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DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Unit: Toxicology and Chemical Substances
European Chemicals Bureau

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Final Minutes of the Biocides Technical Meeting TM IV 07 in Arona, 2-4 October 2007

INTRODUCTION

The meeting was chaired by E. van de Plassche and for specific items on the agenda G. Fotakis, B-O Lund, G. Deviller and W. De Coen (ECB). E. van de Plassche welcomed the participants to the TM IV 07. In addition, 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.

The meeting was informed that the contributions are recorded and the recording will only be used for writing the minutes, and afterwards destroyed.

1. Approval of the agenda

NL asked to refer the discussion on item 6e from the General Session to AOB of the Human Health Session. **COM** informed that DG ENV would inform the TM at the General Session on this issue and therefore could not be moved to the Human Health Session. There were no changes made to the agenda which was approved.

2. Adoption of the minutes

There were no comments on the revised draft of the minutes of TMIII07. **COM** informed the TM that a change will be asked at the Human Health Session with respect to the risk characterization discussion in order to clarify some issues. The minutes will be then endorsed.

3. Members of the Technical Meeting

COM informed the TM that the list of participants documents will be updated for the next Technical Meeting.

4. Next Technical Meetings

COM informed the TM that the next Technical Meeting will be held in Brussels.

ENVIRONMENT SESSION

4. Environmental Emission Scenarios

4a. PT21: ESD for marinas

COM informed the TM that there has not been much progress with respect to the development of the scenario for marinas. A proposal from CEPE has so far been submitted with respect to changing the boat density compared to the value proposed in the OECD ESD. In addition **COM** informed the TM that there is an ongoing discussion on the dimensions of the marina. CEPE and NL will submit a proposal on marina scenario that will be discussed at TM V 07.
NL commented that in the e-consultation group for antifoulings they asked for data from MS on the marina dimensions. NL sent questions to the group but no answers/proposals have been yet received. **NL** asked MS to send their opinion within a period of two weeks.

Conclusion:

- MS to react on request for additional data on dimensions of marinas to the NL by October 16;
- **NL** and **CEPE** to submit proposal on marina scenario for TM V 07.

4b. EUSES 2.1

COM introduced the project on EUSES 2.1. This was followed by a presentation on the Beta version of EUSES 2.1 from the contractor Dr. J. de Knecht from the National Institute of Public Health and Environment (RIVM). It appeared that some members of the TM did not receive the Beta version or were not able to run the program based on the files posted on CIRCA. This will be checked by the **COM** and the contractor.
DE asked if the COM has the intention to organize another workshop when MS gain more experience with EUSES 2.1 and if the COM will consider to organize training courses. **COM** responded that: i) the intention is to include also the remaining ESD for PT18 on "Insecticides, acaricides and products to control other arthropods for household and professional uses", but this still has to be decided; ii) a workshop to discuss experience with EUSES 2.1 can be organised although the present project will be finalised in the near future; iii) **COM** will consider to organize training courses.
The contractor indicated that based on the internal and external testing by the participants, from Member States and industry, of the June workshop they are confident that EUSES 2.1 has adequately incorporated all ESDs. **NL** asked when EUSES 2.1 will be available. The contractor indicated that only one minor change is still to be incorporated, which will be done in the week after the TM.
The contractor mentioned that in PT1 and PT6 some scenarios are included where it is unclear if these scenarios shall be incorporated as these substances can be regarded as cosmetics or biocides. **DK** indicated this is more a case for the CA meeting, as there are many borderline cases.
For PT21 the contractor indicated that service life, where MAMPEC is used in the Review Program, is not included in EUSES 2.1. In addition for PT21, the scenario for application and removal described in the ESD, was extended to a calculation of the

concentration in surface water (harbour and rivers) and soil. The method incorporated to calculate these concentrations from the emission rate was presented. **COM** mentioned that this addition was presented at the June workshop and preliminarily agreed upon. The contractor said that the addition is fully described in the background document distributed for this TM.
SE asked if EUSES 2.1 has to be used in the evaluations of substances. **COM** indicated that EUSES can be certainly used for the evaluation of substances within the fourth priority list by the applicants as well as by the RMS. First of all the print-out of the program can be added to the CAR, making it easy to check the exposure assessment carried out. In addition, EUSES can be used to run scenarios modifying default or input parameters. However, for the evaluation of substances within the third priority list maybe EUSES 2.1 can also be used as one and maybe both ESDs will be included in the program.

Conclusion:

- Comments on the Beta version of EUSES 2.1 will have to be sent to joop.de-knecht@rivm.nl and erik.van-de-plassche@ec.europa.eu ultimately 31 October;
- The presentation given by the contractor will be distributed to the TM.

4c. PT18 and PT 2, 3, 4: Workshop on Environmental Exposure Assessment
COM made a proposal to the TM to organise a workshop on the environmental exposure assessment for PT18 and PT 2, 3, and 4. **COM** noted that in discussions with MS before this TM, some MS wanted to have a PT18 workshop. Other MS argued that the existing ESDs are robust enough for PT18 and decisions can be taken on a case by case basis. **COM** indicated that for desinfectants it is probably necessary to have a workshop on environmental exposure assessment. **COM** added that during the BPD conference organized by Info Life Sciences in Berlin in September 2007, participants from industry agreed to participate and give input for such a workshop. **DK** welcomed the proposal made by the COM and expressed more interest on PT 1, 2, 3, 4 and 5. **DK** proposed also to include in this proposal PT 6 and 13 instead of maybe PT18. **UK** agreed with DK. **DE** commented that they would also like to discuss outstanding issues related to PT8. **NL** agreed with DK and asked if MS have identified problems with respect to the environmental exposure assessment of PT18. **NL** added that a workshop needs to be organised for substances to be evaluated from the 4th priority list. This should take place in 2008 before summer. **DK** replied that it would be difficult to organise such a workshop at this point, since the CARs for the substances of the 4th priority list are not yet available. **NO** agreed with DK. **FR** proposed to collect all questions raised regarding the environmental exposure assessment of PT18 before TM V 07 and identify if there is a need for further discussion. **COM** commented that SE has already send some questions to COM. **SE** added that issues related to PT18 have been raised at the e-consultation group. **NO** asked to have discussions specific to each PT via e-consultation groups. **UK** commented the number of e-consultation groups is increasing but some issues related to the risk assessment and waiving arguments should be brought to the TM for discussion. **COM** replied that the most critical issues are identified and discussed at TM. **COM** also asked MS to send proposals with what they consider important for discussion at TM level. **NL** noted that it is very difficult to involve everyone in the e-

consultation groups and there is a need to inform the TM on these discussions. **AT** supported the organisation of workshops. **IE** added that the workshop could be held at the same time with the CA meeting in Brussels. **IE**, **DK** and **PT** said that it would be preferable to organise small workshops for each PT rather than one workshop for all PTs. **FI** agreed to have the workshop organised by the ECB and added that FI would not be very interested in a workshop for PT18. **FR** proposed to have the workshop at the same time with the TM.

Conclusion:

- It was agreed to organise a workshop on environmental risk assessment for PT18 that will be held connected to TM V 07. **COM** and **FR** will prepare the workshop.
- For PT 1, 2, 3, 4, 5 ,6 and 13 a workshop will be held connected to TM I 08.

5. AOB

5 a. TWA paper

DE introduced the document. The paper consists of two parts: the derivation of values for the aquatic tests in stable test concentrations cannot be maintained and the derivation of values for soil test where no analytical measurements are performed. The first part is taken from the OECD guidance on difficulty substances, which is applied in the existing substances program. For the soil part the difficulties are that for some PTs for some use scenarios continuous exposure is expected. Because of this the PPP approach, where nominal concentrations from the ecotoxicity tests are compared with initial exposure concentration cannot be used as such. It is suggested to have different approaches for different degradation half lives. Based on the comments received for degradation half lives below 2 days it should be checked if the main metabolite has to be incorporated in the risk assessment. For 2-4 days degradation half life, the TWA approach or the geometric mean value can be used. Based on the reactions received the preferred approach seems to be the TWA approach to harmonise with the PPP area. It is important to decide which DT50 is to be used as the value in artificial soil will differ from field soils.

DK and **NL** welcomed the proposal made by DE, and agreed with the suggestions. **SE** commented that the proposal to divide in three different degradation classes, where **SE** would propose one trigger (less than 2 days or more than 2 days). The calculation of TWA is only valid for first order kinetics for the degradation rate, **SE** asked to include this in the document. **DE** agreed that this can be incorporated in the document, although there is no proposal on how to deal with the situation where first order kinetics do not apply. **COM** noted that within the PPPD one trigger of 2 days is used. Where a distinction needs to be made between BPD and PPPD however, is the continuous release for some biocides. In addition, **COM** noted that the guidance developed shall not lead to waiving of testing and that having one trigger value may lead to a more focused assessment with respect to metabolites and parent substance. **IND** mentioned that they could agree to one trigger value of 2 days although they could also agree to the text using the three classes as the guidance is open and not too restrictive. **IND** would argue that the decision shall always be case-by-case and that the procedure shall only be triggered by the seldom case that there is continuous release to the soil compartment. In addition, **IND** requested that the possibility of additional testing shall always be kept in mind, for example degradation tests in artificial soil or semi-field studies. **COM** indicated that indeed more testing is always

an option. However, the guidance is prepared for rapidly degradable substances where such additional data are not available. **IND** stated that chronic testing for terrestrial organisms simulating continuous release is technically difficult. As the use of a DT50 value of 2 days may lead to very low effect values **IND** stated that this may not be used as a trigger to ask for such studies. **IND** proposed to base the assessment on an acute study with the parent substance and investigate if relevant metabolites occur. **DE** stated that there are biocidal uses where there is long term exposure to rapidly degrading substances. **NO** welcomed the document and stated that for wood preservatives the situation of continuous release occurs. **NO** asked what to do in case of a DT50 value higher than 2 days where several metabolites are formed. In this case, the addition of metabolites and parent substance is difficult as there is most likely no information on the biological activity of the metabolite. **DE** replied that then further information can be requested. **NO** said that these metabolites are often formed in amounts less than 10% of the parent substance. Subsequently, these are not identified and no information on their biological activity can be asked for. **DE** proposed that the assessment shall be carried out for those metabolites formed in more than 10% of the parent substance. The applicant can show in addition that the remaining metabolites are not biological active, for example by the use of QSARs. **NO** commented that this is not possible as no identification or data can be asked for since these metabolites are formed in less than 10% of the parent substance. **NL** stated that if the metabolite is biological active this shall be observed in the acute tests available. **FR** stated that the approach which has been agreed before is that the metabolite is as toxic as the parent substance in such a case. **DE** said that they would like to highlight in the document that there are several alternative approaches in such a case. **AT** indicated that there is no harmonized view on the evaluation on metabolites and that this should be considered in the proposal. **AT** asked for more detailed guidance on the assessment of metabolites. **COM** stated that this will be taken into consideration. For the moment the approach is indeed more case-by-case, although **COM** reminded there is already experience in the Review Program, with dichlofluanid, which can be used.

Conclusion:

- The TWA will be the preferred approach. The limitations of the approach will be described (situation that the degradation pattern does not follow first order kinetics);
- The classes will be reduced to two: less and higher than 2 days for the half-life in soil;
- **DE** will update the version and distribute it for TMV07, including IND, for endorsement. The additional calculations performed by the **COM** will be sent to DE and incorporated in the next draft version.

5b. OECD Task Force on Biocides

The chair of the Task Force informed the TM about the discussions of the last OECD Task Force Meeting on Biocides. The ESD for insecticides for household and professional uses has been finalised. The document will be published but it was agreed to include text indicating that the current default values for "building type" and "simultaneity factors" used are conservative and if real data is available this should be used instead. The issue of further work on missing ESDs for all PTs has been raised at the meeting. All delegations including the European Commission are invited to consider all PTs for the possible future development of missing ESDs.

With respect to the guidance document on leaching from treated wood, for wood not in contact with ground, it has been mentioned that the draft guidance indicates the pros and cons of the three different dipping regimes. Regarding the leaching from treated wood and the possibility to develop guidance for wood in contact with ground, it was agreed not to pursue further work for the development of such guidance. It was agreed to include in the website of the task force text saying that the adopted test guideline for wood in contact with water can be used in the case of wood in contact with soil if no other data is available. The existing methods for soil (e.g. AWMA) as well as some US methods available will also be listed in the public website.
The pre-validation work for the test guideline on efficacy data for hard surface disinfectants has been completed: 29 labs will participate in the ring trial for validation and the validation will be available in the second half of 2008. It is noted that the current validation applies only to liquids and the delegates were invited to indicate which type of consumer products in the market (e.g. wipes, sprays)are most important to be considered in the future for developing a guidance document or a test guideline. The group also agreed to explore ways to harmonise definitions and/or performance standards for label claims.
The guidance document on the evaluation of efficacy for antimicrobial treated articles will be finished as a guidance document.
For the possibility of developing a guidance document on efficacy testing for treated articles, Japan agreed to provide financial and technical support to develop a test guideline based on ISO and Japanese industrial standards. It first needs to be determined how much validation work has already been carried out and what additional work is required in the future.
For the development of guidance document for efficacy of biocidal products used in pools and spas it was agreed that some points need to be elaborated and all delegations were invited to send relevant data by the end of November.
At the meeting Australia highlighted that the weight of evidence for the efficacy of silver ions, or silver and copper ions together does not indicate that the efficacy is sufficient for the safety of bathers.
With respect to the development of guidance document for determining the leaching rate of antifoulings the delegations were invited to indicate if they have any objections to use the mass balance method. If no objections are raised then the task force would explore the possibility to develop a guidance document.
The draft guidance document on assessing human exposure to biocidal products will be finalised and distributed to the OECD relevant groups for review.
The chair of the task force added that for the development of guidelines for physicochemical properties, the scope of such guidelines and the possibility for funding from industry will be explored. It has been identified that eight or nine OECD guidelines for physicochemical properties are used in different way by different countries. It has been estimated that around 17 million Euro would be saved if there was harmonisation on the use of these guidelines.
The task force agreed to develop a vision document for the future work of the OECD task force. All delegates and the European Commission are requested to consider providing funds as the resources available are not sufficient to carry out the work. The programme is not covered by Part I and II of the OECD budget and is only funded by extra budgetary funding; at present only five out of thirty members have financially supported the work programme for 2007.
The internet address for the OECD work on biocides is:
http://www.oecd.org/department/0,3355,en_2649_32159259_1_1_1_1_1,00.html.

5d. Status of PBT WG 2nd generation anticoagulants

COM reiterated the CA decision that the PBT assessment for the 2nd generation anticoagulants will be forwarded to the PBT working group and that NO will coordinate the process. **COM** reminded MS that the deadline for sending the factsheets to NO is the 15 October 2007. **COM** asked MS to give an update on the progress with the preparation of the fact sheets. **NO** said that for difethialone the factsheet was sent to the applicant and NO is waiting for their response. **NL** informed that the factsheet was sent to the applicant and NL is awaiting response. **IT** will inform NO and the COM after the meeting. **FI** confirmed that the factsheet is under preparation and will be sent to NO within the deadline.

IE asked if there will be consequences for the available anticoagulant rodenticides in the European market due to the possible restrictions imposed. **COM** replied that for the 2nd generation anticoagulant rodenticides there is still an ongoing discussion for the draft Annex I decision for difenacoum with DG SANCO. DG SANCO asked to take into account the paraquat court case for which a decision was made by the European Court of Justice during last summer. According to DG SANCO this decision could have an impact on the BPD work and could affect the decision on Annex I inclusion for difenacoum. **COM** added that a note related to this issue has been prepared and sent to the legal services of the Commission. Depending on the opinion of the legal services this issue will be rediscussed at the 27th CA meeting.

COM noted that the PBT assessment will not delay Annex I inclusion for the 2nd generation anticoagulants. A different approach compared to other biocidal active substances is followed already for the 2nd generation anticoagulants: the Annex I inclusion for these substances is limited to five years instead of ten and it is also made clear in the specific conditions for Annex I inclusion that at the time of renewal of the Annex I inclusion a comparative risk assessment will be performed. At that time, products containing the active substances will have been authorised and there will be a better overview of what is available in the market for rodent control and maybe additional data will be available.

IND asked if the outcome of the PBT assessment will result in a revision of the final CARs and whether this is foreseen to delay the assessment of the substances or not. **IND** also asked if it can be reassured that the PBT assessment will be harmonised since for the estimation of bioaccumulation for example two methods of calculation are available. **IND** questioned the harmonisation of the comparative assessment unless the same criteria apply. **IND** asked COM to inform on the time schedule with respect to the future meetings of the PBT working group.

COM said that the last meeting of the PBT working group under the current legislation will be held in November 2007. The activities will be then transferred to ECHA where a subgroup under the one of the Scientific Committees of ECHA will deal with the PBT assessments. Invitations will be sent in the near future to the MS to nominate experts for the establishment of the Scientific Committees. The Scientific Committees will then have to establish sub-groups, of which one will be a group dealing with the PBT assessment. **COM** added that there it is considered at the moment to have an additional meeting of the PBT Working Group in March 2008, but this is still under discussion with ECHA and DG ENV. For substances not finalised under the current legislation, the ECB will prepare hand over files to ECHA to avoid interruption of the process.

COM concluded that the outcome of the PBT assessment will not delay the inclusion of the substances on Annex I. The outcome of the PBT assessment will be useful for

the puroposes of the comparative asssessment in five years and will also provide useful information to IND on what data needs to be submitted in order to perform the comparative assessment.

Conclusion:
Factsheets on the PBT assessment for the second generation anticoagulants will be sent to NO by October 15.

GENERAL SESSION

0. Update from 26th CA meeting

DG ENV reminded the process of final decision-making in relation to Annex I inclusion and then informed the participants on the state of the art:
Suphuryl difluoride and Dichlofluanid: included in Annex I (PT8).
Difethialone (Annex I) and Carbon dioxide (Annex IA): a positive opinion was given by the Standing Committee in June, EP and WTO have been consulted.
Clothianidin and Etofenprox: a positive opinion was given by the Standing Committee at the meeting in September 2007. During the next CA meeting the assessment report and Annex I inclusion Directive for Propiconazole, Tebuconazole and Difenacoum and CO_2 will be discussed and voted. The assessment report and Annex I inclusion Directive for K-HDO, Thiabendazole, Thiamethoxam and Chlorophacinone will be voted at the 28th CA meeting but a first discussion will take place during the 27th CA meeting.
The decision of including the CO_2 in Annex IA will be soon finalised, however, discussions are ongoing on the eventuality to also include the substance in Annex I. Concern has been raised about the limited data package available and about the fact that the reference product is very specific. A decision on this issue will be taken during the next CA meeting. The limited data package submitted to the RMS leads to discussions on the way of drafting specific provisions in Annex I. Documentation on the CA meeting discussions will be provided during the next TM meeting.
Review of the Directive: a survey to assess the impact of the implementation of the Directive was conducted by an external consultant on behalf of the Commission. The outcome of the survey showed that the system is considered very complex and expensive especially from small/medium-sized enterprises. There is, however, general support as the Directive aims at protecting the environment and public health and at harmonizing procedures and rules.
The main objective of the review of the Directive is to streamline and clarify certain parts of the text and to address shortcomings. A proposal to address the main issues will be submitted to the Council and to European Parliament by the end 2008.
At the beginning of 2008 a proposal to address some urgent issues will be submitted. This will mainly regard the extension of the transitional measures. The intention is to achieve an amendment of the Directive by mid 2009. Other urgent changes, which could be submitted with this proposal, concern the definition of frame formulation and to legalise the procedure of the post Annex I process. This remains however to be confirmed.
Review programme: the document concerning the outcome of the mid-term review seminar was finalised. During the meeting, actions aimed at improving the effectiveness of the review programme were agreed upon. Some of these actions have already been put into practice, i.e. standard quality check of the reports before uploading on CIRCA made by the ECB, standard operating procedures developed in relation to deadlines compliance and to progress reports. UK made a proposal with regard to the measures that should be taken in case dossiers present incomplete data sets or in cases of clear risk.
Chromium: it was agreed that decisions in relation to this substance will be taken on a case by case basis. The evaluation of one data set has already been performed; in

this case the fixative function of chromium was acknowledged to be demonstrated. During the next CA meeting a final decision on this set of data will be taken.
Guidance documents: there is a need to streamline the process of developing guidance documents. It is necessary to state clearly the date of application of guidance documents. Industry should be consulted before the development of guidances and this was already done for the guidance on technical equivalence.

CEFIC will draft a document in relation to "In situ generation", based on the document prepared by the UK taking into account the comments received. Then the issue will be discussed at the 27th CA meeting.
ECB will prepare a document with respect to the guidance development process and on the way to streamline the process.

In situ generated substances: CEFIC will try to bring further the draft document prepared by the UK taking into account the comments received. Then the issue will be discussed again at CA level.

PT remarked that two documents on incompleteness have been elaborated: one concerns the completeness check and the other relates incompleteness at evaluation stage. The first has already been endorsed at the CA meeting whereas the second is still under discussion. **PT** underlined the importance of clarifying to which documents the discussion is referring to. **DK** pointed out that concerning incompleteness, the document provided by the Commission states that the company should be considered not compliant if a missing key study is not provided within one year. **UK** in its document proposed to work rather on a case by case basis. **COM** commented that only in exceptional circumstances a period of more than 12 months should be granted for missing studies.
COM updated the TM on the discussions ongoing in relation to the MRL document. Clarification should be made for biocidal substances with regard to the establishment of maximum residue levels taking into account that there are substances already used in veterinary products or in plant protection products.

1. Tracking System

1a. Progress reports
COM reminded to use the ENV-BIOCIDES@ec.europa.eu e-mail address for any comment with respect to the tracking system. **COM** informed the TM that MS already sent the list of the dossiers submitted for the 3rd priority list. A second list of substances for which companies indicated the interest to take over the role of the participant for substances of the 2nd priority list has been published on the web site of DG ENV.

4. UK paper on handling incomplete evaluations
UK prepared a revised document taking into account the comments received. **DK** supported the initiative but raised concerns with respect to the legal aspect on the use of the document. **DE** agreed with **DK**. **DE** pointed out that this issue is addressed in Art. 10 (3) of the Second Review Regulation[1]. **DE** commented that according to the

[1] Clarification from DE after TMIV07: The relevant article is article 10 paragraph 3, 2nd sentence of the 2nd Review Regulation. It refers to article 8 paragraphs 3, 4 and 5 of the same

Directive 98/8/EC CMR substances (Cat 1 or 2) cannot be included in Annex IA and it should be clarified if this is valid also for inclusion in Annex I. **NL** agreed with **DE** and **DK** and suggested to check if it is allowed to upload a short evaluation report on Circa. **AT** proposed to limit the discussion to known cases where the evaluation of the substance cannot be completed because of insufficient data available. **COM** clarified that according to Directive 98/8/EC CMR substances cannot be authorised for amateur use, but can be included in Annex I for professional use. Following a comment from **DE** and **PT** it was decided that it should be checked whether Art. 8 (3) comprises incompleteness during the assessment or not. **AT** asked for clarification on the steps following the eventual RMS's decision of on Annex I exclusion recommendation. **COM** answered that following the decision on Annex I exclusion of a substance, a short CAR should be submitted for commenting by the MS. **AT** raised concerns with respect to the fees paid for the evaluation of a full dossier. **NO** commented that the issue should be considered at CA level.
COM informed that the legal feasibility of the procedure described in the document will be checked and the document will be sent to the CA meeting for further discussion.

5. In situ generation
See above: Update from 26th CA meeting

6. AOB
6a. Painkillers in rodenticides – Presentation by U.F.A.W
The director of the Universities Federation for Animal Welfare and his colleagues gave an overview of the projects developed in order to improve animal welfare related to the use of rodenticides.
Three main aspects concerning rodent control were addressed during a Workshop organized in order to improve animal welfare: to promote research using more humane methods, to give advice to the public on the most appropriate methods to use taking into account animal welfare and to establish an advisory body in charge of providing independent advice on what improvements might be needed. The economic burden for the development of more humane methods is the obstacle that mainly slows down research within this field.
In order to develop more humane methods, a study was conducted aiming at decreasing the time of animal's death. This could be accomplished either by rendering the animal more susceptible to the poison or by altering the metabolism of the poison. In addition the use of non steroidal anti-inflammatory agents to produce analgesia was also taken into consideration. Phenylbutazone that has low dose-effect ratio in rats, long analgesic activity and pharmacodynamic interaction with warfarin was co administered with warfarin to rats. It was shown that adding an analgesic agent to the anticoagulant has the potential to decrease the time to death, in particular to decrease the time of the onset of symptoms. A possible improvement to the formulation could be the microencapsulation of phenylbutazone in order to mask its nasty taste and prolong the analgesic effect.
The TM was asked to provide advice on possible ways to promote this activity and on possible regulatory implications.

Regulation in case the participant does not provide the requested additional information within the given time period, cannot justify a further extension of the time period and no other participant for this combination of active substance and product type is in the process.

IND raised concerns on the efficacy of analgesic substances considering that the animals need certain food consumption before the intake of the poison. The presenters said that the aim of the research was to reduce the time of the onset of symptoms to death and not to reduce the time between consumption of food and the onset of symptoms. **AT** supported the use of analgesics as long as it can be shown that the period of analgesia covers the period of pain. AT added that the elimination half life of analgesics can be around 6 hours whereas the rodenticide effect last for 3 to 4 days. AT also said that it should be known if the analgesic used is already approved for medicinal and veterinary use. Non-clinical data on rodenticides together with non-clinical/clinical data on analgesics is needed for the classification of formulations containing rodenticides and analgesics. **NO** agreed with AT but added that the efficacy of rodenticides may change in the presence of analgesics and synergistic effects should be taken into account. **NO** said that there should be data available for such products to indicate that the analgesics added are substances of no concern for human and environmental endpoints. **SE** said that NSAID can interact with Warfarin and other anticoagulants and added that there will be greater risk for secondary poisoning. In addition NSAID have side effects and SE would have reservations on their use in rodenticidal products.
IE was in favour of the principle but raised concerns with respect to steroids entering the environment, and the development of cross resistance. IE said that experimental data should be submitted to indicate if there are any impacts for human health and the environment. **IND** said that for the secondary poisoning of birds and mammals with these formulations the exposure will also be reduced unless the substance has synergistic effects with the rodenticide. **COM** thanked the presenters for bringing this issue to the attention of the TM.

6b. Dossiers acceptability for active substances for several product types (PTs): Outcome of e-consultation

COM informed the TM that AT, via e-consultation, asked for the opinion of the TM on how to handle one dossier submitted for the third priority list for several PTs, where it was identified that the completeness check was difficult to perform. Several MS reacted and sent their opinions which were collected in one document and distributed to the TM for discussion. This issue has already been discussed at the last CA meeting. **COM** said that according to the document endorsed at the 26th CA meeting it was agreed to try to avoid duplication of work, to re-use CARs or combine for several PTs; the latter could apply for disinfectants. **COM** noted that this approach will reduce the number of documents distributed for discussion and will increase the efficiency of the peer review. **AT** said that there was no agreement at the CA meeting but only endorsement of the document in principle. **DK** added that the CAs did not agree with the one in all approach and if this is the case DK would like to reopen the discussion at CA level. **COM** said that some MS disagreed but the document was endorsed. It still remains to decide the procedure to be followed in order to minimise the number of documents. **COM** asked not to reopen the discussion held at CA level but the TM should agree on a way that the combination of CARs for multiple PTs can be made. **AT** said that during the completeness check for one substance (for multiple PTs) for which AT is the RMS, the applicant did not submit the latest version of the CAR and it was difficult to allocate studies to different PTs. In addition the applicant did not specify which parts of the combined dossier belong to the different PTs. **AT** commented that it is not the task of the RMS to rewrite the CAR. **DK** agreed with AT

and noted that they had advised the applicant to submit separate documents for each PT for disinfectants and indicate one Master dossier for one PT. Then reference will be given to this Master dossier for the other PTs. **DK** added that DocIIA will be the same for all PTs and FR had followed the same approach. **DK** indicated that FI supports to have one assessment report and it should be a case by case decision where flexibility should be allowed always avoiding duplication of work. **UK** agreed with DK for flexibility and asked to have the documents structured in a clear and transparent way. **NL** said that the aim of this work is to have the information for each PT at product authorisation traceable. **NL** proposed to have individual reports for each active for each PT on circa which could then be used at product authorisation in an efficient way. **COM** commented that whichever approach is followed the CARs should be structured in a way that the information can be traced easily at product authorisation. **COM** said that if the applicant does not submit the data in a transparent way then resubmission should be asked. **NO** indicated that one approach cannot apply for all PT and the combination of the information in one CAR is possible for certain PTs. **NO** agreed with the document endorsed at the CA meeting and added that for multiple PTs there should be a discussion on the dossier structure when submitted by the applicant. **DE** said that during a previous submission of a dossier to DE, the applicant prepared a master dossier with additional documents for each PT but DE will be preparing individual CARs for each PT by copying the identical parts of the report. **DK** noted that for IBPC a CAR report for PT 8 was submitted, and for PT6 and 13 a separate CAR will be prepared but reference will be given to the decisions made for PT8. **FR** said that, like DE, they will distribute full CARs for each PT. **FR** asked whether one assessment report can be prepared that will be updated when new PTs are included. **FR** also proposed to have individual LOEP for each PT in the assessment report. **SE** supported the flexible approach and noted that for silver, 26 dossiers would have to be prepared but SE will combine them in one dossier. **COM** said the decision of having one CAR or not depends on the time of submission of the data for different PTs. If the data is submitted at the same time then the all in one approach would be preferable.
COM said that it is obvious that individual DocIIB is needed for different product types but it still needs to be decided if it is possible to have one DocI that would include the information for several product types. **COM** indicated that this would be feasible for disinfectants but it may not be possible for other product types. **AT** commented that the applicant can be asked to give the information on which parts are relevant for each product type to allow easy completeness check. **COM** said that it is needed to have indicated in the CAR which information apples for each PT. **DK** said that following the evaluation of IBPC under PT8 the task force has been increased by one member. Therefore for the evaluation of IBPC for PT6 and PT13 it is possible to have more data available. **DK** asked to take this issue into account when preparing the proposal for the next TM.

Conclusion:
It was agreed that **COM** will prepare a written proposal for the next TM with respect to this issue to reflect the discussion and comments from MS; it will also be highlighted that there is a need for flexibility.

6c. Request for making minutes of the TM publicly available
COM explained that it has been requested by NGOs to have the minutes from TCNES and TC C/L made publicly available. Following legal consultation it has been

agreed that these minutes will be made publicly available. Based on this decision, **COM** asked if the TM would agreed that the minutes from the Technical Meetings for Biocides can also be made publicly available. **COM** indicated that there is no issue of confidentiality according to the legal services of the Commission. In addition CEFIC agreed to check the minutes before distribution to make sure that no confidential information related to the substances' discussions is included. **COM** proposed to prepare a draft version of the minutes after each TM that will be also sent to CEFIC; CEFIC will then distribute the parts related to the substances' discussions to the corresponding applicants and when confidential data, if any, has been removed, this draft will be endorsed by the TM and will be made publicly available.
AT asked if the name of the substance will appear in the minutes. **COM** confirmed this. **DK** asked if it would also be allowed that all the applicants are present during the discussions of all CARs. **COM** replied that this is not possible since there may be discussions on confidential issues which will have to be removed from the minutes. One participant from **IND** said that they would not agree having information related to the discussion of the individual substances publicly available. **COM** said that it would be possible to prepare two versions of the minutes: one confidential and one non confidential. **COM** informed the TM that there is a community law with respect to the right to know. **COM** said that for the New Substance Regulation, the minutes from the closed sessions will not be made publicly available but in this case the information is protected by the Regulation. The minutes from the open sessions will be made publicly available. **COM** concluded that this issue will be further discussed with IND to find a way forward.

6d. TNsG Revision of the Analytical Methods
AND
6e. TNsG Proposal for setting MRLs
COM proposed to defer these items to the next TM since there has not been enough time to review and send comments on these documents. **COM** also expressed reservation with respect to the need of these documents at this stage. **DE** agreed to have this item for discussion at the next TM and asked MS to send their comments with a copy to the COM. **UK** commented that according to the TNsG on data requirements for active ingredients for biocides it is stated that analytical methods in all relevant environmental media are required. It was agreed at one TM in 2006 that this data should not be routinely required for the purposes of Annex I inclusion only. **UK** added that for toxic substances or substances with residues in food this data should be required. **UK** pointed out that analytical methods for soil and water are not necessary. **DE** replied that this document is the first proposal and agreed that currently, analytical methods are not required for the evaluation of biocidal substances. **DE** said that guidance is needed for future purposes. AT informed the Meeting that the issue on drafting a guidance document concerning the setting of MRLs has already been started some years ago under the chairmanship of Mr. Klaus Berend.
It was agreed that for the proposal on Analytical Methods, MS will send comments in writing to DE with a copy to the COM within one month. COM will also trace the past discussions on this issue and a decision will be made on the way forward.
With respect to the proposal on setting MRLs for Biocides, **COM** informed the TM that consultation within the Commission will be initiated to identify if there is a need for developing further this document. Therefore, no written comments will be sent until further information from the Commission is provided. SE and NL had already

prepared comments on the MRLs proposal and these will be sent for information to DE and the COM.

TOXICOLOGY SESSION

4. AOB

4a. MOE versus AOEL approach

COM introduced the item: **DE** sent a proposal asking the TM to decide on the use of only the AOEL approach instead of both the MOE and the AOEL approach which is the current practice for the risk characterization of biocides. **COM** added that no other issues on risk characterization revision will be discussed at this TM. **COM** noted that the MOE or MOS approach is not used anymore for new and existing chemicals although this approach is still used by other regulatory programmes (e.g.: U.S E.P.A). **COM** informed the TM that DK had sent in writing their opinion on this issue agreeing with the use of the AOEL approach only. **UK** suggested maintaining a flexible approach. **COM** noted that a final decision needs to be made to have a harmonized approach for the CARs and to finalize the risk characterization document for biocides. **AT** added that the reason that MOE approach is also used for biocides was for reasons of compromise in the past where no definite decision could be reached on which of the two approaches to adopt. **AT** said that since the MOS approach is not used anymore for the risk assessment of new and existing chemicals then it should also not used in the area of biocides. **PT** commented that they would prefer to use both approaches whereas **FR** agreed with the proposal made by DE as this would avoid duplication of work. **COM** asked the MS to vote on whether only the AOEL approach or both the MOE and AOEL approach should be used for the risk characterization of biocides. The outcome of the voting was 13 MS voted in favour of the use of both approaches and 8 MS preferred the use of only the AOEL approach. Therefore based on the decision of the majority it was concluded that both the MOE and the AOEL approach will be used in all CARs for biocides.

COM added that both approaches should be used in both tiers of the risk characterization. **PT** asked if the tier approach that appears in some CARs is an agreed way to perform the risk characterization. **COM** clarified that the revised risk characterization document will include the tier approach which will be harmonized with the tiered approach presented in the new TNsG for Human Exposure.

4b. Standard body weight for professionals

COM commented that it has been observed that the body weight value of 70kg has been used in some CARs whereas in others the value of 60kg as indicated in the TNsG is used. It has been agreed that the value of 60kg should be used in the future CARs. In case the value of 70kg has been used in CARs which are currently finalized no changes shall be required but the RMS should indicate in the report which value was used to perform the calculations. The initial proposal from the COM was to add a note in the report that new calculations should be made at product authorization stage using the value of 60kg as body weight for professionals. **NL** informed the TM that in some MS this would be in conflict with the National Legislation where the value of 70kg has to be used for product authorization purposes. **COM** commented that this could be a problem for mutual recognition and in borderline cases where this difference could result in different decisions. Therefore COM will refer this issue for discussion at the next CA meeting in November 2007.

4c. Other

1) COM informed that the 26th CA meeting endorsed the decision made by the TM with respect to the use of spraying method by amateur users.

2) COM informed the TM that the ECB will do the revision of the final draft of the risk characterization document. The revised version will be sent to the TM by the end of October allowing 4 weeks commenting period before the next discussion at TMV07.

3) COM informed the TM that the commenting period for the revision of the TNsG Human Exposure has ended. Comments from MS have been received and when the final revision is made the document will be made available at the ECB website.
COM added that there has been a proposal sent to the Commission by TNO on setting an experts' group that would also review the relevant parts of the CARs that will be discussed at the TM. **COM** noted that it would be difficult at this stage to change the procedure since the exposure experts from MS are already involved in reviewing the exposure assessment of the CARs. **COM** said that there is an existing human exposure group and the UK is hosting a password protected website. **COM** would propose to have also the version control group included in this group and when general or specific issues, related to the TM discussions or to the update of the TNsG for Human Exposure, arise these would be then brought to the TM for discussion.
DE commented that they would be interested in participating in the version control group. **UK** said that MS have to nominate experts and invitations will be sent to join the group. **AT** asked to describe in the minutes the procedure to be followed. It was agreed that COM will liaise with UK and distribute the relevant information to the MS so that they can nominate their experts for the version control group as well.

4) COM asked the TM to clarify what is meant with respect to the approach to be followed within the risk characterization document in borderline cases. **COM** indicated that the way the minutes from the previous TM present this issue, it is not clear whether comparison with the allometric scaling principle or with other approaches like the DNEL approach overall shall be made in borderline cases. The latter would also include the lowering of the assessment factor for professionals. **COM** reminded the TM that during the discussions at TMIII07, the majority of the TM did not support the use of a lower assessment factor for professional users.
DE commented that when there is concern following the comparison of AOEL to exposure some flexibility should be allowed in borderline cases; if exposure with personal protective equipment (PPE) would not result in any risk, **DE** would propose that at the last tier to be able to compare with the DNEL approach in total and not only with the allometric scaling principle. In the latter case, if rat data is used then this comparison would not be helpful. **DE** added that the purpose is not to compare whether the DNEL approach should be preferred to the AOEL approach or to have this as a refinement step but only as a comparison. **COM** commented that when no risk is identified with the use of PPE then no comparison with other methodologies is needed. Comparison with the DNEL approach would be needed if there is risk identified even with the use of PPE. **UK** agreed with DE that in borderline cases a flexible approach should be adopted. **SE** disagreed with this approach and with lowering the assessment factor for professionals. **SE** added that in certain cases the allometric scaling principle could be used for the purpose of refinement but in general

SE would prefer to use the currently used methodology. **COM** asked what approach should be followed when risk is identified with the use of PPE and no further refinement is possible. **SE** replied that calculating the risk using other methodologies should not be the way forward but instead risk mitigation measures should be taken into account. **NO** supported SE and would not support the lowering of the assessment factors for professionals. **FR** commented that they would favour the flexible approach proposed by DE. **FR** added when an unacceptable risk is identified then the RMS should have the flexibility to refine or compare with other methodologies. **COM** asked DE what would the outcome of this comparison with the DNEL approach would be; would it mean that if no risk is identified with the DNEL approach that this should be adopted in the specific case and be the outcome of the risk characterization? DE commented that the use of the AOEL approach with the use of PPE resulted in a borderline situation for potassium sorbate with the risk ratio 0.7 which formally indicates no concern. In this case DE wishes to have the choice to take into account the overall toxicity data for the substance and the uncertainties in the exposure estimation. **DE** would like to mention in the report that other approaches lead to a different conclusion. **DE** said that this qualitative discussion if included in the CAR would help to make the final decision. **AT** commented that MS should follow the agreed methodology based on the risk characterization document to be finalized very soon. **COM** concluded that from the above discussion it is obvious that no firm conclusion can be reached at this stage. **COM** proposed to await until the revised version of the risk characterization document is ready where the COM will make an effort to present this issue in a way that would satisfy the MS. **COM** added that in the minutes of TMIII07 a note will be added with respect to this issue indicating that no agreement has been reached yet and the discussion will be continued at TMV07.

EUROPEAN COMMISSION
DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Unit: Toxicology and Chemical Substances
European Chemicals Bureau

TMIV07-item1-DraftAgenda-ver3.doc

17/09/2007

Draft AGENDA

Biocides Technical Meeting

in Arona

2-4 October 2007

START: Tuesday 2 October 2007 at 9:00
FINISH: Thursday 4 October 2007 16:00

DEADLINE FOR DOCUMENTS: 7th September 2007

INTRODUCTION

START: Tuesday 2 October 2007 at 9:00

1. Approval of the agenda

2. Adoption of the minutes
(TMIV07-item2-draft minutes TMIII07
TMIV07-item2- minutes TMIII07_rev1.doc
TMIV07-item2-minutes TMIII07 FI com.doc
TMIV07-item2-minutes TMIII07 DK com.doc
TMIV07-item2-minutes TMIII07 SE com.doc
TMIV07-item2-minutes TMIII07-UK com.doc)

3. Members of the Technical Meeting
(TMIV07-item3-Members of the TM)

4. Next Technical Meetings
TMV07 11-14 December 2007
TMI08 11-14 March 2008
TMII08 10-13 June 2008
TMIII08 14-17 October 2008
TMIV08 9-12 December 2008
(Additional TM for 15-18 July 2008 depending on available CARs for discussion)

ENVIRONMENT SESSION

START: Tuesday 2 October 2007 at 09:30
FINISH: Tuesday 2 October 2007 18:00

1. SUBSTANCES in PT 8:
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table)

First discussion for the following substances
1a. Fenpropimorph (RMS: ES)

1b. Boric oxide (RMS: NL)

1c. Boric acid (RMS: NL)

1d. Disodium octaborate tetrahydrate (RMS: NL)

1e. Disodium tetraborate (RMS: NL)

Second discussion for the following substances

1f. Chlorfenapyr (RMS: PT)
Before this substance is discussed the proposal from PT on the Termite Control Scenario for wood preservatives will be discussed.
(NOTE:

- The documents for the Termite Control Scenario have been uploaded under the substance folder on Circa
- The documents for the PBT assessment have been uploaded under the substance folder on Circa)

2. NEW SUBSTANCES
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table)

First discussion for the following substances

2a. Indoxacarb (RMS: UK)

4. Environmental Emission Scenarios

4a. PT21: ESD for marinas
(COM to inform)

4b. EUSES 2.1
(TMIV07ENV-item4b-EUSES2.1 ECB Letter
TMIV07ENV-item4b-EUSES2.1 zip1
TMIV07ENV-item4b-EUSES2.1 zip2)

4c. PT18 and PT 2, 3, 4 Workshop on Environmental Exposure Assessment
(TMIV07ENV-item4c-Workshop on ENV Exposure Assessment PT18,2,3,4)

5. AOB

5 a. TWA paper
(TMIV07ENV-item5a-TWA paper.Doc
TMIV07ENV-item5a-TWA paper Cefic com.doc)

5b. OECD Task Force on Biocides

5c. Aquatic PNEC Derivation for DCOIT
(TMIV07ENV-item5c-DCOIT Background info tox tests NO.doc
TMIV07ENV-item5c-DCOIT Aquatic PNEC Derivation NO.doc
TMIV07ENV-item5c-DCOIT Aquatic PNEC Derivation Applicant com.pdf)

5d. Status of PBT WG 2nd generation anticoagulants
(COM/NO to inform)

GENERAL SESSION

START: Wednesday 3 October 2007 at 09:00
FINISH: Wednesday 3 October 2007 17:00

0. Update from 26th CA meeting
(COM to inform)

1. Tracking System

1a. Progress reports
(TMIV07GEN-item1a-Progress Reports New Active.pdf
TMIV07GEN-item1a-Progress Reports Existing Active.pdf)

2. SUBSTANCES in PT 8:
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table)

First discussion for the following substances

2a. Fenpropimorph (RMS: ES)

2b. Boric acid (RMS: NL)

2c. Boric oxide (RMS: NL)

2d. Disodium octaborate tetrahydrate (RMS: NL)

2e. Disodium tetraborate (RMS: NL)

3. NEW SUBSTANCES
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table)
First discussion for the following substances

3a. Indoxacarb (RMS:UK)

4. UK paper on handling incomplete evaluations
(TMIV07GEN-item4b-Handling Incomplete Evaluations UK.doc
TMIV07GEN-item4b-Handling Incomplete Evaluations SE com.doc
TMIV07GEN-item4b-Handling Incomplete Evaluations FI com.doc)

5. In situ generation
(COM to inform)

6. AOB
6a. Painkillers in rodenticides – Presentation by U.F.A.W
(TMIV07GEN-item6a-Painkillers in rodenticides UFAW.doc)

6b. Dossiers acceptability for active substances for several product types (PTs): Outcome of e-consultation
(TMIV07GEN-item6b-Dossiers acceptability several PTs
TMIV07GEN-item6b- Summary of Midterm review)

6c. Request for making Minutes of the TM publicly available
(COM to inform)

6d. TNsG Revision of the Analytical Methods
(TMIV07GEN-item6d- TNsG Revision of Analytical methods DE.doc)

6e. TNsG Proposal for setting MRLs
(TMIV07GEN-item6e- TNsG Proposal Setting MRLs DE.doc)

TOXICOLOGY SESSION

START: Thursday 4 October 2007 at 09:00
FINISH: Thursday 4 October 2007 16:00

1. SUBSTANCES in PT 8.
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table)

First discussion for the following substances

1a. Fenpropimorph (RMS: ES)
(NOTE: Additional comments from the applicant and response by the RMS have been uploaded on the substance folder on Circa)

Final discussion for the following substances

1b. Potassium Sorbate (RMS: DE)
(NOTE: An updated DocIIC13 and Responses from the RMS on outstanding issues have been uploaded on the substance folder on Circa)

2. SUBSTANCES in PT 14:
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table)

Final discussion for the following substances

2a. Aluminum Phosphide (RMS: DE)
(Revised RCOM table and Documents available on Circa under the Substance Folder)

3. NEW SUBSTANCES
(The documents for this agenda item are distributed via the confidential CIRCA site for the evaluation reports; the main discussion document will be the consolidated commenting table)
First discussion for the following substances

3a. Indoxacarb (RMS:UK)

4. AOB

4a. MOE versus AOEL approach
(TMIV07TOX-item4a-AOB-MOE vs AOEL-DE.doc)

4b. Standard body weight for professionals
(TMIV07TOX-item4b-AOB-Standard bw Professionals.doc)