Biocides Technical Meeting
08-12 June 2009

INTRODUCTION

The meeting was chaired by E. van de Plassche and for specific items on the agenda by A. Airaksinen, M. Bouvier d'Yvoire, P. Piscoi and L. van der Wal (DG JRC), and C. Kusendila (DG ENV). E. van de Plassche welcomed the participants to the TM II 09. Representatives from the MS, NO, CH, CEFIC 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 stated that items 5b, 5c (closed session), 5d and 5e are added to the agenda.

2. Adoption of the minutes

The minutes of the Technical Meeting and the special session on product authorisation were adopted without changes. **COM** thanked **SE** for providing the draft minutes of the special session on product authorisation.

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.

2. *Paper on evaluation of tests on nitrogen and carbon transformation in soil*

   This will be discussed under item1 of the Environmental Session of this TM.

3. *Prepare addendum to the TNsG on data requirements section 7.0.2.3.2 on requirement of water-sediment study depending on Kp value.*

   The addendum will be distributed by **COM** after this TM for written comments.

4. *Finalisation thought-starter leaching rate for PT 07, 09 and 10*

   The **UK** is currently finalising this document.

5. *Finalise document on assessment factors for local effects*

   This document was finalised and published on the JRC-IHCP web-site on biocides by **COM**.

6. *Submit entry in registry of intention for Annex XV dossier for harmonised C&L for first and second generation anticoagulants and inform COM*

SE informed that they will submit an entry in the registry of intentions for bromadiolone. **COM** asked **IT** to inform about the status for brodifacoum. All other involved RMS have submitted an entry except **DK**. **COM** will ask ECHA for a joint discussion of all these substances in the Risk Assessment Committee.

7. *RMS for PT 06 active substances to send the relevant information from their received submission on the categorisation and the emission factors to FR*

   This will be discussed in the Environmental Session of this TM under AOB.

8. *Finalise HEEG opinion on Choice of secondary exposure parameters for PTs 2, 3 and 4*

   This opinion is almost finalised and will subsequently be distributed via CIRCA and published on the JRC-IHCP web-site on biocides.

9. *Include TM decisions from Environment Session and prepare procedure on adoption and updating the Manual of Technical Decisions*

   The procedure on adoption and updating the manual will be discussed under the General Session of this TM under item 8a. COM will incorporate the decisions from the Environmental Session for TM III 09.

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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

2009

TM III	5 -9 October	CA	15-18 September
TM IV	30 November - 4 December	CA	15-18 December

2010

TM I	15 – 19 February	CA	9-12 March
TM II	14 – 18 June	CA	25-28 May
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. DCOIT (RMS: NO)

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1b. Fenoxycarb (RMS: DE)

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2. SUBSTANCES in PT 19

2a. DEET (RMS: SE)

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3. SUBSTANCES in PT 18

3a. Imidacloprid (RMS: DE)

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4. SUBSTANCES in PT 14

4a. Difenacoum (RMS: FIN): combined Assessment Report for multiple applicants

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5. AOB

5a. First meeting of the DRAWG

Point of information. The first meeting of the Dietary Risk Assessment Working Group (DRAWG) took place on Monday 8 June. As the chairperson of the group, Isabel Guenther (**DE**) gave a summary presentation to the TM of the DRAWG meeting. This presentation will be made available on CIRCA. Minutes of the DRAWG meeting will be generated separately from the TM minutes.

5b. International Public Health Pesticides Workshop

Point of information. A workshop on the registration of pesticides (chiefly insecticides) used for Public Health purposes, in particular disease vector control, took place in London on May 19-21. The meeting was hosted by the Chartered Institute of Environmental Health, and gathered over 100 participants from 22 countries with a mix of backgrounds (Industry, regulators, Public Health, International organisations, NGOs). The workshop was designed to improve the availability of safe, efficient, and cost-effective insecticides to control insects that transmit disease and that are used in public health programmes around the world. **COM** presented the E.U. regulatory framework for biocides and took part in the discussions. More information, including presentations, is available at: www.iphpw.org.

5c. Dossier of propan-1-ol: *in vivo* COMET assay and possibility of waiving the carcinogenicity study

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5d. WHO/IPCS work on combined human exposure

COM informed that WHO/IPCS recently published a document entitled "Framework for Risk Assessment of Combined Exposure to Multiple Chemicals" for public consultation at http://www.who.int/ipcs/methods/harmonization/areas/aggregate/en/index.html.

5e. Information added to the JRC-IHCP web-site on biocides

COM informed via a room document on new information added to the JRC-IHCP web-site for biocides: HEEG opinions and training material of the Oslo workshop on human exposure.

GENERAL SESSION

COM welcomed the participants and opened the general session. **COM** proposed two agenda items to be added to the AOB: 8e and 8f. **IND** asked the COM for introducing on the agenda a brief updating of the recently launched site EBIN, aimed to collect the available information on biocides at EU level: item 8g. As there were no further comments or additional topics, the agenda for the GEN session was adopted with the above mentioned points included.

1. Update from 32th CA meeting

COM informed the meeting about the outcome of the 32th CA meeting. Reference is made to the minutes of this meeting published on CIRCA.

2. Biocides-REACH Interlinkage

At the last TM a document prepared by **DE** was discussed on the applicability and usability of the REACH guidance documents for the biocides framework. The document is currently under revision and it will be tabled for the next TM in October.

3. Tracking System. Progress reports

COM informed the TM that the progress report is available on CIRCA and invited the MS to send written comments via the generic biocides e-mailbox.

4. SUBSTANCES in PT 08:

4a. DCOIT (RMS: NO)

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4.b. Fenoxycarb (RMS: DE)

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5. SUBSTANCES in PT14

5a. Difenacoum (RMS: FI): combined Assessment Report for multiple applicants

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6. SUBSTANCES in PT18

6.a. Imidacloprid (RMS: DE)

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7. Technical Guidance Development for Product Authorisation

COM introduced the revised thought starter on guidance development for product authorisation. Regarding the background document presented by **DE** at the last TM at the special session on product authorisation, on the health part and as well on the environment part, some comments were received and revised versions will be prepared and uploaded on CIRCA.

COM reminded MS to send in comments on the guidance for physico-chemical properties extracted from the Dutch national guidance as only a few comments have been sent so far. It is intended to discuss this document at the October TM.

COM proposed two options for the further action. The first one would be to organise a dedicated workshop where **COM** asked MS to volunteer for the organization of a workshop to be held in Brussels on 21-22 of October, on the condition that enough material will be gathered on the topics identified in the thought starter. The alternative option would be to contract out the guidance development.

Several MS expressed the need for a dedicated workshop, although available resources are an issue. It was decided that **COM**, in consultation with **DE** will prepare a draft program within two weeks after the meeting. This draft program will be distributed to the MS with concrete requests for participation in an organizing committee which will contain co-chairing, minuting and drafting discussion documents. MS will be expected to react in two weeks after which COM will decide if the workshop will indeed be organised.

8. AOB

8a. Progress on Manual of Technical Decisions

COM informed that the first Addendum has been sent out, changing the document to Manual of Technical Agreements (MOTA). The Addendum is a proposal that can be commented until July 8th. The MOTeD v1 commenting period was extended to June 30th, mentioning that because of holidays, comments will actually be taken into account until the end of July. The first version to be published will take into account all the comments to MOTA and Addendum 1, and it will be published in August. After this, there will be regular updates which will be given first as separate Addendums, and after a commenting period of 6 weeks these will be included in the MOTA. **NO** asked when an environmental part would be included in the MOTA. **COM** replied that this would be done by the next TM. **CEFIC** asked whether the Addendums could be sent to CEFIC as well. **COM** said that the Addendums can be sent to CEFIC.

8b. Role of Switzerland in peer review process

COM informed the TM that CH participates as an observer in the peer review program and has now offered to comment on the First Draft CAR. COM stated there is no legal obligation for the MS participating at TMs to take into consideration the proposals or opinions of CH. **NL** and **DK** welcomed any valuable scientific input meant to contribute to the progress of the TM and the peer review process; however, the decision shall be taken at CA rather than TM level. **COM** informed the TM about this issue to be discussed at the next CA meeting.

8c. Synergist or active substance

DE informed the meeting about their position following the discussion at TM I 09 on this issue (see document presented at TM I 09) and the comments received afterwards. **DE** has concluded that the substance is to be considered as an active substance, unless the applicant can prove otherwise. The applicant has therefore decided to carry out additional testing. After the results are available, **DE** will in consultation with the applicant decided if the issue needs to be discussed again at TM level.

8d. Revised SOP for TM

COM presented the revised version of the SOP for TM. The need for the document resulted from the numerous references for the legal text to be updated. The present version contains as well more detailed description of the procedure, sets up more clearly the forms and formats for the documents to be circulated, for the easier electronic handling of the information. It is also highlighted the need for bilateral consultations between the MS in the commenting process. **COM** asked for written comments with a dead-line of 2 months after the meeting.

8e. Progress working group on efficacy guideline for product authorisation of disinfectants in PT 2

NL informed about the status of the working group activity. Italy will organize a workshop in Rome in September. **NL** requested from the MS to shortly list the intended uses of the active substances and related products and their applications by mid August.

8f. Choice of reference source in case of multiple dossiers

With respect to the discussion on technical equivalence of difenacoum **(point 5a), NO** raised to the TM the problem of multiple dossiers for the same substance, coming from multiple sources and when the dossiers where submitted at the same time, The question is how the reference and the new source should be chosen in this case, taking into account that both dossiers are complete and the evaluation can be started? The arbitrary decision on the reference and new source could imply a problem when considering the potential new impurities. **FR** had no solution for this situation. **AT** and **NO** commented on the reasoning of Tier II approach for the evaluation of the technical equivalence and difficulties in choosing the Tier I approach as the current guidance is more aimed at product authorisation rather then multiple dossiers for Annex I listing. AT recommended to approach this problem in a neutral way - independent if new or reference source - in order to make the comparison if the substance is technically equivalent or not. The outcome of this comparison should be the same, accordingly. **COM** concluded that there are no solutions for the moment.

8g. European Biocides Information Network

AT presented the "European biocides information network", a database available at https://www.europeanbiocides.net/. This is a non-profit network initiative in cooperation with the Austrian Ministry for Environment. It has been developed to serve industry, small and medium enterprises and authorities and intends to be continuously enlarged and updated on a regular basis and as such to be a time saving one-stop-shop platform with pre-selected and commented hyperlinks, articles and documents. It covers: background, guidance and information on current and upcoming issues concerning biocides under the EU regime; information about member states, contact details of the relevant competent authorities and poison information centres as well as relevant and publicly available regulatory inventories and sources of electronically available legal texts; contributions

from authorities and industry experts aiming at a European wide harmonised understanding and handling of biocides regulations; clarification on specific scope issues; information about test-houses and contact details of specialised consultants and overviews of their services; information and links to scientific journals as well as relevant books on biocidal scientific and regulatory aspects; it contains highlights and information of international organisations with relevant impact on the biocides regime at EU, OECD and UN level; news and facts on meetings and trainings related to the biocides scientific and regulatory world. In the end of the presentation, **AT** asked for contribution from the MS on their national authorisation systems and national guidance.

ENVIRONMENT SESSION

COM informed, on the question by **NL**, that the item about sediment assessment for antifoulings (PT 21) was removed from the agenda because **UK** was not able to send their expert to this TM. This item will be discussed on the next TM with a revised document, prepared by **UK**.

1. Results E-consultation FR: "Effects on soil microorganisms (Guidelines OECD 216 and 217)"

FR introduced their revised document which included comments provided by **DE**, **NL**, **UK**, **FI** and **COM** (uploaded separately on CIRCA), on the assessment of effects on soil microorganisms. The consultation was initiated to achieve harmonisation of the assessment for soil microorganisms, since two protocols are mentioned in the OECD guidelines (i.e. PPP protocol with 2 test concentrations, and biocides protocol with 5 test concentrations). **FR** informed that the MS agreed to use the PPP approach when the study is already available. The endpoint must be obtained from the 28 days results unless effects are worse after 100 days. Results can only be expressed as "amount of nitrate formed" when a minimum of 5 concentrations is tested. When the PPP protocol is used the effects should be expressed as "rate of nitrate formed". For **NL**, **UK** and **FI**, the EC_{25} can be used as NOEC value. For **DE** only an effect value <10% could be considered as NOEC and suggested that when the effect is between 10-20%, it should be considered a LOEC. This LOEC could then be divided by 2 to be used as a NOEC. **FR** agreed with the LOEC approach by **DE** but, to be consistent with variability in test, with a 15%-25% range. **FR** wondered if it was a disadvantage for biocides, compared to PPP, when a lower value than 25% is used. For PNEC derivation, **FR** concluded that an AF of 100 can be used on the NOEC value even if a soil micro-organism study is the only long-term study. This approach has been used in earlier dossiers (etofenprox and dichlofluanid). No comments were received on the choice of the duration of the test (28 days or other timepoint), neither on how endpoints should be expressed (i.e. as "rate of nitrate formation" or "quantity of nitrate formed"). **DK** could support the use of the PPP protocol if no effects (>25%) are found in the test. **IT** stated that EC_{25} cannot be calculated from 2 test concentrations. Furthermore, **IT** supported the statistical approach as put forward by **DE** which was also supported by **DK**. **DE** clarified that the 25% value comes from the PPP-framework, where this effect on soil micro-organisms is deemed acceptable because of the need for the use of PPP to protect crops. By taking into account the variability instead of the end result only, more insight is gained on the value of the end result. **NL** supported a broader range of results (i.e. 25%) because of the heterogeneous character of the soil micro-organism community, which was supported by **FI**. **COM** indicated that a harmonised approach is favourable; on the other hand no EC_{25} can be derived using 2 concentrations only, and especially if the variability in these tests is so high. Therefore **COM** preferred the French approach or using the 25%-value. **DK** appreciated the aim for a harmonised approach, however for biocides a proper dose-response is required in order to perform a proper risk assessment. **IE** supported the 25% approach. **DK** commented the test is not well suited for biocidal purposes, still accepted it only if there was no blurred effect (i.e. a clear concentration where no effects are seen). **DE** asked about the implications for substances already in the commenting round and if new tests could be required, which was affirmed by **COM**.

Conclusion:

COM concluded that tests using the PSM design (two test concentrations with a control) can be used for the environmental risk assessement of biocides in special

circumstances. First, a statistical evaluation (student t-test) of difference of the test concentrations to the control is conducted. If no statistical difference is found in both tested concentrations the lowest concentration can be used as NOEC. If a statistical difference is analysed and the effect is > 15 % no NOEC can be derived. The test cannot be used for assessment under the BPD and, if the test is critical for the assessment, a new test using 5 concentrations needs to be requested. If in at least one concentration no statistical difference from the control is found and the effect value is </= 15 % the concentration is the NOEC. The NOEC micro-organisms can be used to derive the PNEC soil by using an AF of 100 even if no other NOEC's for soil organisms are available.

2. SUBSTANCES in PT 14:

2a. Difenacoum (RMS: FIN): combined Assessment Report for multiple applicants

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3. SUBSTANCES in PT 08

3a. DCOIT (RMS: NO)

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3b. Fenoxycarb (RMS: DE)

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3c. Alkyldimethylbenzylammonium Chloride (ADBAC); Applicant Lonza GmbH, Stepan Europe and Field Fisher Waterhouse LLP (RMS: IT)

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3d. Didecylmethylbenzylammonium Chloride (DDAC); Applicant Lonza GmbH, Stepan Europe and Field Fisher Waterhouse LLP (RMS: IT)

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3e, 3f and 3g. Copper (II) carbonate; Applicant WPCTF (RMS: FR) and Copper (II) oxide; Applicant WPCTF (RMS: FR); Copper (II) carbonate; Applicant Spiess Urania (RMS: FR); Copper (II) hydroxide; Applicant Spiess Urania (RMS: FR)

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3h. Leaching test data requirement for Product Authorisation

COM introduced the document. With respect to the questions raised on leaching tests to be provided by the applicant under product authorisation in the document the following was concluded following reactions from **DK, FI, SE, DE, NL** and **FR**:

1. Is there a preference for a test protocol, for example the 2 times 60 minutes according to the OECD guideline, or does the receiving Member State accepts the tests submitted in light of the current experience under the Review Programme and the absence of the results of a second Leaching Rate workshop?

There is a strong preference for the OECD guidelines, applying the 2 times 60 minutes protocol. However, tests carried out following other protocols will not be rejected per se but assessed on their acceptability.

2. Is a separate test for vacuum pressure impregnation and superficial treatment required?

Separate tests are required as the leaching test information needs to reflect the label claim and both treatment lead to different leaching rates. FR noted superficial treatment often led to higher leaching rates compared to vacuum pressure impregnation.

3. Is a separate test for solvent and water based products required?

Separate tests are required if the label claim refers to both solvent and water based products.

4. Is a test not considered acceptable if the retention used in the test differs by a factor or more than 10 compared to the actual one? It is realised that this situation will most likely not occur.

A leaching test using a retention of more than 10 times higher than the actual retention is not acceptable.

4. SUBSTANCES in PT18

4a. Diflubenzuron (RMS: SE)

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4b. Imidacloprid (RMS: DE)

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5. AOB

5a. Progress on ESD for PT 02, 03 and 04

DE informed **COM** that a revised version of the document will be provided by the external consultant, after consultation between **RMS**, consultant and **COM**. It is expected that a revised document will be ready at the end of June. **DK** requests that a list of not-discussed items will be included in this document.

5b. Progress on exposure assessment for PT 06 (RMS: FR)

FR presented the progress on the exposure assessment for PT 06 (in can preservatives), highlighting the numerous exposure scenarios in this PT, the fact that the outcome of the RA is often driven by the $PEC_{regional}$ instead of PEC_{local} and the relevance of the RA. The relevance of the RA is driven by the availability of emission scenarios, availability of specific information on tonnage and the requirements of the regulatory framework. **FR** concludes that a case-by-case approach is needed for PT 06, that cumulative RA is needed for this PT, and that there are limitations within the regulatory framework. This means that, at the moment, we cannot trust the outcome (i.e. no risk) of the assessment for PT 06, because not all tonnage data are available. F.i. a small company with low tonnage can have no risk, while a large company with high tonnage has a risk. Overall conclusion, **FR** recommends to take action and ask the TM members to inform their Competent Authorities that the RA for PT 06 cannot be performed sufficiently, mainly due to the insufficient regulatory framework.

5c. Report back on EUSES training

COM reported back on the EUSES training for MS which took place on May 26 and 27 2009 in Bilthoven, the Netherlands. The training was organised by RIVM, the Netherlands

and well received by the participants (about 15 MS). However, during the training some inconsistencies were found which led to a request for a validation of EUSES by MS. **COM** asked MS to react to a mail to be sent by COM if they are willing to perform such a validation. **NO** asked if EUSES will be used under REACH by ECHA. **COM** informed that ECHA expressed interest to use some modules of EUSES.

5d. R&D project leaching tests PT 06, 07, 09, 10 & 12 (RMS: DE)

DE would like to bring to the attention an R&D project which **DE** has initiated; to bring together the existing test methods for leaching for PT 06, 07, 09, 10 and 12. **DE** wants to evaluate practicality, applicability and significance of new and existing test methods. These test methods will be compared and knowledge gaps will be identified. Results of this R&D project will be presented in a one-day workshop and will be brought to the TM for further evaluation.