EUROPEAN COMMISSION
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection
Chemical Assessment and Testing

Biocides Technical Meeting
15 - 19 February 2010

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, V. Rodriguez Unamuno and L. van der Wal (DG JRC), and C. Kusendila (DG ENV). E. van de Plassche welcomed the participants to the TM I 2010. Representatives from the MS, NO and CH 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 the meeting about the withdrawal of the First Draft CAR for dichlorvos in PT 18 for the meeting. Consequently, **COM** stated, referring to the "SOP for the Biocides Technical Meeting", that it is the responsibility of the RMS to inform the applicant in time that their dossier will be tabled for a TM. In addition, the RMS shall distribute the relevant documents for the discussion in time to the applicant.

The agenda was endorsed without any changes.

2. Adoption of the minutes

No comments were made on version 2 of the draft minutes, so the minutes of TM IV 2009 were endorsed.

In the Environment Session **NL** commented on so-called "post-TM comments" which are inserted in the minutes. As these "post-TM comments" **NL** opposed to inserting these comments in the minutes. **COM** stated these comments are inserted, sometimes on request by MS or IND, which would otherwise not be available to the meeting. **FR** agreed with NL. Consequently, it was decided to not include any more "post-TM comments".

3. Action List TM

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

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

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

   Document was finalised by COM and distributed to the CA meeting in March for endorsement.

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

   Document was finalised by COM and distributed to the CA meeting in March for endorsement.

4. *Include TM decisions from Environment Session in the Manual of Technical Agreements (MoTA).*

   See item agenda item of the General Session. Item will be removed from action list as MoTA is a standard agenda item of the General Session.

5. *Finalise document "Role of efficacy in the BPD evaluation process" for endorsement by CA meeting.*

   Document was finalised by COM and distributed to the CA meeting in March for endorsement.

6. *Finalise and publish addendum to ESD for PT 13.*

   Document was finalised by COM and distributed to the CA meeting in March for endorsement.

7. *Consult with DG ENV on Annex I inclusion of PT 13 following environmental risk assessment.*

   This item will be discussed at the CA meeting in March.

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

   The list will be distributed after TM I 2010.

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

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

10. *Fill in spreadsheet Excel on environmental risk assessment PT 06.*

    Several MS have responded to PL. Item will be discussed at a future TM.

11. *Send comments to CEPE and UK on documents TM IV 09 on sediment risk assessment PT 21.*

    Several MS have responded to UK and CEPE. Item will be discussed under the Environmental Session.

12. *Distribute draft efficacy guidance for PT 08 for written commenting round.*

    There was no new information from FR on this action item.

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

    There was no new information from CEPE on this action item.

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

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

5. Next Technical Meetings

2010

TM 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. Risk characterization for local effects

COM explained the background for the document, mentioning that nine MSs and CEFIC were included in the working group (WG) that drafted the document.

Proposal that minor irritant effects as the sole local effect would not justify a non-inclusion decision.

This was the only issue (p. 7 of the document) that was not yet agreed within the WG. **UK** was of the opinion that calculating an AEC and then ignoring it would not make sense. Instead, if the effects are known to be very minor, then a qualitative assessment would be better, introducing proper risk mitigation measures. Therefore, expert judgment could be used to conclude that there are safe uses. **COM** commented that for non-professionals, PPE cannot be assumed and what would therefore actually be available is classification and labelling. **FR** said that the definition of minor irritant effects is based on reversibility, and this would be difficult to ascertain. It is also a problem that even if the current approach would not result in an acceptable risk for a given product, it would clearly be possible to foresee a different use pattern with much less risks. **COM** agreed that the biggest problem might be to differentiate between minor and non-minor irritant effects, adding that the whole area of RC of local effects is to a large extent based on expert judgment. **AT** supported the paper presented, and the principle that minor irritant effects would not lead to Annex I non-inclusion. **PT** clarified that this document is really based on expert judgment, adding that the conclusions will often depend on whether the user is a professional or non-professional. PT supported the principles of the document. **COM** explained that one of the reasons for providing this new document is that when the dossiers were submitted by the Applicants, there was no guidance for RC of local effects. As a result, it is possible that some representative products were selected which would not pass the examination on the local effects – while there might clearly be other uses and other formulations where the active substance itself could be safely used. Therefore, it would not seem correct to allow an Annex I non-inclusion based on minor irritant effects. **UK** agreed with the aims of assessing for local effects, while having reservations on the conclusions made based on minor irritant effects. One way forward could be to put in place a measure which would prevent the possibility of vastly exceeding the AEC, e.g. by one order of magnitude. **COM** agreed with the principle, mentioning that this is actually implicitly present in the document because it is mentioned that local irritant effects usually first appear as minor effects and get more severe as the concentration or dose increases. **COM** clarified that UK suggestion would then be that the AEC could be exceeded 10-fold but not more, and **UK** confirmed this. **COM** added that it might be better not to simply say that a 10-fold excess would be the exact limit, but that it could be modified if., for example, it is seen that the dose-response curve is steep or otherwise it can be expected that more severe effects could be expected. The TM agreed on this.

NL supported the document, mentioning that there is a lot of information there, which sometimes makes it difficult to read. **NL** therefore suggested introducing flow-charts, volunteering to make them. It was agreed that NL will provide the flow-charts and these will then be accepted separately by the TM.

COM explained that based on some discussions and comments from MSs, it might not be possible to keep the document as a TM agreement as was planned, but instead it should probably be included in the TNsG. **AT** suggested leaving the document as a working document for a while to see whether views would still develop as we start using the

guidance. **NL** agreed with AT, saying that as it appeared that the TM will agree on this document, it could be used from now on, and introduce it into the TNsG later, as the experience with local RC develops. **COM** suggested that it would then be considered a working document that can be used, but it would be finalised at the TM in approximately a year, after which it would be sent to the CA meeting for endorsement.

AT commented on the phrase in Appendix 1 (p. 11) which is "If the mode of action is direct reactivity, the default toxicokinetic factor can be reduced to 1, as no kinetic or metabolic processes are involved". AT said that there are really no data to support this, and that direct reactivity leads to inflammations, cytokine release etc., and that these processes do vary dependly upon the individual. There is e.g. large variation in the human reactions to SDS. The argument that might be used is that the animal tests used are already very conservative, but still AT suggested to delete this sentence. **COM** commented that the current proposal is to actually use the AFs as set in REACH, and the Appendix is describing the further considerations that have been presented in the TM. Additionally, both of the appendices should probably be removed, when the final version to be included in the TNsG will be sent for endorsement at the CA meeting. Nevertheless, the document as it now stands should not contain mistakes and the AT suggestion should be discussed. **UK** asked for further information on why AT wanted to remove the sentence. **AT** replied that reference 13 given in the document (Basketter *et al*., 1996) describes huge variations between individuals. **UK** asked whether this could be agreed on during the following year, before the finalisation of the document. **COM** replied that this should nevertheless be a document that can be used as guidance, and it would therefore be useful to agree on all points now. **COM** asked whether AT could provide a sentence that would make the statement milder, giving further information as just described by AT. **AT** and **UK** agreed, and AT will thus provide a sentence to COM.

AT said that they see a problem in that what is really needed for local effects RC is the assessment of the biocidal product, since the focus of RC for biocides is on evaluating the exposure during the use of the product (not the manufacture of the active substance or the formulation of the product where we may have also active substance exposure). The local effect will be largely dependent on the formulations. Therefore AT suggested that too much time should not be used in deriving an AEC for the active substance, if it can be seen that it is not that useful for the assessment of the risks. **COM** agreed with the line of thoughts, but said that when discussing the products, this means the product authorisation stage. On the other hand, the CARs concern substances for which a representative product needs to be assessed, and as mentioned, these products and formulations were selected when there was no guidance on local RC. **AT** concluded that expectedly in many cases a qualitative approach may be the most appropriate. **COM** said that the comment has been taken into account, but that no changes in the document appear to be necessary.

COM concluded that the document has been agreed by the TM with the changes mentioned above. This document can now be used for the RC of local effects, and in approximately one year, a new version will be discussed and then sent to the CA meeting for endorsement.

2. SUBSTANCES in PT 08

2a. HCN (RMS: CZ)

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3. SUBSTANCES in PT 14

3a. HCN (RMS: CZ)

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4. SUBSTANCES in PT18

4a. HCN (RMS: CZ)

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4b. Deltamethrin (RMS: SE)

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4c. lambda Cyhalothrin (RMS: SE)

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4d. Thiamethoxam (RMS: ES)

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4e. *Bacillus thuringiensis AM 65-52* (RMS: IT)

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5. SUBSTANCE in PT19

5a. Methylnonylketone (RMS: ES)

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6. AOB

6a. Update DRAWG

DE gave an update of the DRAWG work and a timetable for the documents that will be issued for dietary risk assessment (DRA) and management in case of livestock exposure. The draft guidance currently under development will be presented to the TM in June 2010 for commenting by MS and is due to be finalised in July 2010 for approval by the CA-Meeting in September 2010. **COM** took the opportunity to remind the TM that here would be 3 documents related to livestock exposure, i.e. i) the document on livestock exposure estimation guidance developed by the DRAWG, ii) a guidance document developed jointly by the DRAWG and the CVMP of the EMEA on the DRA and MRL considerations of biocidal substances used in animal husbandry, and iii) the document generated by DG ENV on MRLs for biocidal substances, which was endorsed a the CA meeting of September 2009.

DE then presented a proposal to extend the mission of the DRAWG to dietary risk assessment of biocidal substances other than those used in animal husbandry and also to liaise with the body who will be eventually responsible for the MRL setting. This is in line with a document made available to the participants prior to the TM and as a room

document. **COM** thanked DE both for the work done via the DRAWG and for the proposal to extend the scope of the Working Group expressed their support to DE and asked the TM to endorse this scope extension of the DRAWG**. The TM agreed to the proposed scope extension of the DRAWG.**

6b. Update HEEG

COM explained that the first version of the HEEG opinion "Default protection factors for protective clothing and gloves" was discussed in TM III 2009, where it was agreed that some changes would be made, and some additional data would be included. The paper was presented by UK as the main author. **UK** informed that the document did not intend to initiate further research or to re-assess the original reports in detail; the intention was to collect the protection factors that have already been accepted in the TNsGs and/or have been agreed by the TM, and to put these factors in a logical order. The HEEG opinion was agreed by the TM without changes.

COM mentioned that the new co-ordinator of HEEG will be Paul Piscoi, to whom all communications should from now on be directed.

6c. Use of developmental studies in risk characterisation

In a document made available both prior to the TM and as a room document, entitled "*Need for clarifications about the use of developmental studies in risk characterisation*", **FR** asked the TM to consider several issues related to the use of maternal toxicity data in developmental studies, taking into account the possibly different (higher) sensitivity of pregnant dams as opposed to non-pregnant animals. **FR** explained their concerns as per the document provided, and **COM** asked the members of the TM to provide their comments and opinions on that matter by the end of March (6 weeks).

6d. Update by NL on the status of the DNT studies survey

This item was discussed before the two substances deltamethrin and lambda-cyhalothrin. **NL** updated the TM on the progress of the survey. Some MS still had not provided **NL** with the requested information, and it was requested that they should do so within two weeks. By then **NL** will proceed to the analysis with the available data. The data will be analysed by NL (at CTGB and RIVM) and will be presented at TM II 2010.

6e. Species or strain used for the DNT testing of biocidal substances and need for an additional assessment factor.

Note: This item was discussed before the toxicology session of deltamethrin and lambda-cyhalothrin.

Background: **SE** requested a general discussion in the absence of Applicants on the appropriateness of adding an extra uncertainty factor when deciding on AELs based on DNT studies, when the RMS believes that the species or strain chosen is not the most sensitive one. A document summarising the position of **SE** was made available on circa before the TM.

Discussion: **SE** explained their rationale to the TM. For deltamethrin and lambda-cyhalothrin, clinical signs of neurotoxicity have been shown in studies performed with several species. The lowest NOAEL was obtained in studies performed with dogs. DNT studies are available for both deltamethrin and lambda-cyhalothrin. These studies were conducted on the Wistar rat, and the results were negative. The view of **SE** is that there might be some uncertainty in the DNT protocol in those cases, when direct dosing of pups has not been considered, and exposure level in offspring is not clear. Although **SE** might have some concerns related to the design of the DNT study, **SE** did not think that this

needed to be discussed during this meeting. Instead **SE** wished to focus the discussion on the concern that there were no data for the most sensitive species and no data for the most sensitive strain. All standard toxicity studies with deltamethrin were conducted in CD rats, with exception of the DNT study for which Wistar rats were used. Comparing data from standard neurotoxicity studies, Wistar rats seemed to be a less sensitive strain with regard to neurotoxicity of deltamethrin. There were no clinical signs of neurotoxicity reported for these rats administered deltamethrin via the diet at doses up to 16 mg/kg bw/day, whereas clinical signs of neurotoxicity were evident in the CD rat at a dose level of 14 mg/kg bw/day. **SE** stated that the choice of the strain used in the deltamethrin DNT study might therefore be questioned, adding that the OECD guideline 426 recommends the most sensitive strain to be used, since in the guideline it is stated that "if there was an earlier test that raised concerns, the species / strain that raised a concern should be considered." For lambda-cyhalothrin, clinical signs of neurotoxicity were evident in dogs at a dose level of 3.5 mg/kg b.w., whereas in a study performed in Wistar-derived rats, similar signs were only observed in the acute neurotoxicity study at 35 mg/kg bw, and there is one study in CD rats in which such signs were observed at 15 mg/kg bw. The DNT study was performed in Wistar-derived rats, at dose levels below 35 mg/kg bw. **SE** held the view that the results of this DNT study did not provide the assurance that there should be no effect in young animals. Therefore, SE applied an uncertainty factor of 3 because the (lowest) NOAEL value is that of adult dogs. SE wished to know the opinion of the TM on this procedure.

COM attempted to define three distinct issues in order to better focus the discussion, i.e.: i) Sensitivity of the species or strains used; ii) Documentation of the exposure of the offspring, which should be discussed together with the substances themselves, and iii) Use of an additional factor of 3 to cover for the uncertainties on DNT studies. **COM** read to the TM the text of point 7 of TG 426, which in **COM**'s view left some room for discussion:

Selection of animal species

1. *The preferred test species is the rat; other species can be used when appropriate. Note, however, the gestational and postnatal days specified in this Test Guideline are specific to commonly used strains of rats, and comparable days should be selected if a different species or unusual strain is used. The use of another species should be justified based on toxicological, pharmacokinetic, and/or other data. Justification should include availability of species-specific postnatal neurobehavioral and neuropathological assessments. If there was an earlier test that raised concerns, the species/strain that raised a concern should be considered. Because of the differing performance attributes of different rat strains, there should be evidence that the strain selected for use has adequate fecundity and responsiveness. The reliability and sensitivity of other species to detect developmental neurotoxicity should be documented.*

COM then invited reactions from the floor n the adequacy of the additional uncertainty factor.

UK expressed the hope that the survey on DNT studied proposed by NL would shed some light on the specificity of the different strains used, across the different substances to which they will have access. **UK** also held the view that if, following a concern about DNT, a DNT study has been done by IND according to the standard, which indicates the rat as the model of choice, then the results of the test should be accepted unless there is an extraordinary reason not to do so. If the test comes out negative, then there is no need for an extra assessment factor.

SE explained that in the case of lambda-cyhalothrin, the guideline was followed, except that it was not the most sensitive species that was tested (for DNT). Therefore, although the guideline was followed, it remained that, according to the rest of the data, the dose that was chosen in the study was below that where an effect could be seen in the rat, so that a

negative result could be expected, already before performing the test. **SE** further insisted that the problem was that the DNT study was not done in a species that **SE** believed could be sensitive to this effect.
COM stated that there was a problem about defining what the most sensitive species for DNT was. **COM** stated that, as pointed out by NL in a former discussion, SE was using un underlying assumption that the most sensitive species or strain for adult neurotoxicity was also the most sensitive species for developmental neurotoxicity, and such an assumption needed either to be accepted by the TM, or documented. **COM** also mentioned the possibility of other factors, in particular toxicokinetics, that could complicate the direct extrapolation between the adult and the developing organism.
DK supported the position of UK, and stated that they thought that the rat was the correct species to be used, and that no extra Assessment Factor was necessary.
DE reminded the TM that two workshops on pyrethroids and DNT had been held on November 15, 2001 and one on June 19, 2002, where the results of the Eriksson studies were discussed. One of the main conclusions was that there were some indications for an effect of pyrethroids on the neuromorphological and behavioural development in some but not all strains of mice, and that there was no evidence for similar effects in other laboratory animals relevant to human risk assessment. Therefore **DE** considered that there was no need for further DNT testing because the DNT studies were, like most studies that are available for pyrethroids, compliant with the current guideline, which incorporates some degree of flexibility. In summary **DE** supported UK in considering that no further DNT testing and no extra assessment factor were necessary.
NL supported UK in considering that no extra assessment factor was needed. **NL** added that there were several gavage studies evaluated by the JMPR showing that the rat sensitivity was similar to that of the dog, and also that a five-fold difference in sensitivity had been observed between two studies in the dog. Therefore NL considered that the apparent greater sensitivity of the dogs relative to the rat was not substantiated.
SP supported the view that no additional assessment factor was needed. SP added that they would welcome, although more appropriately in another forum, a scientific discussion on the difficulty of assessing DNT in general.
COM stated that such a debate would be welcome, including the data of the survey organised by NL together with other elements. **COM** also insisted that the TM also needed to make decisions on substances scheduled for discussion. **COM**'s understanding at this stage of the discussion was that the TM was globally not in favour of an additional safety factor.
EL thanked SE for the comprehensive presentation of the issue, and reminded the TM that the same question had been debated for the substances when evaluated as a PPP. The opinion of most MS in that framework was that an additional assessment factor was not necessary. However, **EL** expressed the concern that for deltamethrin as a biocidal substance, there were major data gaps on the mode of action of pyrethroids in general, at the voltage-sensitive sodium channel, since it is not known how, during the development, the pyrethroids bind to the different subtypes of the alpha subunits. There are differences between experimental animals and humans in the expression of these alpha subunits during development. Some of them are expressed in the rat during development and some of the same types are expressed in man only in adulthood. In the case of biocidal products, especially in European southern countries, the infants are highly exposed to mosquito-repelling devices, which are used extensively and for many hours during the day, which is a cause for concern in Greece. **EL** wished that the Annex I inclusion text should include the need for a cautionary statement (on the label) to avoid exposure to pregnant women and young children for vaporisers. **COM** stated that there were probably different opinions among MS concerning the need for such cautionary phrases for pyrethroids, since the situation is currently not homogeneous in the different MS. **COM** suggested that in view of country-specific positions, especially based on relatively controversial

evidence, this type of discussion could take place at product authorisation stage. **COM** also observed that in case of a country-specific higher exposure of certain population groups, the solution should not be the addition of an additional safety factor in the risk assessment, but should be reflected in the exposure assessment at product authorisation stage, and possibly lead to country-specific risk management measures. **EL** added that they were not suggesting an extra safety factor, but simply stating that available studies did not allow us to demonstrate or exclude the effects of pyrethroids on the newborn, because there are major data gaps in their mode of action during development. **EL** therefore wished a cautionary phrase to be included in the Annex I inclusion statement. **UK** considered that although the mode of action was not defined, some reassurance that no major developmental effect took place could be obtained from the 2-generation reproductive toxicity study. **EL** replied that the design of the 2-generation study was not adequate to detect DNT. **DE** disagreed that there was a big data gap for the pyrethroids in general, since many 2-generation and DNT studies were available. DE stated that if it was thought that the problem was in the study design or conduct, then the logical action was to try and revise the OECD Test Guideline, but not to decide that DNT is a class effect of pyrethroids. **DE** added that for other substances no DNT studies are available at all, because this is not part of the normal data requirements, but especially for this class of substances, and because they have been discussed for 20 or 25 years, we have a huge variety of studies. **DE** considered that it was acceptable to discuss adaptations of the study design of the DNT study, for example, as proposed by DE in 2006, to make analytical methods available to see whether the substance is entering the brain tissue of the pups, or is crossing the placenta or goes into the milk, but that it was not acceptable to require more and more studies for this class of substances. **NL** supported DE, adding that NL was going to analyse the wealth of data available in terms of DNT studies accumulated over the past 25 years, which may show that there is no big data gap. Also **NL** considered that S-phrases should not be discussed at Annex I inclusion stage. **EL** Gave the precision that they were talking about a basic research data gap, and not a data gap in terms of regulatory toxicology. **EL** added that given the data on the mutations of the voltage-sensitive sodium channels in humans, in rats and in knockout mice, it appears that problems with voltage-gated sodium channels have an impact on brain development, and **EL** was of the opinion that this should be taken into account. According to **EL**, the impact is on the sodium channels and the basic information on the binding of the substances is not available.
Also because some effects on the muscarinic receptors have been described, and nothing is known about the dopamine receptor, only contradictory results that make no sense are available. Also, more pharmacokinetic data between mother and foetus would be needed. Therefore **EL** stated that a simple DNT study could not cover these data gaps. **COM** stated that requesting that all mechanisms should be understood in order to be reassured was extremely demanding and difficult to sustain. For many endpoints the mechanism is not known or is quite hypothetical, and we usually simply accept that the results of the studies are negative. If it is thought that the standard study design is not adequate, then the effort should focus on the guideline and not on the substances, otherwise there are inconsistencies in the regulatory position. **COM** added that there remained always the possibility to use S-phrases at product authorisation stage, but that this was not helpful in terms of hazard assessment. **COM** reminded the TM that the issue discussed was whether or not an extra uncertainty factor for DNT should be incorporated into the risk assessment for deltamethrin, for lambda cyhalothrin, and also for other pyrethroids in general. **AT** considered that it was useful to express uncertainties in the CAR, even in Doc I, so that authorities would be aware and could decide what to do at product authorisation stage. **AT** reminded the TM that a similar procedure was provided for in REACH, where uncertainty analysis is described in chapter R19 of the Guidance on information requirements and chemical safety assessment, available form the ECHA website. **AT** suggested for instance that the uncertainties could be described qualitatively as a first step, and quantitatively as

far as possible. **FR** stated that hey had no objection to add uncertainty factors to account for uncertainties, but that deciding on the factor to be applied was problematic. If the problem was that of bioavailability of the substance to the pups, then additional toxicokinetic data should be required. If such data do not become available, then it would be logical to apply an extra factor to be determined. This factor could then be withdrawn when more information becomes available. **COM** agreed that the reasoning was valid for the example described by FR, but mentioned that the specific issue under debate was that of the uncertainty linked to the choice of the species for the DNT study. **SE** emphasised that it was very important that the most sensitive rat strain is used. **SE** was of the opinion that even though, when comparing the sensitivity of the dog to that of the rat, the sensitivity may appear to be the same, it was nevertheless important to consider the strain of rat used, because **SE** had noticed that the Wistar rats seemed to be less sensitive for deltamethrin and lambda-cyhalothrin, and this could be the same for other pyrethroids as well. **COM** suggested that SE could express their doubts and uncertainties in the CAR, without necessarily imposing an extra assessment factor, if the opinion of the TM was that it should not be applied. This would avoid applying an arbitrary assessment factor, while not disregarding the concerns of SE. **COM** requested that the TM would decide on that proposal, in an attempt to find a solution. **SE** asked whether it would then possible to indicate restrictions for children and pregnant women if the risk assessment did not indicate a risk, in the absence of the extra uncertainty factor. **COM** stated that this was very similar to EL's proposal, which may be a pragmatic solution. At product authorisation stage, such a phrase could be added depending on the level of expected exposure of children. **UK** felt confused by the fact that in a situation where the regulatory tools, i.e. the tests, were telling us that there was no hazard, we did not believe it and were trying to invent hazards. **UK** added that by so doing, we were unfairly penalising the Industry that had conducted tests to the currently accepted regulatory guidelines. Until new regulatory tools become available to assess the hazard of DNT, we should accept the results of regulatory tests that are currently available to us. **COM** summarised UK position by stating that in essence, **UK** recommended following guidelines. **DE** mentioned that based on all the data available to the 2001 workshop, one of the main conclusions was that if there are DNT effects of pyrethroids, these are weak and difficult to detect, and also that there were doses without effect. **DE** acknowledged that pyrethroids have some neurotoxic effects, probably modulated by pharmacokinetics, but also pointed out that other substances have may have effects on the pups and are not tested for DNT. **IE** supported **UK** by stating that there were guidelines, that the studies had been performed, and we should simply use the data generated rather than making hypotheses. **EL** mentioned a review referenced in the CAR, done by the US EPA, which mentioned the data gaps pointed out earlier by EL. **EL** mentioned that some PBPK models were being developed at the US EPA for deltamethrin, but unfortunately only in adults, so that developmental data were still missing. **EL** considered that pyrethroids had important alerts for neurodevelopment, and called for more pressure being applied to obtain more data. **NL** expressed some concern because in 2002, the problem of pyrethroids and DNT had been raised and discussed at length, and eventually it was agreed that a DNT study would fit the purpose. The Industry had worked in that direction, and telling them now after all the dossiers had been submitted that this was not sufficient was a cause for high concern. **NL** was of the opinion that the regulators had requested studies, that these requested studies had been produced, so that now the regulators should accept them. **AT** insisted that whatever the final decision on an uncertainty factor is, uncertainties should be made transparent according to the models proposed in REACH guidance. Even if a good strategy to deal with the uncertainty could not be found, it was important to leave it apparent in the assessment. **COM** stated that there was an issue of burden of proof, since the issue of the DNT of pyrethroids had been discussed and worked upon for more than 20 years, as pointed out by DE, with a lot of conflicting results. Meanwhile, a regulatory

methodology was developed, and imposed on Industry. Results were generated using that methodology, and they were essentially negative. In spite of this, we were still, or at least some of us, considering that DNT was a true effect of pyrethroids, and additionally that it was a class effect. **COM** was also concerned about the legal position of the TM, if more and more data were asked without any satisfactory conclusion. **COM** added that there were many cases where there were uncertainties about the science and the mechanisms of effects, and that this was not used as a reason for adding uncertainty factors. It is the usual practice to rely on tests that have been designed in such a way as to be sensitive enough to give enough reassurance. Eventually, if some authorities had doubts on the validity of the tests used, it was a good thing that these doubts should be expressed and discussed. **COM** was in agreement with SE, AT and EL, but also stated that such doubt should not lead the TM to block the process of Annex I inclusion. **COM** thus supported the view that results generated according to the guidelines should simply be accepted. **COM** re-iterated the proposal that: i) the doubts of the RMS should be discussed in the CAR; ii) it could be asked in the CAR to pay particular attention to exposure to pyrethroids where products will be used in such a way as to cause exposure of children at an age where they would be sensitive to DNT effects, possibly also suggesting measures to reduce exposure of such children. In that way, the Annex I inclusion of these substances would not be penalised and the doubts of some MS would not be hidden either. **PT** stated that this was a question of hazard, and therefore of classification. **PT** suggested that the available information on pyrethroids could be gathered and put together in an application for classification in order to resolve the issue. **NL** commented that in their view, it was quite difficult to assign a risk phrase to a substance for which there is a suggestion that it might have a certain effect but for which there was no positive evidence, in spite of a lot of work undertaken from many different angles. Therefore, it would be exaggerated to ask for a label only because some work of the mid-eighties, which could not be repeated, suggested that an effect had happened. **EL** mentioned that they were not aware of a classification that would apply to DNT. R 63 would be a possibility, but it does not cover the infancy period. **COM** agreed with NL that it was difficult to propose a classification for a hazard that had not been identified positively, but only as a doubt on negative results. **PT** gave the precision that the proposal to consider a classification dossier for pyrethroids was not in the short term, but certainly after the analysis planned by NL on the info on DNT included in the biocidal pyrethroids dossiers. **COM** was concerned because theythought that the TM should not rely on the analysis organised by NL to solve all DNT issues with pyrethroids, and stated that the results would certainly help globally, but that the TM still had to make decisions on individual substances as they came up for discussion. **COM** also expressed serious doubts that DNT could be defined as a class effect of pyrethroids, given the heterogeneity of the available evidence. **AT** insisted that it would be both fair and a good technical exercise for the TM to express formally the uncertainties in the CAR. **COM** checked that the position of AT was that the doubts and uncertainties should be explained in the CAR, but that no extra assessment factor should be used. **AT** confirmed that this was their position. **COM** then asked the TM if this could be regarded as the position of the TM, and invited reactions from the participants, in particular from SE as the RMS for the pyrethroids under discussion. **SE** then stated that they had to respect the opinion of the TM, and therefore to be satisfied with that. No other participant reacted. **COM** then re-expressed the decision to ensure that all members were satisfied with the agreed position that *where there were uncertainties perceived by the RMS of a pyrethroid on the DNT studies, these should be expressed in the CAR, but that the currently available evidence did not support the use of an extra assessment factor*. In this way, the information that the RMS was not completely satisfied was not lost, and would be available for CA to use at product authorisation stage. **COM** added that it seemed to them to be a reasonable compromise. **NL** intervened to stress that the overall discussion showed that it was important for all available data to be sent to them for analysis. **COM** supported NL's

statement and invited the TM members to satisfy NL's request. **EL** stated they also had pyrethroids under evaluation, one of them being structurally close to deltamethrin, but that the Applicant had not submitted any specific data on neurotoxicity, and requested guidance from the meeting on how to handle this situation. **COM** stated that they were not aware of any guidance on this particular point within the biocides guidance documents, and that sending officially the information on the absence of data to NL using the appropriate questionnaire was useful. **COM** then closed the session stating that they were satisfied that a compromise had been found, while acknowledging that like all compromises, it might feel uncomfortable to some of the TM members.

Conclusion:

The TM reached an agreement that where uncertainties are perceived by the RMS of a pyrethroid on the DNT studies (especially negative studies), these uncertainties should be formally expressed in the CAR. The TM also agreed that the currently available evidence does not support the use of an extra assessment factor to cover for the perceived uncertainties on DNT in the dossiers of deltamethrin and lambda-cyhalothrin.

GENERAL SESSION

1. Report 35th CA meeting

COM reported on the 35th CA meeting. COM informed that the second version of the "SOP for the Biocides Technical Meeting" and the guidance document on the relevance of REACH guidance is available from the JRC-IHCP biocides web-site. The agreed notes on the evaluation of multiple dossiers and comparative assessment will be incorporated in the future in the "SOP for the Biocides Technical Meeting" and/or the MoTA.

2. Tracking System. Progress reports

-

3. SUBSTANCES in PT 08

3a. HCN (RMS: CZ)

-

4. SUBSTANCES in PT 14

4a. HCN (RMS: CZ)

-

5. SUBSTANCES in PT18

5a. HCN (RMS: CZ)

-

5b. Deltamethrin (RMS: SE)

-

5c. *lambda* Cyhalothrin (RMS: SE)

-

5d. Thiamethoxam (RMS: ES)

-

5e. *Bacillus thuringiensis AM 65-52* (RMS: IT)

-

6. SUBSTANCE in PT19

6a. Methylnonylketone (RMS: ES)

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7. Update MOTA

COM informed that the second addendum of the MoTA is uploaded on CIRCA with a dead-line for comments of February 23. With respect to the incorporation of environmental aspects in MoTA COM informed that a first draft will be forwarded to the TM II 2010.

8. AOB

8a. Identity of substances with multiple isomers

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8b. Adding contact points to RCOM table

A proposal from **NL** to include, on a voluntary basis, specific contacts for the RMS per aspect, as laid down in a room document, in the RCOM table to be uploaded on CIRCA at the start of the 90 day commenting period (so when the First Draft CAR is uploaded) was adopted. Either a generic contact can be included or specific contacts for each aspect.

ENVIRONMENT SESSION

COM informed that two projects recently started:

- "Revision OECD Emission Scenario Document for Wood Preservatives following experience under the EU Review Programme of the Biocidal Products Directive" to be carried out by SCC in Germany. This project will be carried out under the umbrella of the OECD Task Force on Biocides. COM informed that it was still possible to nominate experts for the Steering Group and asked MS to react within 2 weeks after the TM.
- "Estimation of emission from treated wood: evaluation of experience under the EU Review Program of the Biocidal Products Directive" to be carried out by Bio Intelligence Service in France in a consortium with Aston Consulting Services. A Steering Group has been formed.

For both projects a kick-off meeting took place. Members of the Steering Groups will be informed about the future planning of the projects.

1. SUBSTANCES in PT 08:

1a. HCN (RMS: CZ)

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1b. Chlorfenapyr (RMS: PT)

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2. SUBSTANCES in PT 14

2a. HCN (RMS: CZ)

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3. SUBSTANCES in PT18

3a. Emission estimation for insectides for household and professional uses

COM introduced the document ("TM2010-ENV-Revised Proposal COM on PT 18 scenario") thanking industry and several MS for their contributions. **COM** proposed to discuss this proposal point by point.

3a1. Number of houses

SE commented on the wording in several places of the document: i) based on 2.5 persons per houses and 10,000 population equivalents per STP the result is expressed as "houses" which should be replaced by "households" (or dwellings), and ii) in several places "apartment" shall be replaced by "apartment building". **SE** stated that based on the same data as used in the COM proposal, they calculated a number of 2500 house equivalents for outdoor treatment. **IND** proposed to also correct for outdoor treatment, referring to calculations assuming 2.1 persons per households. **SE** and **DE** agreed with the COM proposal to not correct the number of 4000 households for indoor treatment. **BE** and **NL** requested to clearly explain in the final document how the values are derived and on

which data they are based. Following a question by **SE**, **COM** and **FR** clarified that the default value for the treated surface for general treatement is 38.5 m^2. **IND** stated this value is overconservative for apartments as the average surface of an apartment is around 70 m^2 based on the statistics from Germany. **COM** stated this may not be an overestimation for apartments in Southern Europe which contain almost entirely hard surfaces subject to wet cleaning. **UK** remarked that however not the whole surface is treated.

COM concluded:

- For outdoor use a number of 2500 households will be used as default based on the proposal by **SE**. This proposal will be incorporated in a revised document by COM. In the revised document the terminology will also be clarified following the comments from SE;
- For indoor use a number of 4000 households will be used as default;
- For the surface area for general treatment 38.5 m^2 will be used as default.

3a2. Number of commercial buildings

COM introduced the proposal of 400 commercial buildings. **UK** stated this was still overconservative, where a value of around 200 to 300 would be more sensible. **IND** stated that in the estimation of 256 for the UK all types of buildings are included except schools. Based on Frech guidelines for the dimensions of a school, IND estimated schools would add around 10,000 m2. Consequently, IND stated the total number for the UK would be around 270 to 280 indicating the number of 400 is overconservative. COM stated that they investigated wether government buildings are included in the statistics from the year 2000 onwards. COM stated most likely these buildings are included, but this will have to be confirmed by the UK Office for national Statistics. COM agreed that schools are not included in the statistics. COM then proposed a number of 300. SE agreed as this would cover the UK and SE statistics, noting that the NL statistics are based on economic activities and not on real estate data. NL asked to provide more insight into the way the values are derived and more statistical background. DE agreed with the value of 300, asking to introduce the additional comments by IND on the inclusion of schools. COM agreed to this. NL then also agreed to the number of 300, stating that under product authorisation regional variation may have to be taken into account.

COM concluded:

- For the number of commercial buildings 300 will be used as default providing it is confirmed that government buildings are included in the UK statistics;
- The comments from IND on the inclusions of schools in the UK statistics will be incorporated in a revised document.

3a3. Number of hospitals

COM introduced the proposal to include the hospital in the commercial buildings. **DK** introduced their proposal consisting of 3 options: i) scale the "average EU hospital" (based on data from Eurostat of 600 beds per 100,000 inhabitants) down to the standard STP with 10,000 population equivalents i.e. 60 beds and surface area 1/10 of 14265 =1427 m^2; ii) tonnage approach using hospital fraction of main source released to STP of 0.007; iii) separate scenarios for households, commercial buildings and hospitals each to a separate STP and summing up the resulting PEC/PNEC values for risk assessment. **UK** and **COM** commented that in option i the hospital is in fact regarded as a commercial building, as the treated surface is calculated (1427 m^2 in the DK proposal) where the waste water volume feeding into the STP is kept at 200 liter per inhabitant. **DE** preferred option i, but asked IND about the importance of the label claim “use in hospitals” resulting in the current separate scenario for hospitals. IND explained that the label claim is important for the

protection of by-standers in hospitals, but not for estimation of releases to the environment. Additionally, **IND**, following a question by **DE**, stated that in hospitals the treated surface is smaller compared to commercial buildings as in a hospital the rooms where patients are present are not treated. Based on these explanations **DE** could support the proposal from COM to include the hospital scenario into the commercial building scenario if hospitals are included in the UK statistics for commercial buildings and the reasoning of IND is included in the revised document.

COM concluded:

- No separate assessment for hospitals will be included. The number of commercial buildings of 300 is considered to include also hospitals.
- COM will check if the hospitals are included in the UK statistics for commercial buildings.

3a4. Surface of commercial buildings

COM introduced the proposal of 609 m^2 for commercial buildings. **IND** stated the value proposed is still overconservative based on their calculations. **DE** stated they could support the value providing hospitals are included in the statistics.

COM concluded:

- For the surface area to be treated for general treatment the default value is 609 m^2.
- COM will check if the hospitals are included in the UK statistics for commercial buildings.

3a5. Targeted applications in houses and commercial buildings

COM stated several options are available as mentioned in the document. **IND** stated that for the "chemical barrier scenario" the surface area of 505 m^2 as agreed upon in the "PT 18 Workshop" will have to be reduced as the default surface area for commercials buildings is now reduced from 3280 to 609 m^2. **IND** suggested 93 m2 based on the same percentage of the total surface as used for households (15% equal to 20 m2). The same approach could be used for spot treatment according to SE. **DE** and **SE** stated that a set of default values would be needed for targeted applications in order to harmonise the evaluations within the Review Program. **UK** doubted if for spot applications it will be possible at all to define reasonable default values.

COM concluded that a proposal for commercial buildings default values for the surface area treated for several target applications will be prepared by them for the next TM.

3b. HCN (RMS: CZ)

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3c. Deltamethrin (RMS: SE)

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3d. *lambda* Cyhalothrin (RMS: SE)

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3e. Thiamethoxam (RMS: ES)

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3f. Diflubenzuron (Applicant Chemtura; RMS: SE)

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3h. *Bacillus thuringiensis AM 65-52* (RMS: IT)

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4. SUBSTANCE in PT19

4a. Methylnonylketone (RMS: ES)

-

5. AOB

5a. Problems related to ESD for PT6, PT10 and others

DK introduced the document where they identified three problems in the evaluation of several active compounds in different PTs:

5a1. Release estimation during service life for PT 10 to take into account leaching to STP from a treated house located in the city

DK stated that the distinction between the population in cities and rural areas relates to release to STP and soil, respectively. The values for façades of buildings in cities are 'guestimates' and not based on real data. **DE** stated that in Germany 84% of the population lives in cities, where a city is defined as having more than 5,000 inhabitants. No information was available in **DE** for the façade types. **NO** asked if the issue of houses versus apartments and if commercial buildings should be considered. No answer could be given by the meeting at this point of time on this question.

COM asked MS to send in comments to DK by April 2.

5a2. Dimensions of the receiving soil compartment for PT 10

DK proposed to apply 50 cm as their first preliminary assessments leads to a risk at 10 cm. **NL** stated a document is available from the Technical Soil Committee in The Netherlands on this issue. **NL** will distribute this document. **DE** stated that the choice of 50 cm for PT 08 was a political decision taken at CA level. Consequently, also in this case such a decision shall be taken at CA level, if many substances fail the proposed dimensions. However, **DE** proposed, in line with PT 18, to make a distinction between disturbed and undisturbed soil, i.e. 20 cm and 10 cm soil depth. This proposal from **DE** was accepted.

5a3. On-site treatment for PT 06 applications

DK asked how to deal with on-site treatment in an industrial waste water treatment plant. **UK** stated they had similar cases for paper mills and tanneries where industry was unwilling to provide information on the efficiency of the on-site treatment. It was decided, following a proposal from **DE**, to require data on the efficiency of the on-site treatment. If data are available, the on-site treatment can be incorporated in the exposure assessment, where the resulting effluent will be emitted to the municipal sewage treatment plant, using the standard STP from the TGD. If no data on the efficiency are submitted, 100% release to the municipal sewage treatment plant will be assumed.

With respect to the default for the average capacity of a laundry suggested in the document from **DK** of 3 ton/day, **DE** stated that the default in the ESD is 8 ton/day. **DE** stated that unless further data are available to substantiate to change the default value from 8 to 3 ton/day, **DE** could not accept the suggestion from **DK**. **COM** concluded that unless further data will be submitted by other MS to DK the default will not be changed. **COM** asked MS to send in data to **DK** by April 2.

5b. Sediment risk assessment for PT 21

COM stated this issue was discussed at the last TM. Comments were sent in by several MS to **CEPE** and the **UK** on their respective documents. However, it was not possible to table revised documents for this TM. **NO** stressed the importance to find a harmonised approach for this issue and recommended to have some bilateral consultations before the next TM. **UK** thanked the MS for their comments and stated that the discussions at next TM may profit from the fact that the first PT 21 dossier will be discussed then. **COM** agreed with the proposal from **NO** on the need for bilateral consultations and will consult with the **UK** and **CEPE**.

5c. Preparation for TM

NL stated they would prefer to obtain the outcome of bilateral consultations in advance and be informed for example one week before the meeting of the identified outstanding issues to be discussed at a meeting. **UK** stated that it is not always clear when proposals on changing the guidance (for example default parameters in the ESD) have to be implemented. **COM** stated that in the SOP for the TM it is recommended to identify outstanding issues before the meeting. However, **COM** recommended not to include this as a compulsory action for the RMS. **NL** stated they were preparing a questionnaire on the preparation for TM discussions.