painting and in assessing a dossier the specific value for that active substance is to be used. The value of 2% is just an example. **DK** remarked that since there is a mention stating that the density value has to be changed if different from 1, a similar mention should be made for the dermal absorption value. **UK** accepted the recommendation. **NL** said that the model seemed correct, but it describes the worst case situations, with large brushes and high quantities of solvents used for cleaning. As an observation **NL** mentioned that the amount of paint left on the body after painting should be by far larger than the amount of paint due to the washing of the brushes. **NL** questioned the necessity of having a model for cleaning of a

brush since the exposure represents only a small part of the total exposure. **UK** argued that such a conclusion may be reached only after roughly evaluating what would be the exposure due to washing the brush. **EL** asked if information is available on the solvents to be used with different types of paint and the relative risk of these solvents. **UK** answered that probably the type of the solvent would be indicated on the label but generally turpentine is the solvent of choice. **UK** clarified that the scope of the paper covers the biocide and not the solvent.

Conclusion: the HEEG opinion was endorsed by the TM subject to inclusion of the TM's comments.

6b. Use of the benchmark approach

DK provided a room document and presented it. **DK** is the rapporteur for triclosan PT1. Other authorities used the rat for their risk assessment. However, **DK** and the Applicant considered the hamster more relevant, as their ADME properties are closer to humans. Yet, in case of the hamster, due to the study design, a too high value for the NOAEL is obtained. **DK** tried to use the benchmark software of US EPA. With this approach a more relevant benchmark dose as a reference for risk assessment was obtained. **DK** suggested including the benchmark dose in the draft CAR along with the traditional NOAEL approach; and discussing the outcome of the risk assessments during the commenting period and at the TM.

UK asked why the NOAEL is considered to be too high if the hamster is the most relevant species to perform the hazard assessment. According to **DK** this is due to the study design, the doses chosen were not appropriate. **FR** asked more details on the dose relationships. **DK** explained that the NOAEL value is the second highest tested dose. The highest tested dose is 300mg/kg/day while the second highest (the NOAEL) is 75mg/kg/day. The two lower doses did not have any effect. **FR** supported **DK** to use the benchmark dose.

FR recommended using the PROAST model instead of the US EPA model. With PROAST all data needs to be filled in for the evaluation. With the EPA model some steps can be left out. For better reproducibility PROAST is recommended. **DK** agreed. **COM** inquired whether similar results are reached with the two models. **FR** responded that similar results can be obtained. However, the US EPA software allows to skip some of the data and evaluates based on the available data. With the other software when not all necessary data is provided no results will be obtained.

AT supported **DK** to use the benchmark approach since it is scientifically better compared to the NOAEL approach. It will be a good example when both methods are discussed. **COM** thanked **DK** for the proposal.

Conclusion: **DK** will proceed with the application of the benchmark approach.

GENERAL SESSION

1. Report 38th CA meeting

COM informed the meeting about the outcome of the last CA meeting.

2. Tracking System: Progress reports

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3. SUBSTANCES in PT 08**3a. Diamine (RMS: PT)**

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4. SUBSTANCES in PT 14**4a. Combined Assessment Report Brodifacoum (RMS: IT)**

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4b. Combined Assessment Report Bromadiolone (RMS: SE)

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4c. Corn cob (RMS: EL)

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5. SUBSTANCES in PT 18**First discussion for the following substances****5a. Silicon dioxide – amorphous - Applicant Rentokil (RMS: FR)**

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5b. Silicon dioxide – amorphous - Applicant Evonik Degussa GmbH (RMS: FR)

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5c. Bifenthrin (RMS: FR)

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5d. Margosa extract (RMS: DE)

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6. SUBSTANCE in PT19**First discussion for the following substances****6a. Cis-tricos-9-ene (RMS: AT)**

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7. SUBSTANCE in PT 02**7a. Hydrochloric acid (RMS: LV)**

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8. AOB**8a. MOTA**

COM stated the new version of the MOTA is undergoing an internal quality check.

8b. Establishment of a working group on efficacy for PT 05

DE informed about this agenda item. MS will communicate DE on their nominations to the Working group on efficacy for PT 05

8c. Report on the OECD Biocides Task Force meeting September 2010

COM made available a room document and presented a summary of the discussions taken at the OECD Biocides Task Force meeting on 2-3 September 2010. The document will be uploaded in CIRCA after the TMIII.

There were two (2) questions addressed to TM participants:

1. Deadline end October 2010: to send nominations for the Expert Group on Physical/Chemistry Studies for Biocides to Steve Smith (srsmith@scj.com), copy to the Secretariat (Sylvie.Poret@oecd.org) by end October 2010

NL representant at the OECD stated that harmonisation of physico-chemical methods (pH, density, viscosity and stability) is an important issue in USA and other OECD countries because they not always accept data produced with OECD or EU test methods. Within the EU there is no such problem because MS accept OECD and UN test methods.

2. Deadline 10th November 2010: to send additional nominations to the Expert Group on Biocides Treated Articles (EBTA) to the Secretariat (Marie-Chantal.Huet@oecd.org) copy the EBTA Co-Chair (ina.stephan@bam.de)

COM will consult with the OECD secretariat the possibility of giving access to TM participants of documents produced by the OECD Task Force on Biocides and to upload via CIRCA site.

ENVIRONMENT SESSION

1. SUBSTANCES in PT 14**1a. Combined Assessment Report Brodifacoum (RMS: IT)**

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1b. Combined Assessment Report Bromadiolone (RMS: SE)

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1c. Corn cob (RMS: EL)

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2. SUBSTANCES in PT 18**2a. Silicon dioxide – amorphous - Applicant Rentokil (RMS: FR)**

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2b. Silicon dioxide – amorphous - Applicant Degusa/Evonik (RMS: FR)

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2c. Bifenthrin (RMS: FR)

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2d. Margosa extract (RMS: DE)

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3. SUBSTANCE in PT19**3a. Cis-tricos-9-ene (RMS: AT)**

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4. SUBSTANCE in PT 02**4a. Hydrochloric acid (RMS: LV)**

5. AOB

5a. Outcome e-consultation DE on environmental risk assessment PT 22

Due to illness the **DE** expert could not be present during the TM; however, **DE** presented their document with the outcome of the e-consultation regarding the risk assessment for PT22. **DE** further invited **MS** to react on the outcome of the e-consultation before drafting a conclusive report on this issue.

DK, supported by **SE**, indicated that in **DK** the main area of concern will be groundwater and not soil.

DE highlighted that certain risk mitigation measures, such as the requirement of an impermeable soil layer underneath cemeteries, were not applicable or suitable for certain **MS**. **NL** underlined that no such soil layers are present in **NL** and **NL**, supported by **FR**, would like to focus on generic risk mitigation measures.

COM concluded that **MS** will send their comments to **DE** within one month after which **DE** will prepare a conclusive report on the environmental risk assessment for PT22.

Conclusion: **MS** will send their comments and reactions on the e-consultation within one month after the TM, after which **DE** will prepare a conclusive report on the environmental risk assessment for PT22

5b. Problems related to ESD for PT6, PT10 and others: outcome of consultation after TMI 2010

DK presented their document with the outcome of the e-consultation relating to problems with several PTs. Comments were received by **SE**, **NO** and **FR** on the issue of leaching of PT10 substances from houses, where the proposal by **DK** was that leaching from 100% of the houses will be used as a start for risk assessment, with 4000 detached houses in the city catchment area, and market share might be considered as a refinement option.

NO, supported by **SE**, reacted that for refinement purposes maybe an attempt should be made to divide the private housings between apartment buildings and detached houses. It is also likely that PT 10 products are used on large buildings, so they should perhaps also be included. Regarding the number of detached houses vs. apartment buildings and the number and size of commercial buildings, **NO** suggested to look at the scenarios for outdoor use of PT 18 products (ESD and proposals put forward at TMI 10).

FR agreed with the proposal by **DK** that 100% of the houses are treated with PT10 substances, additionally **FR** preferred to use a simultaneity factor based on a frequency of use instead of market share as a way for refinement. **DK** was uncertain how to derive values for simultaneous use, **FR** proposed a similar approach for derivation of the simultaneity factor as for PT18. **NL** supported **FR** to use a simultaneity factor.

COM concluded that **SE** and **NO** will consult bilaterally with **DK** with regard to the definition of apartment buildings and larger buildings.

DK introduced the next issue regarding the soil volume used for assessment of PT 10 substances, and proposed to use a similar approach as for PT8, i.e. initially 10x10 cm should be assessed, after which refinement might consist of increasing the soil volume.

NL, supported by **DE**, reacted on this issue stating that a more scientific argumentation is needed for the choice of the relevant receiving compartment. **NL** additionally introduced the possibility to include recovery or recolonisation as a refinement option. **COM** did not agree to take into account recovery and highlighted that recovery has not been considered a refinement option so far, because of the constant release of biocides.

DK then introduced an issue regarding industrial effluents within PT6 where an applicant claimed internal treatment of the waste water would result in no discharge into effluent. **DK** normally assumed 100% discharge as a tier 1, with a fraction thereof to be released as higher tier, if data exist. **DK** furthermore highlighted differences in treatment technologies used in Europe. **DK** asked for opinions on how to deal with this issue. **NL** stated the situation in **NL** where a permit is required for **IND** in which a certain quality of the effluent is required before discharge.

DK introduced the cumulative assessment for PT6, and how to deal with combined exposure through industrial buildings as well as normal houses. **SE** reacted and supported a cumulative assessment for PT6 and will send comments to **DK**

Conclusions:

- **NO** and **SE** will consult bilaterally with **DK** regarding the definition of apartment buildings and larger buildings.
- **SE** will consult bilaterally with **DK** regarding the cumulative assessment of PT6 substances.

5c. Follow-up TMII2010-ENV-item 5d-Harmonisation of FOCUS groundwater models

Background: At TM II/2010 Germany presented a document "TM II2010-ENV-item 5d-Harmonisation of FOCUS groundwater models PEARL_DE.doc" in order to adapt the models available for pesticide application for biocidal active substances to some extent. **DE** received comments from **FR**, **NL**, **SE**, **SI**, **UK** as well as supplementary information from **PL**.

During the discussion at TM III/2010 a revised table for the selection of input parameters as well as a summary of comments to the questions was presented. It should be however be born in mind, as stated by **DE**, that further adaption of the models is necessary. The aim of the document is to harmonise the assessment for the meantime.

Proposal for a harmonised approach

1. Preferred model: PELMO vs. PEARL

The TM agreed that the preferred model to perform the refine groundwater assessment of biocides was PEARL.

2. On the input parameters proposed by German UBA.

According to **DE** new scenarios should be developed for manure application. However, it was proposed for the time being, to use the scenarios available taking into account the proposed parameters.

On the development/use of the scenarios, **NL** suggested to contact colleagues working on the Veterinary Medicines (EMA), since the same problem had been faced within the framework of medicinal products for veterinary uses. Indeed, **DE** is in contact to colleagues working on environmental assessment for veterinary medicinal products and the subject is still under discussion. In this regard, **DE** informed also about a starting project focusing on the adjustment of FOCUS groundwater scenarios on the requirements for biocide evaluation for different applications: a) use of insecticides, in

stables and manure storage systems, b) use of b.p. with emission to the atmosphere and subsequent deposition on soil and c) sewage sludge application and that would help to support the definition of standard scenarios for the biocidal application.

NL additionally asked more information on the following points:

- Application data: selection of the 5th of April.

NL asked for more clarification on the rationale behind the choice of **DE**. **DE** explained that this was selected in order to cover for a representative realistic application date.

Also related with the proposed application dates, **NL** expressed their concern that Annex I inclusion might depend on dates that actually were not tested because they were not allowed in different regulatory frameworks. They wonder whether a new calculation would be then needed for national authorisation. **NL** would suggest keeping things simple and waiting to see how it worked at national level.

DE shared the concern of **NL**; however they reminded the TM that at this point we were trying to define an EU approach and to work towards a single worst case scenario. Therefore, **DE** would suggest sticking to their proposal, leaving national particularities for the national product authorisation. **NL** suggested to explicitly stating that the TM agreed upon a specific scenario, but that this did not reflect the reality in whole Europe.

- Application rate: conversion factors (x 850, x 3400). Relevance of having both factors on the table was questioned.

DE explained that the inclusion in the table was a request by **UK**. The soil density is a default value in ESD (No 14) for PT 18.

- Coefficient for uptake by plant: **NL** questioned the deviation proposed by **DE**.

DE clarified that the proposed value (uptake = 0) represented the realistic worst case scenario. In the PPP assessment it could be chosen between 2 values (0 = non-systemic compounds; 0.5= systemic compounds). For manure application to agricultural soil within the biocides seemed more appropriate to choose the 0 value. This reasoning will be additionally mentioned in the document.

- Selection of crop type. **NL** found a discrepancy between the crop type selected in the FOCUS for ground water scenarios (winter cereals) and the one presented by **DE** (winter wheat). **DE** clarified the issue. Discrepancy could be due to a mistake in transcription from FOCUS/Pelmo. However, there is no difference between both types of crops.

3. Application data of liquid manure on arable land. Selection of the preferential option.

Most experts suggested using option b). However **DK** would prefer to use both options since either both could represent worst cases. Comments from **DK** would be sent to **DE**. No conclusion was reached but **DE** supported the objection of **NL** to keep the scenarios as simple as possible:

- a) 5th April (maize): one-time application of 170 kg N/(ha·year)
- b) 3rd October (80 kg N/ha) and 15th Mars (90 kg N/ha) (winter wheat):

4. Number of scenarios demonstrating an acceptable risk for Annex I inclusion.

DK suggested using all the scenarios and supported the proposal of **UK**. **UK** would propose that Annex I listing could be recommended when the majority of scenarios (i.e. 5 out of 9) for both the arable and grassland simulations demonstrate a safe use against the 0.1 µg/L limit.

SE agreed in principle with the PPP procedures, one scenario showing acceptable risk should be enough to allow for Annex I inclusion. **SE** stated however, that this was more a policy discussion since whether or not one acceptable scenario would be sufficient depends on if the approach was going to be taken into account only for Annex I inclusion and if additional groundwater assessment will be done at National authorisation level. According to **SE** if the scenarios were not going to be assessed at National level, then only one acceptable scenario would be insufficient. The actual number of acceptable scenarios needed at Annex I level is a policy decision that should be discussed at CA level. .

NL stated that the TM is in the position to decide whether one scenario showing a safe use is enough (same approach as PPP), but if the decision deviate to consider a different number of scenarios this should be sent to the CA for the political decision to be taken. At this point, **DE** agreed that the decision should be taken at CA level.

NL however, did not see the need to deviate from the approach followed in the PPP framework. **SE** reiterated that in this case it is important that Member States make additional groundwater assessments at National authorisation level.

COM concluded that only one scenario showing an acceptable risk was needed for Annex I proposal. This was supported by the TM

Discussion was closed. **DE** will amend the document incorporating the results of the discussion. **The revised document will be then sent for endorsement at CA level.**

5d. Questionnaire concerning top coating of wood preservatives

AT introduced a room document, including a questionnaire indicating issues with top coatings used on wood preservatives. Due to the late submission of the room document the discussion did not result in ways forward for **AT**, therefore **COM** concluded the discussion and further concluded that reactions on the room document including the questionnaire can be sent to **AT** within one month, after which **AT** will generate a discussion document to be discussed at a further TM. The questionnaire will be provided by **AT** in an anonymous form so **IND** can react on this topic as well.

Conclusions:

- **AT** will send out the questionnaire in an anonymous form after which **MS** and **IND** will send their answers, comments and reactions within one month.
- **AT** will prepare a discussion document with the results of the questionnaire to be discussed at a future TM.