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

16/06/2008

Final Minutes of the Biocides Technical Meeting TM I 08 in Arona, 11-14 March 2008

INTRODUCTION

1. Approval of the agenda

The meeting was chaired by E. van de Plassche and for specific items on the agenda G. Fotakis, G. Deviller (ECB). E. van de Plassche welcomed the participants to the TM I 08. 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.

2. Adoption of the minutes

There were no comments on the revised draft of the minutes of TMV07 which were endorsed.

3. Members of the Technical Meeting

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

4. Next Technical Meetings

COM informed the TM that the Technical Meeting initially scheduled for July 2008 will be cancelled due to limited resources of JRC and therefore only the TMII08 in June will take place during the summer.

In addition, COM will inform the TM shortly after TMI08 on which substances will be discussed at TMII08 as due to limited resources of JRC, several substances may have to be postponed to another TM.

ENVIRONMENT SESSION

1. SUBSTANCES in PT 8:

Second discussion for the following substances

1a. Dazomet (RMS: BE)

Other Issues PT8

1b. Groundwater assessment

COM introduced the document which intends to give guidance on the groundwater exposure assessment for wood preservatives for the soil studies applicability for mobile or persistence substances and DT_{50}-K_{oc} input values for PELMO/PEARL models.

DK welcomed the paper which is useful but asked to change the sentence in the introduction stating that substances with higher K_{oc} **and** lower DT_{50} values do not leach to ground water by "is not likely to", because it occurred that such substances were found in groundwater. **COM** agreed and will make the modification. **DE** welcomed the paper and thought it is a good summary, but asked why the Tier 1 assessment according to the TGD formula is not mentioned in this paper. **COM** clarified that it was not the intention of this paper to modify the general scheme of groundwater assessment and that Tier 1 assessment according to the TGD should be maintained. The guidance document intends only to precise the Tier 2 assessment using PELMO/PEARL models and this will be explained in the introduction. **UK** thought that the TGD tier 1 assessment is not reliable and understood during the previous discussions on dichlofluanid that it was abandoned. **DK** agreed with UK that it was previously decided that the TGD tier 1 assessment was not relevant for the wood preservatives. **DE** highlighted that the TGD assessment might be relevant for other PTs e.g. PT18 and the decision should be taken for each PT. **FR** asked clarification on the TGD assessment for PT08 because if it is a worst case, can it still be provided as a tier 1 assessment or is it not accepted at all. **DK** agreed with FR that it is a worst case so it could be used as tier 1 assessment for PT08 and also other PTs. **COM** explained that the TGD assessment is simpler to conduct so it might save time to keep it as a tier 1 approach. The TM agreed on it and COM will make it clear in the new version of the document.

NL said that PELMO/PEARL models were developed for organic compounds, so they should be applied carefully. One should also be aware that the leaching studies considered as higher tier studies are performed only in one soil under one weather condition. The usefulness of those results is presently discussed under the PPP area.

FR questioned the normalisation from 20 °C to 12 °C to be used in the model calculations, as it seems that temperature variation over years is part of the models and that correction are integrated in these models. **SE** stated that according to PPP experts the model depends on the DT_{50} at 20 °C and that it shouldn't be changed. **NL** also contacted the PPP experts and they confirmed that the normalisation at 20 °C

should be kept because there is a temperature correction module in the PELMO/PEARL models which correct the temperature of the DT_{50} according to the different scenarios. **SI** confirmed this. **COM** concluded that a DT_{50} value normalised to 20°C shall be used. **IE** informed that one should be aware that PELMO tends to underestimate the concentrations and PEARL is a more conservative model. **SI** stated that the models were developed based on research for pesticides and that there is no validation for biocides. **SI** added that there is a document on biodegradation which describe the input parameters for the models. **COM** asked SI to provide the reference of this document. **DE** thought that a discussion on the FOCUS kinetics document will also be necessary in the future and asked to detail the data requests in the guidance document. **DE** added that the geometric mean is not used for the K_{oc} value but only the arithmetic mean. **COM** agreed to provide more detailed guidance for the data requirement and will check the methodology for the K_{oc}. **DE** mentioned that there is on going discussion in EFSA on the normalisation of the soil moisture content for the DT_{50} value and once guidance will be available it will be provided to the TM.

Conclusions

An updated version of the groundwater assessment paper will be provided at the next TM taking into account the comments made by the MS.

2. SUBSTANCES in PT14

Second discussion for the following substances

2a. Warfarin (RMS: IE)

2b. Warfarin Sodium (RMS: IE)

3. SUBSTANCES in PT18

First discussion for the following substances

3a. Nitrogen (RMS: IE)

4. Other Issues PT18

4a. FR e-consultation Fipronil

4b. PT18 requirements for testing on bees and beneficial arthropods / e-consultation

COM and **FR** introduced the agenda item starting with the first two questions from the e-consultation: testing requirements on bees and utilisation of tests on bees in the environmental risk assessment.

With respect to the data requirement for bees the proposal of **FR** is to only require testing in case of large scale-outdoor applications. Following a question from **COM**, whether there are such biocidal products, this appears to be the case for products against mosquitoes for human health reasons. **NL** stated that if there will be broad application to soil, exposure to bees via the route soil – plants shall be considered. **FR** agreed in principle with this comment, but stated that there is no decision scheme available in which case this systemic exposure is relevant and will have to be considered. **DE** made reference to a product under evaluation, and for which a paper was distributed for the PT18 workshop of 11 December 2007, where the product was applied on trees. However, **DE** considered tests on soil dwelling insects more relevant for this product. **IND** agreed with the proposal from FR.

With respect to the risk assessment it was agreed that the PPP methodology is not applicable. **IND** stated that a quantitative risk assessment methodology will have to be developed instead of considering risk mitigation measures based on the outcome of the toxicity tests with bees. **COM** stated that at the moment no method is available and welcomed a proposal from IND.

Conclusions

Tests on bees shall only be required in case of large-scale outdoor applications like fogging;

At the moment no method is available for biocides on how to perform the risk assessment for bees. The method applied under PPP is not applicable.

If tests on bees are performed, or are available, based on the outcome of these tests risk mitigation measures can be considered.

With respect to non-target arthropods (NTA) **FR** proposed to require testing only in case of large scale-outdoor applications. **IND** informed the meeting on the testing strategy normally applied for the development of pesticides. The outcome of these tests will most likely not be applicable for risk assessment purposes for biocides, as the exposure route (spraying on crops) is different. **IND**, supported by **DE**, proposed to, if testing is required for biocides, test soil dwelling organisms like springtails instead of following the testing strategy from PPP (documented in the ESCORT II workshop).

Conclusions

Tests on non-target arthropods shall only be required in case of large-scale outdoor applications like fogging.

At the moment no method is available for biocides on how to perform the risk assessment for bees. The method applied under PPP (ESCORT II) is not applicable.

If tests on non-target arthropods have to be performed, tests on soil dwelling organisms shall be preferred.

4c Report Workshop Environmental Risk Assessment PT18

COM introduced the agenda item. First the outstanding issues listed in the cover note from ECB were discussed:

Section 5.1 of draft Workshop Report: based on a comment from **DE**, it was agreed that the first tier will be based on the label claim: if for example there is no claim for use in hospitals the first tier will include only emission from small and large buildings. This will be clarified in the text.
Section 5.9 of draft Workshop Report: **DE** proposed to stick to the Dutch proposal, i.e. in addition, PEC calculations for further soil distances and depths according to NL proposal should be reported in the CAR. For Annex I inclusion, it was agreed to use for the soil receiving compartment for the soil depth: 10 cm in case of no mixing and 20 cm in case of mixing.
Section 6.1 of draft Workshop Report: it was decided to use the nitrogen immission standards from the EC Nitrates Directive (91/676/EC) of 170 kg N ha^{-1} yr^{-1} for all soils (arable land and grassland).

The following other issues were discussed:
Section 6.2 of draft Workshop Report: the footnotes numbers 8 and 9, as proposed by **DE** and **UK**, were accepted.
Section 8.2 of draft Workshop Report: following a question from **SE**, **COM** stated this issue will be discussed at one of the future Technical Meetings.

Conclusions

COM will incorporate the decisions from the discussion at the Technical Meeting and present a revised version of the Workshop Report at the CA meeting in May 2008 for endorsement.

5. AOB

5a. DE Data Requirements Bioaccumulation/Biodegradation Pyrethroids

5b. UK Thought Starter: Leaching Rate PT07, 09, 10

TM is invited to provide comments in writing to the UK, copy to the generic e-mail address of ENV.BIOCIDES, before April 14.

GENERAL SESSION

COM presented the Biocides section on the ECB website for following changes on the structure and the content. **COM** informed the TM that the documents have been formatted and converted to pdf where relevant. The website focuses on the procedures and decisions at Technical Meeting level. **COM** introduced the ESIS database for biocides where the Assessment Reports and Annex I inclusion decisions can also be downloaded.

1. Update from 28th CA meeting
1a. Update from the workshop on the revision of the Directive 98/8/EC
2. Tracking System
2a. Progress reports

COM gave an update from the last CA meeting. Detailed information can be found in the minutes of the 28th CA meeting. In addition **COM** provided information from the workshop on the revision of the Directive 98/8/EC.

3. SUBSTANCES in PT14

Second discussion for the following substances

3a. Chlorophacinone (RMS: ES)

4. SUBSTANCES in PT18

First discussion for the following substances

4a. Nitrogen (RMS: IE)

5. Efficacy – Guidance Document for Efficacy of Rodenticides

NL informed the TM on the changes made on the document presented at TMV07 taking into account the comments raised during TMV07 and during a subsequent commenting period. **NL** said that Chapters 1 and 2 concerning Annex I inclusion and product authorisation were joined. A new paragraph was added with respect to the requirements for a palatability test. **NL** noted that Appendix 5 on resistance was replaced by a document provided by DE. The inclusion of this item seems controversial as several experts commented on its appropriateness in relation to the scope of the guidance.

COM reminded the TM that the aim of the guidance is to replace the Annex on efficacy currently included in the TNsG on Product Evaluation in relation to rodenticides and that in this TNsG another section on resistance exists. **COM** added that once agreed this guidance document will be presented to the CA meeting for endorsement followed by a public consultation phase. **COM** will propose a short

public consultation period as enough discussions already took place during the working group meetings on rodenticides. **COM** also expressed satisfaction on the document achieved.

NL raised concerns about the fact that the document should also address voles. **NL** commented that it is clear in the document that for each claim against particular rodents efficacy has to be demonstrated. **IND** commented that control of voles would be related mostly to agricultural applications. **COM** informed that certain products (such as chloralose) could be candidate for such applications. **IND** commented that the control of voles would be of concern in some countries like Spain, Germany and France and that this could be considered as a borderline case between the Biocidal Products Directive and the Plant Protection Products Directive. **COM** proposed not to amend the guidance and add a reference in the document on this issue. This was agreed by the TM.

In relation to the text related to resistance, **DE** pointed out that for rodenticides resistance and efficacy should be evaluated together and therefore the appendix on resistance should be included in the guidance. **COM** replied that in the TNsG a section on resistance is already present. **NL** commented that the section regarding resistance should not be included in the guidance on efficacy, since issues could be raised by revision of the guidance document on resistance. **DE** replied that the document on resistance reflects the outcome of the most recent debates on the issue, and the need for a further revision seems improbable. **AT** supported DE saying that the document on resistance should be included in the guidance on efficacy as already agreed in the previous meetings. **AT** added that resistance should be considered as part of the efficacy testing. **COM** commented that the TNsG, section 6.2 already addresses the resistance and proposed eventually to replace it with the document provided by the DE. **COM** concluded that these decisions could be taken during the consultation period. **FIN** supported the proposal by the COM to replace section 6.2 with the new document. **NL** proposed to develop a new guidance on resistance based on section 6.2 and on the document provided by DE, in order to guarantee the comprehensiveness of the document. **COM** asked if NL could provide DE, in consultation with other MS, a proposal for an amendment on section 6.2 of the TNsG. **NL** replied that due to a lack of resources it will not be possible for **NL** to work on this issue. **DE** proposed to add the paper on resistance on section 6.2 of the TNsG which had already been forwarded to the OECD working group and which was used as a basis to develop the document on resistance for rodenticides. **COM** asked AT for clarification on the state of the art of the paper on resistance within the OECD Biocides Task Force. **AT** informed that the paper was commented and that it was decided that OECD will work on sections regarding efficacy and resistance for disinfectants and the EU will deal with the remaining issues including the part related to rodenticides. Any progress on the development of the paper will be communicated by AT during the next TM. Following several comments from DE and NL**, COM** proposed to replace current section 6.2 with the document prepared by DE, considering that for other product types limited information is available. **DE** asked AT to bring the matter for discussion to the OECD task force. It was agreed to discuss the issue within COM before asking for a formal advice from the OECD task force.

Conclusion

COM will combine the proposal by DE on resistance with the existing text in 6.2 of the TNsG. The final document on efficacy for rodenticides with the last

changes incorporated will be sent to the CA for endorsement. A 3 month public consultation period will then follow.

6. Technical equivalence

COM reminded the TM that the document presented was endorsed at the 24th CA meeting and the public consultation period ended in September 2007. During the public consultation period comments were received from IND and from several MS and the revised document was presented at TMV07. Some additional comments were received from IE, DE and NL.

A response to comments table has been prepared by COM and discussed during TMI08. **COM** would not agree in referring to the FAO/WHO Manual and to the guidance document on assessment of equivalence of substances regulated by directive 91/414/EEC.

Section 5.2, Evaluation process (Comment from IND): **DK** supported the proposal made by IND to differentiate between relevant and non-relevant impurities. **DE** said that in this section no other condition should be added to the sentence "The limit of each impurity or additive is not exceeded". The text should not be changed, because the evaluation of technical equivalence should not only be based on toxicity but also on identity. **NL** proposed to insert the table already present in Document Sanco/10597/2003. **FR** and **IE** supported NL. **COM** will amend the document accordingly.

Section 6.1.2, Evaluation process (Comment from IND): **AT** proposed to leave the text unchanged, because the phrase "not significantly more toxic" could be open to several interpretations. **COM** agreed not to change the text.

Section 6.2.2, Decision-making (Comment from IND): **DK** accepted to change the factor of 2 to a factor of 5 in relation to ecotoxicological testing data comparison. **COM** will amend the text accordingly.

Section 4 Definitions, Equivalence (Comment from DK): **DK** agreed to leave the text unchanged.

Section 5.1 Data requirements (Comment from DK): following comments from DK, IE, NL, FR and AT in relation to the requirement on LOD and LOQ, it was decided to change the text as follows: "Limit of Quantification for significant and relevant impurities."

Section 4 Definitions, Reference source (Comment from NL): **IE** asked in which case a change in equipment could influence the composition of the substance. **COM** explained that a change in the batch size could lead to differences in the composition.

Section 6.1.3 (Comment from NL): **COM** proposed to leave the text as it is in relation to the request of "strong grounds for requiring new toxicity studies". **IE** commented that emphasis should be placed on the comparisons of the synthetic pathways. **COM** replied that this is addressed in section 5.1, where the description of method of manufacture is required. **AT** supported COM saying that the synthetic pathway is included in the manufacturing process. Following comments from **IE**, **NL** and **FR** it was decided not to further change the text proposed.

Section 5 Evaluation of equivalence of sources of the substance (Comment from IE): **COM** proposed to add a note that comparison should be based on the dry

technical material (TC) unless it shows to be unstable. **IND** commented that in certain cases the comparison based on the dry technical material would not be appropriate.

IE proposed to add to the TNsG an appendix listing impurities of known toxicological concern as the one included in the SANCO document 10597/2003. **COM** commented that in Appendix III a cross reference to this list will already be present.

Conclusions

COM will revise the document, in light of the discussions and the comments received, which will then be forwarded to the CA meeting for endorsement. The document will then be placed on the ECB website.

7. TNsG Revision of the Analytical Methods

COM introduced the item. **COM** informed that comments from IE, NL and FIN have been received on the draft document that was presented at TMV07. The comments from FIN have not yet been addressed in the document for discussion at TMI08. **COM** noted that new text has been inserted in the document as part of the introduction containing definitions and general information. This information was taken from the OECD and DG Sanco documents and it was agreed to give reference to these documents at the beginning of the TNsG of the Analytical Methods. **NL** commented that regarding the **confirmatory techniques** the DAD is not specific enough to be used as a confirmatory technique and asked to make the text more specific. **NL** will send a text proposal to DE.

FIN raised a comment asking if there is a need for an **analytical method for sediment** which should be mentioned separately. **COM** asked if there would be different requirements for an analytical method for sediment compared to the ones required for the soil compartment. **DE** replied that the analytical method for sediment is already covered by soil and ground water. The same approach is followed within the PPP area and the sediment is not considered separately as matrix. **NL** agreed to include sediment separately as a different matrix. **COM** asked what the detailed proposal for this matrix would be. **FR** added that the analysis of sediment is described under the TNsG on Data requirements. It was agreed that DE will check which method can be followed for sediment. NL and FR will provide also a text proposal with respect to this issue.

The comments raised by NL on the **analytical methods for soil** have been addressed by DE and no further discussion was required. **DK** commented that in the last paragraph it is stated if the active substance degrades very fast then analytical methods for residues in soil are not required. **DK** said this is under normal conditions but in case of continuous exposure the method should be required as well. It was agreed that DE will add that in case of continuous exposure analytical methods for residues in soil should be required.

It was clarified that with respect to the LOQ, **FIN** asked to clarify in the text that if the PNEC is lower than 0.05mg/kg the LOQ should be set at 1/3 of the PNEC value. If this is not possible justification must be provided to prove the validity of setting the LOQ at 0.05mg/kg. **DE** said that the value of 0.05mg/kg is the lowest value and should not be lowered further. **DE** said that the same argument is used for setting the LOQ for surface water at 0.1µg/L which is the limit value for drinking water. **FR** agreed that the generic value of 0.1µg/L is protective for human health but may not be

sufficient to protect the environment. **FR** added that if there are effects observed at concentrations below the value of 0.1µg/L or the LOQ there should be sufficient analytical methods to allow monitoring for the environment. **FR** agreed with the proposal from FIN that precautions should be taken if the PNEC is lower than 0.05mg/kg.

FR also asked if the NOEC value should be used instead of the PNEC value. **COM** reminded the TM that it was agreed at the last TM that for the water compartment the NOEC value will be used. **COM** asked why for the air compartment the AF are included, since the AEL value is used for setting the LOQ, and not for the soil and water compartment. **FR** replied that for the soil and water compartment the values derive from the approaches followed under the PPP area where no AFs are used but the NOEC values are compared to trigger values. This is not the case for the air compartment where for the analytical methods the same approach as described in the OECD document is followed.
DK asked why for the soil compartment 1/3 of the PNEC value is used as LOQ when the PNEC is higher than 0.05mg/kg and for the surface water the PNEC value itself and not 1/3 shall be used when the PNEC is higher than the limit value of 0.1µg/L. **DE** will provide a response after the TM.
It was agreed that the PNEC has to change to NOEC for both the soil and the surface water regarding the setting of LOQ. If the NOEC is higher than 0.05mg/kg the latter will be the LOQ. In case the NOEC is lower than the 0.05mg/kg it remains to be clarified by DE if the LOQ should be set at 1/3 of the NOEC or at the NOEC value. The same question applies for the surface water part of the document.

With respect to the text on **analytical method for the air** compartment **IE** asked why the bystander is included with consumers. **IE** commented that this part is relevant for the operator exposure. It was agreed to replace consumer and bystander by general population. **IE** said that the most important aspect is the operator exposure which will be higher than the consumer and as a worst case should cover the assessment for the general population as well. **COM** commented that since for the general population the AEL medium term is used for setting the LOQ the same approach should be followed when the OEL values are not available. **COM** noted that if no OEL values are set these cannot be set by the Biocides group. **FR** asked why the AEL medium term is used and added that this value could not relate to any specific population but rather to specific scenario associated with exposure duration. **COM** clarified that the medium term AEL is also used in the DG SANCO document. **DE** said that the same equation proposed for the general population is used for the operator under the PPP area.

AT asked not to use the term consumer in this part of the document. **AT** said that for the purposes of the BPD it should be taken into account that for certain professions a long term AEL value should be used instead for the setting of the LOQ in air. **COM** noted that chronic AEL is usually lower than the medium term AEL and therefore using the chronic AEL value for setting the air LOQ would result in lower LOQ which would be the worst case. COM noted that in the DG SANCO document it is mentioned that either the AOEL Inhalative or the systemic one should be used and if both values are not available then the ADI should be used. COM commented that in this case it would be expected that the threshold value is for long term exposure and represents a worst case.**COM** proposed not to indicate the time frame regarding the AEL to be used in the equation but add a footnote to indicate that the lowest AEL available should be used. **COM** also proposed to use the approach proposed for the

general population also for the operators. It was agreed that DE will check these proposals and provide an answer or modify the text.

With respect to the methods for particle associated and gaseous residues no changes are required in the corresponding text.

Regarding the **analytical methods for water** it was agreed that the NOEC instead of the PNEC value will be used for setting the LOQ and it will be clarified like in the case of the analytical methods for soil whether the NOEC or 1/3 of the NOEC will be the LOQ in case the NOEC is lower than the limit value of 0.1µg/L.

NL had raised a comment on the **analytical methods for body fluids and tissues**. It was agreed that a text proposal will be sent by NL to DE regarding the inclusion of metabolites.

It was agreed that for the **analytical methods for food and feeding stuff** the text reading that when MRLs do not exist the CA should calculate them, will be removed. It was also agreed to include veterinary medicines in the sentence that reads: *If the active substance of a biocidal product is not used in plant protection products, MRLs are not available*. Regarding the comment by IE that the LOQ should be between 10-20% of the MRL value, DE will check for consistency with the DG SANCO document and if needed will make the necessary changes.
NL raised a comment related to analytical methods for complex mixtures. IND commented that the document should not be substance specific. It was agreed that NL will send a text proposal to DE regarding complex mixtures that should be general and not substance specific.

Conclusions

MS will send remaining comments and the agreed contributions as stated in the minutes above before April 28 to DE.

DE will revise the document in light of the discussion and the comments received which will then be sent to the CA meeting for endorsement before being published for public consultation.

8. AOB

8a. Request for making Minutes of the TM publicly available and Manual of Technical Decisions

With respect to making Minutes of the TM publicly available, **COM** said that one option is to send the minutes from the open session to CEFIC also for commenting. The endorsed open session minutes will be then made available on the ECB website. **COM** added that for the minutes of the closed session it is proposed that the COM will send the parts related to the discussion of individual substances to the corresponding applicants for commenting as well. The contact details of the applicants are included in the CAR. **NL** welcomed the proposal, and asked if it would be preferable to publish the minutes of the open session to the public site of CIRCA. This was accepted by the TM. **AT** asked to make all the minutes available to accession countries (Turkey and Croatia). **COM** replied that this would not be possible for the minutes of the closed session and will check with the legal services to clarify.

Conclusions

The proposal made by the ECB was accepted; the minutes of the open session will be published under the public site of CIRCA following commenting by the TM, CEFIC and endorsement at the TM. The minutes of the closed session will not be made publicly available but the COM will send the parts related to the discussions of individual substances to the corresponding applicant for commenting.

COM informed the TM that COM is currently working on the development of a Manual of Technical Decisions that will contain decisions taken in previous TMs and the document will be updated regularly to include most recent information. This document will not contain decisions related to Scoping issues. **PT** asked if the background information for each decision will also be included in this document. **COM** replied that the current format developed includes a question and answer on a specific item in an anonymous form also indicating the TM where the issue was discussed. **BE** supported the idea of including background information for each decision. **NL** proposed to name the document Handbook of Technical Decisions. **AT** and **NL** commented that the document should be endorsed at CA level as long as decisions are included. **DK** disagreed commenting that even if the document is endorsed at the CA meeting it will still not be legally binding and therefore there is no need for CA endorsement. **DK** added that discussions for which a decision has been made and included in the Manual should not be reopened.

Conclusions

COM concluded that the first draft of this document will be made available in the future TM for discussion. With respect to the need for CA endorsement of the document, COM will clarify at the next CA meeting if there is a need to do so or not.

8b. Quality Check Criteria for Draft CAR submitted to COM by RMS for discussion at TM

COM introduced the item. COM said that as agreed in the mid-term review ECB performs quality checks of the First Draft CARs before distribution to the MS via CIRCA. **COM** presented the quality check criteria that are followed during the quality check of the First Draft CAR. **DE** supported the idea of not requesting additional data after completeness check although in general terms this may be needed when thorough evaluation of the dossier is performed. **AT** added that in special cases additional data, like in case of cumulative risk assessment or residue data that will be needed at product authorisation, will need to be requested for the product authorisation phase. **COM** took note of these remarks.

8c. Dossiers acceptability for active substances for several product types (PTs)

COM introduced the item and the document prepared by the ECB, reminding the TM that the flexible approach was decided at the last TM. The main change proposed in the paper is on the way CARs are structured on CIRCA.

NL suggested that an electronic and a paper copy of Doc IIIA should be submitted to the RMS even when the same document has been sent earlier for another PT. **COM** replied that this would depend on the RMS that can either ask for both copies or not.

FIN commented that they would prefer one joint Doc IIA even when there are two applicants for one substance. **COM** agreed with this as it would facilitate the process at the product authorization stage. This would however be up to the RMS to choose.

PT asked how the RMS would make only one Doc IIA if the applicants submit two different data packages. **COM** said that it would be a case-by-case decision but if the two dossiers are evaluated simultaneously, the RMS could decide to select the most appropriate studies on which the LOEP values would be based and prepare one Doc IIA. **FIN** answered that they would list all relevant data on Doc IIA, as it would not matter if there are additional data requirements for some PTs. **FIN** would choose the most relevant study for each endpoint. **FR** supported this suggestion from a scientific point of view but saw difficulties in practice, especially at the product authorisation stage.
ES asked whether one applicant would need to get access to the selected study of another applicant. **COM** replied that this is not the case, since the applicant whose study is not used would also have submitted a full data package; **NL** commented that while for the toxicological endpoints it may be easy to select the most critical value from several studies, this is not the case for many physicochemical or ecotoxicological properties. **NL** asked whether COM could provide assistance in deciding which values to choose. **COM** had doubts whether it would be possible to have such a detailed guidance. **IND** suggested that the only reason to use other data than the one submitted by an applicant would be the invalidity of the submitted data. The clients of a company should not be forced to gain access to another study of a competitor if they have a valid study. **COM** replied that valid studies are suitable for evaluation and product authorisation and there is no need to gain access to another study even if there are more critical results. **DK** said that when there are several applicants for one substance, there would be individual evaluations and the only common document would be the Assessment Report and the LOEP. **COM** replied that the RMS could choose to prepare either separate or combined documents where applicable. **FIN** commented on the DK view, saying that it would be double the work to do everything separately and only prepare the Assessment Report and the LOEP. **FIN** added that it is easier to combine the results from all studies available during the assessment of more than one dossier for the same active substance. **BE** supported DK adding that due to issues of confidentiality, the dossiers will anyway need to be discussed separately. **COM** said that confidentiality is important at the product authorisation stage and not during the Annex I inclusion process. **FIN** commented that the results of the studies cannot be confidential since they have already been published on a website, adding that the truly confidential issues like identity could be kept separate if the applicants would be present together during the discussions at the TM.

DE stressed that the risk assessment should be performed scientifically, and it is irrelevant whether there are two or more applicants for a substance. The data packages need to be considered as a whole, choosing the most relevant values for the LOEP. There cannot be two different risk assessments for one substance. Doc IIIA can be different for the applicants, but Doc IIA and Doc I should be the same. **COM** supported this view, provided that the dossiers could be evaluated simultaneously.

AT suggested that since the applicants pay the fees, they should be able to choose between individual and combined CAR Docs, even if the substance is identical. On the other hand, if there is a difference that cannot be explained by impurities, study setup or other factors, then the substances should be considered as not technically

equivalent, resulting in two different substances and two different Annex I entries. **COM** agreed that if it has to be concluded that there are two substances, the reports cannot be combined.

COM asked for opinions on CIRCA restructuring and whether the LOEP will be needed as a separate document. **COM** further asked whether all the old draft CARs could be deleted once the final version is available, as well as all the MS comments, thereby leaving only the final CAR and the last version of the Response to Comments Table.

DK agreed on the paper and the approach, commenting that the assessment report is not necessarily the same as Doc I. **DK** would also want two separate Doc IIA instead of one. **NO** agreed with the comment by DK on the need to have both the assessment report and Doc I on CIRCA.

NL answered the questions on page 6 of the ECB paper. First, a separate LOEP is needed on top of the structure. Second, the old versions of CARs should be kept available in CIRCA, and if they are to be removed one day, it would be necessary to warn the MSs in time so that they can do the archiving themselves. **COM** promised to give a warning in advance if files will be deleted.

FIN supported the new CIRCA structure and the separate LOEP. **FIN** asked, since the LOEP contains mostly hazard related data, whether it would be possible to move the toxicological exposure scenarios to the assessment report. **FIN** will not need the old file versions when the final version is available. **COM** opposed the removal of the acceptable exposure scenarios from LOEP, since it had just been included there. **FR** would prefer the LOEP without the exposure data, and rather have a separate document with exposure scenarios used, intended uses etc.

Conclusions:

COM will restructure the part of CIRCA where the CARs are uploaded as presented in the ECB paper. MS will be given a notice before this change is made.

The LOEP will be available as a separate document. In cases where there is more than one applicant the LOEP will be a combination of the most relevant results of the data packages.

8d. Data requirements PT3 – Analytical Methods: Outcome of e-consultation
8e.Data requirement Food Risk Assessment FR

Items 8d and 8e were discussed together

COM introduced point 8d and the **NO** paper that was the result of an e-consultation decided upon at TMV2007. **COM** suggested first discussing if a tiered approach could be used and then decide if waiving of analytical methods for food and feeding stuff could be accepted. **COM** added that for Plant Protection Products, these tests cannot be waived.

NO said that they have asked the applicant to elaborate on the waiving arguments, in order to see if it will be possible to estimate whether exposure of the livestock is relevant. This could be based on the physical-chemical properties and the fate of the substance. Livestock exposure estimation should be done using worst-case assumptions. It could then be possible to decide whether waiving of the analytical

methods is feasible or analytical methods and/or metabolism studies would be required.

COM specified that if the livestock exposure estimation with worst-case assumptions reveals risk, then the proposal by **FR** for a 2-tier approach could be followed. The first tier would require analytical methods for the surfaces, and if there would still be risk, the second tier would call for metabolism studies. **COM** further asked how this exposure estimation could be performed, since it appears that there are no models or harmonised approaches available.

IND informed that they have made a refined risk assessment and have sent that to the RMS of chlorocresol. **IND** briefly described the worst-case values used in the assessment of a formulation. **COM** asked for the origin of the default values used in the assessment and if harmonised default values could be found that could be used for other PTs as well. **IND** replied that the relevant information will be sent to the COM after the TM.

COM asked whether NO would also require an exposure assessment or the physicochemical data set would be adequate. **NO** replied that exposure assessment will be necessary and that default values to use in the exposure assessment should be established as well as trigger values for requiring analytical methods and further studies.

FR supported the paper by IND suggesting that there should be a harmonised approach for food risk assessment. **FR** stressed that the real question is whether it is acceptable to perform the food risk assessment using a theoretical approach only. This question should be answered first. For chlorocresol, **FR** does not agree with the theoretical approach in the completeness check stage, since there is not sufficient data on metabolism and on degradation products. **FR** also asked for an explanation about the scenario proposed in the TNsG on Human exposure to calculate food risk assessment for PT4 dossier, namely a child eating a sandwich (part3, page 36). **FR** added that there is a need to work on more realistic scenarios for food exposure in PT3 and PT4 dossiers. **COM** commented that that level of detail may be unnecessary in the completeness check, and could be settled during evaluation of the dossier.

COM suggested that the TM should agree upon the framework on the way evaluations should be performed in cases where food risk assessment may be required. It should therefore be decided whether the theoretical approach could be followed first and if the worst-case assumptions reveal risk, then proceed with the two-tier approach suggested by FR.

FIN commented that the level of details required in the NO paper would seem excessive as a first step, and gave conditional support to the lighter approach suggested by IND. **PT** supported the iterative approach and the theoretical approach.

DE supported the NO paper and the approach suggested therein. Concerning the FR paper, **DE** supported the theoretical approach, but basic data would still be needed like substance stability, surface concentrations of active substance, and degradation products. **DE** suggested certain common default values to be established for surface areas of cages or animal facilities, numbers of animals per m^2, respiratory volumes and frequencies of animals. If calculations would reveal negligible residue levels using worst-case assumptions on these factors, then the theoretical approach would be considered sufficient. More detailed studies would be required if significant exposure of humans or animals could not be excluded.

AT questioned the theoretical approach, suggesting that it would be difficult to draw a line to what could be acceptable. **AT** would require experimental studies.

SE supported first assessing the theoretical worst-case scenario as suggested by NO, and continuing with the two-tier approach of FR if there would be risk indicated.

IND commented that when phenolic biocides are concerned, there are almost no degradation products, and therefore the required refinement of the theoretic first step has been done with the assumption that no degradation takes place. **FR** replied that there has not been any quantification of metabolism. A theoretical approach cannot be based on only the concentration used and the surface area but additional information on residues would be needed. Detailed discussion on the specific requirements in this case was not continued and **COM** noted that the exact data required would always depend on the physical-chemical properties of the substance and the intended uses of the biocidal product.

AT pointed out that such discussions on theoretical possibilities of having residues are very exceptional and opposed to the use of the theoretical approach. **COM** replied that for veterinary medicinal products there are certain criteria by which it can be concluded that MRLs will not have to be established. One of the criteria is that the substance is rapidly and extensively detoxified or excreted, in which case an MRL may not be relevant. **COM** also reminded that in the case of biocides, the products are not often applied on the animals, concluding that a balance should be maintained and not ask for more studies than is relevant.

ES asked whether the paper that would be produced based on the discussion would cover also other PTs like PT4 and PT18. **COM** suggested that the approach could be considered for all PTs where relevant. **FR** commented that unlike COM suggested, there are biocidal products that will be used on the animals and also biocidal products that will be used around the animals on a daily basis and therefore residues will not be negligible. **COM** agreed that decisions will have to be made on case by case basis. **FR** mentioned that they asked all PT3, PT4 and PT5 applicants for measurements and in case there would now be a paper with a tiered approach, then all the applicants would opt for the theoretical estimation first. **COM** suggested that at the completeness check the dossiers could be accepted and additional data can be requested if needed during the evaluation phase. **DE** commented that this suggestion is not in line with the current guidance on dossier acceptability according to which no further data should be required after completeness check. **COM** noted that the intention is to include in a framework paper the data that needs to be submitted to support the theoretical approach. These would include stability, physical-chemical parameters and the uses of the substance.

ES reminded that in the data requirements for PT4, analytical methods for residues in food are always required and asked if it would be possible to use the theoretical approach. **COM** replied that the data could be waived if there is sufficient justification as it is the case for all type of studies.

IND asked whether the analytical methods and monitoring data are only needed for the active substance and degradation products or also for co-formulants, as some MS have requested data on co-formulants as well. **AT** said that in case a co-formulant is a substance of concern it can be treated like the active substance in product authorisation.

Conclusions

COM will draft a proposal to describe the tiered procedure. Information from EMEA and EFSA will be included.

IND was asked to send the default values used in the chlorocresol risk assessment to ECB. The proposal will be sent for commenting and discussion at TMII08.

8f. IUCLID Biocides database – CEFIC

CEFIC asked how the IUCLID files sent by the applicants to the ECB are used and if ECB maintains a central database with all the IUCLID files for the biocidal active substances. **CEFIC** asked if there is still a need to send the IUCLID files. **COM** replied that ECB is preparing a database in-house which is not available outside the ECB. **COM** noted that there is currently ongoing discussion with between ECHA, ECB and DGENV on the type of information that needs to be sent to ECHA for the purposes of pre-registration and inquiries. **COM** noted that the information required will mainly focus on the contact details of the applicant and the substances that are in the review programme. It has not been yet agreed if the IUCLID files will need to be sent to ECHA. **CEFIC** asked if the IUCLID files need to be updated and resubmitted to the ECB after the evaluation of an active substance is finalised. **COM** confirmed that as soon as the updated CAR is made available the updated IUCLID file should also be sent to the ECB and the RMS. **DE** noted that the updated IUCLID files are needed. **BE** and **NL** mentioned that this has already been agreed in the past and **COM** added that it has not been enforced so far. **CEFIC** noted that enforcement would be possible even at this stage. **FR** asked if the IUCLID 5 format could be used instead of Doc IIIA for the fourth priority list. **UK**, **DK** and **CEFIC** commented that it may not practically possible for the applicants to change the format from Doc IIIA to the IUCLID format. **COM** concluded that it would not be possible at this stage to ask for such a change but if the RMS and the applicant agree to have Doc IIIA in IUCLID 5 format this is accepted by the TM.

8g. Request from EFSA on information for Bluetongue Insecticides - Repellents

COM informed that a request was received by EFSA to provide a list of the substances used as insecticides and repellents against *Culicoides* within the BPD review programme as well information on efficacy for these substances. **NL** and **BE** informed the TM that to their knowledge there is no efficacy information available for these products. **NL** said that these substances would fall under the VMPD and not under the BPD. **BE** said that it will depend on the claim used in the product. **COM** will forward the question on whether these substances fall under the BPD or the VMPD to EFSA. **COM** will then ask, if needed, MS to send a list of the biocidal substances used against *Culicoides*.

TOXICOLOGY SESSION

COM informed the TM that during the discussion of items 8d and 8e, issues related to the way food risk assessment is performed have been identified. COM will prepare a document with a tier approach which will also be relevant for discussion by the Human Health part of the TM.

1. TNsG Revision: Risk Characterisation for Biocides

COM introduced the document. Comments on the Final Draft have been received and compiled on a table which was used for the discussion at TMI08.

Comment 1 was on a proposal from ECB to restructure the document with the aim to have in the introduction of the document basic information on the AEL and MOE approach as well as on the tier system for risk characterisation. It was agreed to move the abstract after some text modifications to the Introduction.

Comment 2 was by DE and the change proposed by DE was accepted.

Comment 3 was from ECB with respect to the references given for non-threshold effects. **COM** asked first if in the case of carcinogenic substances with non-threshold mechanism there will be a need to perform apart from the cancer risk assessment also risk assessment for the other endpoints by setting AEL values for relevant routes of exposure. This is the approach followed by U.S E.P.A and may also be the case under REACH. **DK** commented what the use of AEL would be if the critical endpoint would be a carcinogenic non-threshold effect which would be the basis of the risk assessment. **COM** added that it seems that for non-threshold carcinogenic effects if a semi-quantitative approach is followed the overall assessment factor applied is so big that the threshold value derived would be the lowest compared to other threshold effects. **AT** said that it would be supported to perform in parallel with the cancer risk assessment the assessment for threshold based effects for the same substance since there will be cases where the substance could be classified as a Cat3 or Cat2 carcinogen and the risk assessment should be based on the total toxicological evidence. In addition **AT** said that in the specific part of the text non-threshold mechanisms are mentioned which may also include sensitisation and irritation and suggested to add some text to distinguish between these and cancer non threshold mode of action. In the latter case it should also be added that two types of risk assessment should be performed: one for the threshold based effects and one for the non-threshold based ones. **PT** agreed with this proposal. **DK** said that it should be clear in the LOEP which threshold value is used in the risk assessment. It was agreed to add in the text that both approaches for non-threshold and threshold effects should be followed where relevant. In addition it was agreed to make clear that the references mentioned in this part of the text are for the cancer risk assessment and to include a reference to the risk characterisation guidance document from REACH legislation where the DMEL approach is described.

Comment 4 was raised by DK on line 97. **DK** asked to clarify that the most relevant critical effect should be a systemic effect. **COM** replied that this may not always be the case for substances that depending on the route of exposure may give rise to external effects which could be at lower doses than the systemic effect and therefore drive the risk assessment. It was clarified that this part of the text is the introduction on the risk characterisation process where the entire toxicological data package shall

be considered. **NO**, **UK** and **DE** agreed with this since the paragraph is entitled identification of critical effect and should include both systemic and local effects. It was agreed that no changes are required with respect to this part.

Comment 5 was raised by NL on lines 171-173 with respect to the medium time frame. **AT** agreed with NL that for substances with long half life the 90 day study should be used for the assessment of a three month exposure time frame rather than for a six month time frame. **AT** proposed to delete lines 171-173 to avoid confusion since it is already mentioned in the text that in general that toxicokinetic properties could influence the duration of the medium term AEL. **NO** and **NL** agreed with this proposal and lines 171-173 will be removed.

Comment 6 was raised by DK on line 193 asking to give reference to EPA and FAO on the use of the assessment factors. **AT** agreed with this proposal. **DE** commented that the default factor of 100 is internationally accepted but would not oppose to add the reference proposed by DK. **PT** proposed to add a footnote instead with the reference proposed by DK and this was agreed by the TM.

Comment 7 on line 201 and 214 was raised by UK on the use of human data for assessment factors. It was agreed to clarify in the text that the use of biomonitoring studies for the purpose of human exposure assessment should be allowed.

Comment 8 and 9 was raised by UK and DK respectively. **COM** commented that it is clearly mentioned in the text that no human volunteer studies should be performed for the purpose of the BPD. It was agreed to delete the phrase that not considering ethically performed studies would be unethical. **DK** said that there are still reservations for giving strong emphasis on the use of human data. **DK** asked to add the information that human data should not be used instead of the animal data. **COM** noted that this text is part of the assessment factors and part of the refinement of assessment factors when there is human data available. **SE** agreed partially with DK but added that well documented human data could be used when existing established epidemiological data or case reports are available, e.g. data of warfarin that is used as medical treatment.. **UK** agreed with this. **DK** asked where in the TNsG is mentioned that human data can be used. **COM** replied that in the TNsG for data requirements it is mentioned that human data can be used. It was agreed to add a footnote giving reference to the Directive and the TNsG on data requirements. **AT** commented that no experimental human data can be used even if they have been performed for other purposes than the BPD as they may not have been performed under the international ethical conventions for such studies. **AT** added that specific distinction should be made on which studies can be used. **PT** added that the use of human data will most likely be made in a qualitative way. **COM** and **NO** replied that studies performed for medicinal purposes should be used. **COM** added that it is already mentioned in the text that only studies performed under internationally accepted ethical standards. **DE** added that human data cannot be ignored when available. Therefore no further changes will be made in the text apart from the clarification with respect to the use of biomonitoring studies.

Comment 10 was raised by DK on line 234-245 to add an introduction to the text for the description of the assessment factors used for local effects with respect to the local AEL. **COM** replied that this is found elsewhere in the document. It was agreed to give reference to the ACUTEX project publication. **DK** commented that there is also a need to clarify where the default value of 2.5 is derived from. **UK** said that it would be preferable to have the in depth discussion on the assessment factors for local

effects when such a case is discussed in a CAR. **COM** concluded that the reference to the ACUTEX project will be added and will also try to add some clarification on the derivation of the 2.5 default value.

Comment 11 was raised by DK on line 247-250. It was agreed to maintain only the reference to the DNEL approach as proposed by ECB in the commenting table.

Comment 12 was raised by DK asking to rephrase the text to make sure that it is not implied that all other regulatory fora are using allometric scaling. It was agreed not to make any changes in the text.

Comment 13 was on the footnote on page 8. It was agreed to add the sentence proposed by DK in the commenting table.

Comment 14 and 15 were raised by DE and NL on line 313. It was agreed to remove "short-term" from the text and to move this paragraph to the beginning of the section as proposed by the ECB in the commenting table.

On **page 10 line 347-351** **COM** proposed to rephrase the text that indicated that no available methods for quantification of skin sensitisation potency for regulatory purposes. **COM** informed the TM on current work ongoing under IPCS/WHO for the development of harmonised guidance for immunotoxicity risk assessment. In addition U.S EPA will soon publish, for consultation, new guidance on immunotoxicity risk assessment and under REACH there is guidance on how to estimate thresholds for skin sensitisation. **COM** proposed to delete the last sentence and add that there is current work under IPCS/WHO in this field which should be taken into account when it is made publicly available. This was accepted by the TM.

With respect to the tier approach: **COM** commented that in cases of substances that are irritant or sensitisers tier 1 cannot be followed since the use of PPE would be anyway required. In addition the type of available human exposure data (potential or actual) would also determine if tier 1 (no use of PPE) can be used or tier 2 should be the first step in risk characterisation. It was proposed to add text to indicate that there may be cases where tier 1 can be omitted due to the considerations mentioned above. This was accepted by the TM.

Comment 16 was raised by DK. It was agreed to delete the phrase "less sensitive populations" as proposed by DK.

Comment 17 was raised by DK on line 487. It was clarified that "taken into consideration" does not mean that another methodology has to be followed. Therefore no change will be made in the text.

Comment 18 was raised by UK with respect to the definition of non-professional users. The proposal from UK was accepted and the text will be amended accordingly.

COM proposed to add reference in part 4.1.8 to the Guidance available from EMEA on the setting of MRLs and this was agreed.

Conclusions

COM will prepare the final version of the document in light of the agreed changes and will distribute it together with the revised RCOM table. UK will aid with the language check of the document. MS can send any remaining editorial comments before the document is discussed at the CA level. The document will be brought for endorsement to the 29th CA meeting in May 2008 and once endorsed it will be released for 3 months public consultation. It was agreed that

RMS should use the document from now on as all the methodological issues have been agreed upon.

2. SUBSTANCES in PT 8.

Second discussion for the following substances

2a. Tolyfluanid (RMS: FIN)

3. SUBSTANCES in PT18

First discussion for the following substances

3a. Nitrogen (RMS: IE)

4. Use of PBPK modelling in risk assessment – Presentation HSL, UK

A presentation on the use of PBPK modelling in risk assessment was given by Dr. George Loizou from HSL, UK. The power of PBPK modelling for the determination of tissue dosimetry as well as for the refinement of assessment factors was presented. George Loizou also gave a demonstration of the software Megan with a case study building a PBPK model. Following questions by MS it was noted that PBPK modelling is not used routinely for risk assessment purposes. It is expected that PBPK modelling will be used in the future in special cases of very toxic chemicals where refinement of the assessment will be needed. It can be estimated that for up to 600 chemicals that will be regulated under REACH there will be a need to use PBPK modelling.

The presentation will be distributed to the MS after the meeting and the Megen software developed by HSL, UK is publicly available at **http://www.opentox.com/megen/**

.

5. Human Exposure

5a. Harmonisation of approaches used in Human Exposure Assessment

COM introduced the item and said that following bilateral discussions with NO it was identified that the approaches followed for the human exposure assessment for PT08 are not always harmonised. Some of these issues have already been presented to the HEEG for an opinion and will also be discussed at the TM. In addition **COM** commented that it would be useful both for the purposes of the review programme as well as for the product authorisation and mutual recognition phases to develop an extensive list of the human exposure scenarios that need to be assessed for each PT depending on the formulation of the product and the uses. This would apply for both primary and secondary exposure and could be updated as soon as new formulations within a PT need to be assessed. The list would contain information on the exposure patterns, formulation of the product and the TNsG models that need to be used to perform the assessment. An example of this type of work was presented by UK (item 5a) where UK listed in a table the secondary exposure scenarios that have been used

in some CARs for PT08 which also indicates that the same scenarios have not always been used by RMS. This document was not though presented to the TM for discussion at this stage but only for information. It will be used in the future for developing a list of scenarios for secondary exposure for PT08.

COM proposed to initiate this work for PT08 and PT14 for which data is already available. COM will prepare a table/questionnaire asking for specific information from the RMS with respect to the exposure scenarios used in the CARs. Following gathering of the information, COM will prepare a general list based on the data provided and will ask the HEEG for an opinion on the proposed scenarios and the models to be used. MS welcomed the proposal and COM will distribute the tables to the RMS after TMI08. **FR** asked if it would be possible to do this work also for PT18 at this stage. **COM** replied that due to limited resources at the ECB, this is not possible at present and future work in this field will be discussed at a later stage. **FR** will send to the ECB a template for human exposure assessment that is currently used by the French CA which could serve as the basis for the questionnaire to be distributed to the RMS.

5b. Tables for Risk Characterisation in the CARs

The tables prepared by the COM were presented at TMV07. Comments for modifications were received by MS. At the TM it was agreed to remove the sentences on intended and unintended uses and they may not apply to all PTs. The acute scenario was agreed to be renamed to short term in order to cover both acute and medium time frames. The oral exposure column in all tables will be placed after the inhalation and dermal columns. **NL** and **FR** asked if it would be possible to add a column to indicate external values that may be used in the risk characterisation. **COM** commented that practically it is not possible to include another column and in most cases the systemic values derived will be used for risk characterisation. COM will find a way to indicate that if external values are derived and are also used in the risk characterisation they should be indicated together with these tables. It was agreed to include these tables both in Doc I/ Assessment Report and in Doc IIC.

Conclusions

The tables will be modified in light of the comments received and will be distributed and uploaded on the ECB website for use in the future CARs. COM asked, if possible, that RMS use these tables in the CARs already under preparation.

5c. Amendment of Mixing & Loading Model 7

COM introduced the item. The document was prepared by FR and discussed at the HEEG. COM noted that due to limited time there may some minor issues for clarification within the HEEG. FR introduced the document highlighting that as a general rule the models in the TNsG version 2 (and BEAT) should be the first choice for solid loading/dumping – liquid manual loading/pouring and liquid (semi-)automated transfer/pumping. If no specific model can be found the RISKOFDERM Dermal model can be used.

There were no comments on the document. It was agreed that the document will be brought back to the HEEG to check if there is a need for text modifications. If no

major changes are needed the document will be considered finalised and will be uploaded on CIRCA.

5d. TNsG Exposure of child/infant – Transfer Coefficient

COM introduced the item. Due to the unavailability of UK, that had prepared the document within the HEEG and the remaining outstanding issues that had not be resolved and agreed upon by all experts of the HEEG, the paper will be rediscussed by the HEEG and brought back to the TM for agreement either following written procedure or discussion at TMII08.

5e. Human Exposure Expert Group

COM informed the TM, that following receipt of the nominations of Human Exposure Experts by MS the Human Exposure Expert Group has been created consisting of 10 exposure experts. The HEEG has started work with three issues that were discussed at TMI08. **COM** said that due to limited human resources at the ECB there may be changes in the near future on whether COM will coordinate the activities of the group or not.

5f. Exposure in can preservatives

COM informed the TM that following a request from FR, MS are reminded that in the case of exposure from the use of in can preservatives it has been decided in the past that the use of paint containing in can preservatives will be considered as primary exposure. **COM** also reminded the TM that it does not make any difference if the exposure is considered as primary or secondary and the assessment does not change. In addition, the discussion on this issue in the past applied for paints and not in general for all in can preservatives as the question was for the use of paints containing in can preservative.

5g. Potential Hand Exposure

COM introduced the item. **COM** said that the paper was prepared and agreed upon by the HEEG. When actual hand exposure is available it was clarified that in the case of products that are sensitisers and/or irritants the actual exposure data has to be used with the provision that users will have to wear gloves. This is also in line with the modification proposed for the tier 1 assessment for the final version of the risk characterisation document. In the case actual hand exposure data is converted to potential hand exposure generally a multiplication factor of 100 has to be used for the conversion. Following question from NO on the appropriate starting point for this conversion; i.e. choice of indicative value and exposure values from old versus new gloves, it was agreed to distinguish in the paper the approaches to be followed when data is available in the model for both use of old and new gloves. It is proposed to use the 75th percentile exposure value for new gloves if available in the appropriate model for the conversion. However, this will be further discussed by the HEEG.

Conclusions

Following the last modification to be agreed upon by the HEEG, the paper will be considered finalised and uploaded on CIRCA.