

## **Final Minutes of the Biocides Technical Meeting TM II 08 in Arona, 14-17 October 2008**

<b>INTRODUCTION</b>
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The meeting was started with a moment of silence to remember Joop van Hemmen who passed away on Friday 10/10/2008. COM made reference to the considerable contribution of him to the biocides area, specifically on the assessment, and development of methods to estimate, of human exposure. Not only did he contribute to the development of the current guidance used in the Review Programme but he was also recognised as one of the main experts in this field in the scientific community. COM also made reference to his contributions as a member of the Human Exposure Expert Group, to which he contributed until very recently.

The meeting was chaired by E. van de Plassche and for specific items on the agenda by K. Aschberger, M. Bouvier d'Yvoire and A. Airaksinen (DG JRC), and C. Kusendila (DG ENV). E. van de Plassche welcomed the participants to the TM III 08. Representatives from the MS, NO, CH, CEFIC and Industry were present at the TM. Representatives from EFSA and EMEA participated in the Food Risk Assessment session. For specific items of the agenda, the interested companies were invited to attend.

### **1. Approval of the agenda**

The agenda was adopted without changes.

### **2. Adoption of the minutes**

COM proposed to change the minutes based on NL written comments in the following way: page 12, first paragraph. "RMS said that for the time being they would use for transient mouthing the direct ingestion with a value of 5 g and for the hand to mouth transfer a value of 10 mg." change to: "RMS said that for the time being they would use for transient mouthing the direct ingestion with a value of 5 g and 10 mg." And: page 21, Doc IIA. "Comment 139: IND stated that based on a recent literature search there are no incidences of resistance. This will be clarified in the CAR." Change to: "NL will clarify in the CAR if more information is needed".

No more changes were proposed, and the minutes were endorsed.

### **3. Action List TM**

On the action list, the following was concluded:

- 1) Refinement of marina scenario for PT21 will be discussed in the ENV session.

- 2) Evaluation of tests on nitrogen and carbon transformation in soil will be discussed in the environmental session.
- 3) The addendum to the TNsG on data requirements section 7.0.2.3.2 on requirement of water-sediment study depending on Kp value will be prepared.
- 4) The Manual of Technical Decisions is still under preparation.
- 5) The questionnaire on ConsExpo has been sent, and more information will be given in TOX session, agenda point 3 (AOB)
- 6) The request to discuss Annex I inclusion for in-can preservatives at CA meeting was passed to DG ENV, but apparently this was not discussed yet at the September meeting.
- 7) Budget approval for BEAT training is being sought, but it is not certain yet.
- 8) ECHA has been consulted on participation of the applicant in the Risk Assessment Committee for C&L proposal and Member State Committee for PBT identification proposal, and this will be discussed in the GEN session
- 9) As SE has prepared a paper concerning creosote and whether the plant toxicity tests assess chronic endpoints this action is considered as completed.
- 10) Update of the guidance document "Risk mitigation measures for anticoagulants used as rodenticides" will be prepared.
- 11) The questionnaire on resistance has not been uploaded on the JRC-IHCP web-site yet.

#### **4. Members of the Technical Meeting**

The lists of TM members and of the E-consultation group were distributed, and MSs were asked to inform COM of any changes to these lists.

#### **5. Next Technical Meetings**

The next TMs are:

TM IV 08	9-12 December 2008	CA	25-28 November
TM I 09	16-20 March	CA	17-20 February
TM II 09	8 - 12 June	CA	12-15 May
TM III 09	5 -9 October	CA	15-18 September
TM IV 09	30 November - 4 December	CA	15-18 December

**TNsG Annex I Inclusion: Risk Characterization Human Health**

At the 29<sup>th</sup> CA meeting the "Draft Final for Revision of the TNsG on Annex I Inclusion Chapter 4.1: Quantitative Risk Characterisation" was not endorsed. Following this decision, COM revised the Chapter 4.1 document according to the comments received from the MSs. Additionally, **DE** rewrote Chapter 4.1.9 to take into account the comments received.

**FIRST PART OF THE SESSION:** All open issues except risk characterisation of non-threshold carcinogens

**Karin Aschberger** (COM) gave a presentation discussing the scientific and regulatory background of the issues concerning 1) assessment factors (AF) used in deriving the AEL for biocides and Derived No Effect Level (DNEL) in the REACH context; 2) the concept of a Derived Minimal Effect Level (DMEL) in REACH; 3) Allometric scaling, and 4) factors used in duration extrapolation. Following the presentation, discussion was opened on the written comments submitted by NL (not present at this session) and DK.

#### 1) **Benchmark dose (BMD) concept**

**NL** had proposed to include the benchmark concept as a dose descriptor in addition to the NOAEL as this method is considered to be more accurate and might become even more relevant in future. **FR** supported the NL proposal and emphasized the importance of the BMD approach, considering it to be scientifically more valid since it takes into account the data from all dose levels. **FR** said that although it may be too late to add this in the TNsG at this stage, they would nevertheless support mentioning it if other MSs agree. **DK** considered that this approach needs to be taken into consideration, and supported mentioning it already in this document. **DK** pointed out that it would be important to have guidance on using the benchmark dose, mentioning also that it may often be difficult for biocides as the tests are only performed with three dose levels. **SE** agreed with **FR** and **DK**, pointing out that it requires mathematical modelling and software. **UK** said that the BMD could be a useful tool, particularly when enough data are available to apply it properly and in cases when a NOAEL cannot be identified. **COM** concluded that an encouragement to use the BMD will be introduced in the guidance and a reference to the REACH guidance will be made, where a lot of information can be found.

#### 2) **Reference to ACUTEX**

**NL** had proposed in their written comment to delete the reference to the ACUTEX document as this is not an official guidance document. **SE** and **DE** preferred to keep the reference while no support was given to deleting it, so no changes will be made here.

#### 3) **Allometric scaling (AS)**

**NL** had asked to add a recommendation to use the allometric scaling (AS) as this is usually the more accurate method. **FR** supported using the AS as a more precise methodology, but in tier 2, when the risk characterisation needs to be refined. The use of the AS should not be restricted only for harmonising with other legislation. **DK** was reluctant to use the AS factors and was worried that the proposed numbers are a

rough estimate and therefore they should not be used blindly. In their view some animal strains might be more sensitive than others, making AS factors erroneous. **COM** remarked that if kinetic data is available it should be used, but in the absence of that, the use of AS would be a better option. **PT** was of the opinion that AS is clearly a refinement of the AFs, so it should be used in tier 2 and not in tier 1. **COM** asked for the rationale why it should only be used in tier 2, since AS factors can result in either more conservative or less conservative figures compared to using the single default assessment factor of 10. **NO** said that the AS might not always be applicable and more guidance on the use of it would be needed. **AT** questioned whether the AS are always more accurate (supporting references are missing), and assumed that AS is not of big relevance either, since species other than rat and mice are hardly ever used. **COM** explained that there is the possibility that e.g. dog data is available, especially for Biocides where such data is required and even if the data is not used for the risk characterisation the AS could be lowered to that value if it is shown that the dog is not more sensitive than the rat. In addition to the AS for the derivation of the interspecies differences there is a factor of 2.5 for the remaining differences which could be skipped when there is evidence that humans are not more sensitive than the test animals. In such a case, the overall interspecies factor would be lower. **FR** commented that AS is in line with the concept of tiered approach, in providing a refinement of the assessment, be it to the more conservative or less conservative direction. More guidance was considered necessary. **AT** asked for more guidance on the use of AS if it is proven that it is a more accurate method. **COM** explained that no additional guidance was included in the TNsG revision as the reference was made to the REACH guidance where this is explained in detail. A repetition of the guidance was not deemed to be necessary. **COM** mentioned that the use of allometric scaling in the context of assessment factors rested upon underlying assumptions, the most important being:

- Effect is related to the area under the time-concentration curve (i.e., AUC is chosen as the internal dose);
- The bioavailability of the substance is the same in both test species and species of interest;
- The clearance scales with the power 0.75 of body weight;
- The kinetics are dose-proportional over the range of doses tested.

It is generally admitted that in the absence of specific data, the first three hypotheses are relatively robust. The hypothesis of dose proportionality is more open to discussion, but since it is also one of the assumptions made by the standard assessment factors approach, it is neutral in the context of choosing between the two methods. There is accumulating evidence supporting these underlying assumptions, but if there is information concerning a particular chemical or animal, then this better information should always be used. **COM** explained that if there is substance specific data, this should always be used, if not, then defaults should be used. **COM** suggested to recommend AS as a default, mentioning also specifically the conditions under which AS should not be used. Reference to the REACH guidance should be made. **FR** asked the TM for a clear opinion on whether AS is to be used as a Tier 2 approach or not. **DK** supported **COM** in mentioning the pitfalls i.e. when AS should not be used, asking for more guidance as given in the REACH guidance. **DK** supported the **FR** view that the refinement does not always need to be less conservative. **COM** pointed out that Tier 2 is usually less conservative than Tier 1, while AS may also result in a more conservative assessment factor. Thereby the approach of using AS in Tier 2 would not be practical. **FR** responded that they understand the concern, referring to

the differences in the scientific and regulatory points of view. For the RC the default AF is 100 and then, if necessary, further refinement of the RC can be undertaken.

**COM** concluded that the text should allow AS, the specific guidance in REACH will be cited, and some of the pitfalls will also be mentioned. AS will be used as an option for refining the risk characterisation in a tiered approach. Refinement in this case can be either in a more conservative (e.g. AS used for mouse data) or less conservative direction (e.g. AS used for dog data).

#### 4) **Additional residues**

**NL** had commented that it is not clear in the TNsG whether additional residues from all sources should be covered. **COM** considered it to be sufficiently clear, and if further discussion is needed, this could be done on Wednesday morning during the discussion on the Food risk assessment. **DE** who had prepared the revision of this chapter (4.1.9) said that they could agree to the NL proposal, but since it is currently not possible to cover all sources of residues, the text should be left as it is. **COM** concluded that as no further comments were heard, the text will be left unchanged.

#### 5) **AF for differences in duration of exposure**

**DK** expressed their worries that referring to specific conversion factors for the duration of a study may result in dossiers with major data gaps. **COM** considered it useful to have the numbers in the guidance, and the DK worry could be dealt with by introducing a statement concerning the data requirements. **UK** said that they found it useful to have figures. **DK** said that one should be careful with large extrapolations and the number should be decided on a case by case basis, reminding that the guidance will be studied by the industry which might result in an increase in submitting dossiers with data gaps. **COM** noted that these factors have no impact on the data requirements, and the guidance should not be interpreted as an agreement to data gaps. **NO** could understand the DK worries but saw also the advantages of having such numbers and recommended to leave these factors in the TNsG, maybe also including a disclaimer that it should have no influence on the data requirements. **PT** agreed with DK and was afraid that applicants could try to use the factors instead of submitting a subchronic or chronic study, questioning especially the extrapolation from subacute to chronic studies. **AT** asked about the logic of the numbers and was afraid that the applicant restricts the testing to the sub-acute study and does not follow the established data requirements. **COM** commented that the data requirements are given in the Biocides Directive and cannot be overruled by any guidance given in the TNsG. It was further explained that there could be conditions where sufficient information is available to know that a prolonged exposure does not lead to more severe effects, or adverse effects do not appear at lower dose levels, while these data might be of insufficient quality to be used for the risk characterisation. Using AFs could then avoid duplicating a chronic study. **FR** said that the extrapolation from subacute to chronic studies could be done when overall information is considered sufficient, taking into account the scientific validity of the justification for extrapolation. Conditions for using the factor 6 should be specified. **UK** reiterated that the first step in dossier evaluation is the completeness check, where the fulfilment of the data requirements is assessed and AFs are not discussed. If no chronic study is submitted, there has to be either a justification for that or the dossier fails at that stage. There should then be no risk of any MS accepting a dossier that does not fulfil the data requirements based on extrapolation in study duration. **COM** explained that a WG had discussed the TGD revision for 3 years, which was the basis for the REACH

guidance and gave some background information on the derivation of these numbers. They are figures for extrapolation rather than conservative values. In addition to the factor of 6 from sub-acute to chronic extrapolation an additional factor of up to 10 could be used for the quality of the overall database which would lead to a factor of 60. It would however be possible to exclude the factor 6 from the guidance, as usually that extrapolation would not take place, or include a clearer statement on the exceptionality of such a duration extrapolation. **AT** asked to add conditions for the use of such factors, and that it should be made clear that data requirements cannot be influenced by that. **COM** summarised that it was concluded to mention that the use of the additional assessment factor of 6 (sub-acute to chronic extrapolation) is not expected to be necessary under normal circumstances, and mention that the factors 2 and 3 can be used on a case by case basis. It will be clearly stated that data requirements cannot be influenced by the use of these additional assessment factors.

#### 6) **AF for the severity of the effect**

**DK** asked to change the additional AF for the severity of the effect to "between 2 and 10" (instead of between 1 and 10), and asked why the text was changed from stating that it has not been more than 10. **COM** considered the proposal "between 1 and 10" more open, and would not give an impression of suggesting a default factor of 10. **AT** supported **DK**. **COM** suggested to write "so far this AF has been 3 or 10". **SE** suggested "between 3 and 10", and **DK** "from 3 to 10".

It was agreed to change the text to "So far this AF has been from 3 to 10".

#### 7) **Reference to REACH guidance**

**DK** asked to delete the reference to REACH in line 242 as it may bring confusion as to which part of the REACH guidance is relevant. **AT** supported **DK**. **COM** proposed to delete it, and this was agreed on.

### **SECOND PART OF THE SESSION:** Risk characterisation of non-threshold carcinogens

#### **Non-threshold carcinogens**

Karin Aschberger (COM) and Henrik Appelgren (SE) gave presentations on semi-quantitative risk characterisation of non-threshold carcinogens. **DK** started the discussion by explaining that DK is reluctant to accept a semi-quantitative risk characterisation, but is very positive about having the present discussion in order to decide how to deal with such substances as biocides in the future. For the time being they would prefer only a qualitative RC. **DK** considered the concept of "negligible exposure" to be a key issue in the assessment of non-threshold carcinogens. The suggested guidance is a big change, considering that it should only be used in very exceptional cases where socio-economic considerations can have a higher priority than the scientific evaluation. The key problem with the DMEL is to define a derived value at which a risk would be accepted. This level could soon be understood as a NOAEL. **DK** would therefore prefer to have only a qualitative assessment describing that there is always residual risk, regardless of the risk mitigation measures implemented. **COM** commented that it is a matter of risk communication to avoid the impression that the DMEL could represent a safe exposure level. We should always be very clear not to give a false statement of safety. **SE** explained that they do not want non-threshold carcinogens on Annex I either. The suggested methodology

should not be understood as a general approach to get genotoxic substances on Annex I. Risk mitigation is always needed and there is no safe level. With the risk level of  $10^{-5}$  (1 lifetime cancer case in a population of 100.000), the risk would be quite low in a working population of 10.000 people exposed to the substance. **COM** said that it will always be very difficult for a non-threshold carcinogen to enter Annex I, and in such cases there will always be socio-economic or public health reasons to support the use of such substances. In addition, these cases will be subjected to comparative assessment to look for substitutes. **AT** mentioned that the RC depends not only on a hazard assessment but also on the exposure assessment, which is the weakest part of the evaluation, as it is based on models that are not validated, or on few data points. Therefore it has to be questioned how reliable the results of a semi-quantitative risk characterisation can be considered. **FR** suggested that the discussion whether a semi-quantitative RC should be performed should be taken at CA level, asking whether the TM has a mandate to decide on the methodology. **COM** responded that it has not been explicitly discussed whether an Annex I inclusion would be possible, but in principle this should not be excluded, and therefore the methodology should be discussed here. **AT** was of the opinion that it is up to the CAs to define which risk levels are acceptable ( $10^{-5}$  or  $10^{-6}$ ) and which further risk management decision have to be taken. The opinion of **COM** was that the methodology should be discussed because the TM will have to deal with non-threshold carcinogens and guidance is therefore needed. **COM** proposed to include a statement in the guidance that qualitative risk assessment will always be performed, and semi-quantitative assessment is an additional tool that can be used to produce more information for risk management. **DK** wanted to discuss more the concept of negligible exposure. Exposure assessment is a weak area in the risk characterisation, and e.g. in the case of creosote, there is no exposure data on the people that will have to climb poles treated with creosote. **SE** commented that such a study is now available for creosote, namely an actual exposure data on pole workers. **DK** considered it better to describe the risk qualitatively and use all the possible safety measures, than to trust a relatively arbitrary number coming from a semi-quantitative assessment. **DK** also mentioned that it is a completely different issue to conclude on the acceptability of an unavoidable contaminant in food or in an industrial process, when compared to the deliberate use of the non-threshold carcinogen as a biocide. **SE** agreed, but pointed out that if it can be considered acceptable to have a non-carcinogenic contaminant present in food, to which exposure is continuous and long-term, then it might be acceptable to use a substance with similar risk level as a biocide, trying to avoid exposure as far as possible. **COM** stressed that non-threshold carcinogens will not be discussed on a regular basis, and most probably there will not even be an application for such substances without strong socio-economic grounds. All these cases will be exceptional, but the point is that guidance is needed for them as well. **SE** added that for some uses the possible alternative substances might be even worse for some other reasons. **DE** said that even if a semi-quantitative RA is done, this does not automatically mean that a substance will be included in Annex I. Other decisions are still possible, but they will be done at a political level. Methods used for semi-quantitative RC form a tool, and the TM should discuss the tool and not the acceptable numbers of dead people, because the latter one is clearly a political discussion and decision. **COM** commented that it is true that the exposure assessment is the weak point of the RC, but this is true also for the threshold effects, when comparing it to the AEL. There is significant progress being made in both exposure modelling and in estimating the degree to which risk mitigation measures actually

reduce exposure. Presently the proposed guidance is written in a way that qualitative and semi-quantitative assessments can be alternatives, but it could be improved by writing that first a qualitative assessment is performed, and when the data allows derivation of a DMEL, a semi-quantitative assessment could be performed. The qualitative assessment should always be preceded by comparative assessment to find alternatives, and followed by strict risk mitigation measures. **AT** expressed their concern that if a quantitative assessment was performed for workers (probably based on weak exposure data) and would show no risk at a level of  $10^{-6}$  this could lead to authorisation of a biocidal product also for the general public. In addition, if products are not classified as carcinogens because the concentration is below the concentration limit for classification (0.01 %), then that product could be allowed for the general public. **UK** commented that the Annex I inclusion could have the restriction that the substance can not be used for any products used by the general public. **SE** said that products containing genotoxic carcinogens can never be used by the general public. If only a qualitative RC is performed, it is in total weaker than if a quantitative RC is used as an additional tool, giving further information. **NO** commented that authorisation of non threshold carcinogens should be avoided as far as possible. They agreed that a quantitative RC could be an additional tool that can be used for decision making, but was concerned about the lack of good exposure data. The concept of "unlikely exposure" as defined in the Annex I inclusion criteria should be discussed at the CA level. **DK** was concerned about the consequences of a quantitative RC if it shows that there is no risk for the consumer. **SE** said that as the use by general public is not possible, it is not a relevant issue to discuss. **COM** agreed, explaining that although the general public is included in the REACH guidance, this will not have any effect in the BPD where use by general public is excluded. In addition, the guidance also takes into account the quality of the data that is used to derive the DMEL, and this should always be described narratively to indicate how trustworthy the DMEL is considered. **UK** said that the qualitative assessment is always done first, and a semi-quantitative RA gives additional information for the decision of risk managers. **AT** was still concerned that if it was decided to include such a substance on Annex I there could be secondary exposure to the general population and whatever the selected risk level would be, it is a very political decision. Measured exposure data or at least validated models should be engaged for quantitative risk characterization of carcinogens. **DK** said that too much faith is put in the methodology, when at the same time the methodology is not trusted enough to use it for the whole population. **COM** commented that we should not forget that the methodology used in RC does not make any decisions, nor does it change the directives. **DE** said that the methodology should be in this guidance. This way we will get substance-related experience from creosote and formaldehyde. These substances have to be dealt with, and tools are needed for that. **DE** strongly opposed the thinking that by introducing an RC tool in the methodology, the general public would be exposed to non-threshold carcinogens as a result. **UK** and **SE** supported **DE**. **PT** asked if there are identified biomarkers for the exposure to creosote. **SE** responded that the exposure levels are measured data, and no biomarkers are used<sup>1</sup>. **PT** clarified that the question concerned monitoring of the exposure, which would be easier if good biomarkers were available. **SE** answered that this has not been discussed so far, and would be quite late to take it up for creosote now. The data from the impregnation plants is good, and that data can be used. **AT**

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<sup>1</sup> SE comment: Actually, biomarkers have also been used, and such data are presented in the revised CAR.



asked to write in the guidance that there must be no exposure of the general public to genotoxic carcinogens, being still concerned that there could be a risk level that is considered acceptable to the general public. **SE** pointed out that the substances will never be accepted for use by the general public. Concerning the risk level, it is said to be of low concern, and not to be acceptable. **PL** confirmed that semi-quantitative **RC** is just another tool to help in the assessment and the document should be accepted. **COM** said that it seems to be mainly a terminology problem and that the general view seems to be that an additional tool is required. **COM** then asked whether it would be ok to rephrase the text so that it is clear that qualitative assessment is always performed, and risk mitigation measures put to place, and only then, if the data allows, the semi-quantitative assessment would be performed. **SE** agreed that it would be ok. **DK** said that putting these considerations in the guidance would be a significant improvement, including the suggestion that semi-quantitative assessment “may” be performed instead of “should”. It should also be mentioned in this chapter that all non-threshold carcinogens are subjected to comparative assessment. **FR** asked for some more details of the methodology to be included in the guidance. **COM** replied that it would be better not to rephrase the methodology because rephrasing may result in unwanted changes in the message, and the full guidance is available in REACH. While the text currently refers to the REACH guidance part R.8 which is a precise description of the guidance, there is also a short description of the methodologies in Part B of the guidance. Reference should be given to both parts. **AT** reminded the meeting again to consider the consequences. If a product is authorised in one MS, there can be mutual recognition in all other MSs. One has to be aware of the responsibility. **FR** said that there should be a distinction between guidance and the political decisions, and that the latter should be discussed in the product authorisation and mutual recognition facilitation group. **COM** considered that overall there appeared to be an agreement, suggesting that all comments would now be taken into account in preparing a new version of the document. **DK** asked whether reference to the methodologies would now be made more detailed. **COM** proposed to change only few sentences in the guidance, mentioning that qualitative assessment will always be done, and then after applying all risk mitigation measures, perform a semi-quantitative risk assessment if the data allows. No further description of the methods would be given, but an additional reference would be made to Part B of the REACH guidance. It will be checked that the residual risk will not be said to be acceptable, but phrasing like “low risk level” will be used. **IE** suggested not to reduce the guidance from the present form. **DK** asked to make it clear that a comparative assessment has to be performed for non-threshold carcinogens, and that such substances should only be allowed as a last resort. There should be as little description of the methodology as possible, so that it would not be needed to change if REACH guidance changes. **DK** was worried that using the guidance would lead into a wrong direction, and hoped that the PPP procedures would be taken more into account since there as well there is an authorisation procedure for the substances. **IE** commented that we can not put a complete prohibition on a substance as easily as in the PPP area. **AT** said that it is a political decision to accept a certain risk level, and highlighted the need to develop common risk communication approaches, e.g. with regard to the calculation of the exposed population. These issues will need to be discussed at the CA level and in the product authorisation and mutual recognition facilitation group. **IE** agreed with the **AT** conclusion on discussing at the CA level. **DE** asked to check the definitions at the end of the document to ensure that they are the same in all similar documents.

**COM** concluded that the TNSG will be revised based on this discussion and will then be handled at the next CA meeting.

<b>TOXICOLOGY SESSION</b>
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**1. SUBSTANCES in PT 8.**

**1a. Copper (II) carbonate, copper (II) hydroxide and copper (II) oxide (RMS: FR)**

**1b. Copper (II) oxide (RMS: FR)**

**1c. Copper (II) carbonate (RMS: FR)**

**1d. Copper (II) carbonate (RMS: FR)**

**1e. Copper (II) hydroxide (RMS: FR)**

**1f. Alkyldimethylbenzylammonium Chloride (ADBAC), (RMS: IT)**

**1g. Didecyldimethylammonium Chloride (DDAC), (RMS: IT)**

**2. SUBSTANCES in PT18**

**2a. Aluminium phosphide (RMS: DE)**

**2b. Trimagnesium phosphide (RMS: DE)**

**3. AOB**

**3a. Transient mouthing terminology**

**COM** introduced the suggestion to change the wording of “transient mouthing of poison bait” to “mouthing of poison bait – an exceptional scenario”. The proposal was endorsed without changes.

**3b. Harmonised approach for exposure assessment of PT13 products (metal-working fluids)**

**FR** introduced the HEEG opinion of exposure assessment for professional users of metal-working fluids. It was especially pointed out that wearing of gloves should not be assumed when handling objects near turning machines, and that BEAT indicative value for hand exposure is not reliable and new values are suggested. **DK** thanked the HEEG for providing the values, and asked how values like this will be implemented when they are not part of a guidance document. **DE** suggested including in the Manual of Technical Decisions all references to the endorsed HEEG opinions, to which **COM** agreed. **AT** informed that there will soon be measured data on human exposure to metalworking fluids from the American Chemistry Council. The proposal was endorsed without changes.

**3c. Questionnaire to build a database on default values for assessment of professional human exposure in disinfectant dossiers**

**COM** asked MSs to send in the filled questionnaires if there is any data available, as otherwise the information could not be shared between the RMSs working on the disinfectant CARs.

<b>Food risk assessment</b>
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As a follow-up to TMII\_08, the objectives of the session on Food Risk Assessment (Food RA) and MRLs were: 1) to exchange views between participants on the issues at stake and 2) to discuss the proposed approach, focusing on the criteria to trigger a food risk assessment and possibly set MRLs. The current proposal is described in a document entitled "Step-wise approach on data requirements for the estimation of residues in food of animal origin and the need to perform food risk assessment", of which a second version was made available on CIRCA (TMII08GEN-item6-Residues in Food Framework.doc) prior to the TMIII\_08.

A first presentation was given by Mr Juergen Gutknecht, on behalf of **IND**, speaking in the name of CEFIC, of the EBPF (European Biocidal Products Forum) and of his own former company, Bactria. Among other points, it was emphasised that Food RA and MRL setting were two different processes, and that a common tiered approach across all MS was necessary. The need for setting priorities according to the risk of consumer exposure to biocides residues was emphasised. Also it was considered that in the long term, both food of animal origin and food of plant origin should be considered. It was proposed as a first step to examine the various PTs with a priority ranking for Food RA. PTs 3, 4, 5, 20, were proposed as high priority, and PTs 2, 8, 18, 19, 21 as medium priority. PTs 1 and 11 were considered low priority, and PTs 6, 7, 9, 10, 2, 14 to 17, 22 and 23 as not relevant either due to the improbability of exposure, or to the existence of legislation other than the BPD e.g., Regulation (EC) 1935/2004 on food contact materials. The problems posed by divergences of status (e.g. biocide vs veterinary medicinal product or food additive) of some substances / products was pointed out. The question of cumulative risk assessment, i.e. exposure to the same substance via different product types, was also raised, and the need for both acceptable models and a clear legal basis was indicated. Finally, it was stated that for various reasons, the Veterinary Medicines legislation was probably not an appropriate basis for MRL setting in the biocides area.

A presentation was then made by **FR** (Ms Nathalie Arnich, from the French Food Safety Agency, AFSSA). The most important biocide PTs AFSSA is concerned with are PTs 3, 4, 5, and 18. **FR** would agree with a first approach dealing with food of animal origin. The current version of the framework document was then reviewed, together with the comments made by **FR** and their justification. The need for developing models of exposure of the animals was recognised. A number of possible reference sources for the development of exposure scenarios were indicated, e.g. documents ENV/JM/MONO(2006)4 from OECD on the use of insecticides in stables, document 7031/VI/95 rev.4 of 22/07/1996 of EEC on livestock feeding studies, and EMEA document EMEA/CVMP/ERA/418282/2005-corr on the environmental impact assessment for veterinary medicinal products. The need to make choices between default values from different regulatory frameworks was mentioned. For instance, the default body weights of food producing animals are different between the veterinary medicines and the PPP frameworks. The use of a trigger value for step 2, i.e. refined food RA, was advocated, and it was proposed to use the value of 0.1 mg/kg diet from the PPP regulatory framework, with the necessary technical adaptations. The process of MRL setting was described. The requirements in terms of metabolism and distribution studies were mentioned, together with the problems posed by

extrapolation between species. Examples were given, which illustrated the need for some flexibility in the approach, given the diversity of the situations.

Both **IND** and **FR** presentations were then opened for discussion. **COM**: stated that the problem was to strike the right balance between information requirements and feasibility. **DE** asked for the presentations to be made available on CIRCA, which was agreed; then followed a rather technical discussion involving **FR**, **NL**, **EMEA**, **IND**, **COM** and **DE** on the requirements in terms of metabolism and distribution studies for MRL setting, as well as of using in vitro / ex vivo metabolism studies. The differences between the requirements for veterinary medicines and those for pesticides, apparently less comprehensive, were emphasised. The distinction between major and minor species and the possibilities of extrapolating between species were discussed, including the requirements for lactating cows and egg-laying poultry. Note post meeting by **COM**: Document EMEA/CVMP/477/03/FINAL defines the major and minor species in the context of MRL setting.

**AT** agreed upon the idea of prioritisation of food RA on a PT basis, while indicating that this should not be absolute, since some particular uses may lead to unacceptable residues in non-priority PTs. **AT** also pointed out that food for personal consumption should also be considered for risk assessment, although not for MRL setting which concerns only food destined to be placed on the market. Mixed situations could also be envisaged. **AT** raised the question as to whether trigger values for MRL setting should be fixed or flexible, adapted to the ADI of the substance considered. **COM** expressed concern at the complexity of this approach, which corresponds to a higher tier than the choice of trigger values for food RA. **AT** mentioned the possibility of using marker residues as a simplifying tool, as well as the need to consider the exposure of fish to anti-fouling substances. **COM** agreed that the efforts in the biocides area should not be focused on how to set MRLs, this being better done by other bodies, but on how to initiate the process, based on a) exposure calculations and b) PT priority setting. **COM** followed-up by separating a) on the one hand the two different methodological frameworks of EMEA and EFSA for MRL setting, and b) on the other hand that of food RA of biocides, which had to be developed by the group. **COM** invited MS to form voluntary working groups on the different issues to be resolved. **COM** concluded the first part of the session on food RA by insisting that efforts should be focused on exposure estimations rather than methodology for MRL setting. **IND** mentioned that PT 20, because it was intentionally added to the food, would be profitably considered as a starting example. **AT** mentioned the necessity to define precisely the tasks, the actors and the budgets needed for the overall task of food RA, and then to work out a theoretical example, taking into account all comments made. **COM** concluded emphasising the complexity of food RA, and the need for pragmatic tools to control its feasibility. The second part of the session was dedicated to further developing the framework document for Food RA, in the light of the preceding discussions and comments. **COM** informed that **NL** would start in 2009 a very relevant project on consumer risk assessment for biocides, dealing with exposure models as well as methods for MRL setting. The current version of the framework document was briefly summarised, and the main sources of comments acknowledged with thanks (**NO**, **NL**, **FR**, joint paper by **AT** and **DE**). The current document is focusing on food of animal origin. After a step 1 of exposure estimation, it should be determined, on the basis of a trigger or threshold value to be defined, whether to proceed to step 2, consisting of refined modelling of exposure estimation

using appropriate data, e.g. estimation of the fate of the a.s. in the environment of the animals, possibly metabolism and distribution data, which may be requested at that stage. At the end of this second step, the food RA can be carried out and it should be decided whether an MRL is necessary. The process of MRL setting would then be initiated in co-operation with the appropriate body, which might be for example EMEA for food of animal origin, whereas for food of plant origin EFSA would be logical. The issue of organising this co-operation is still under discussion. **COM** then invited discussion of the framework approach. **COM** expressed the wish to keep the discussion focused on steps 1 and 2, and not to include in the framework document an approach by PT or the issue of cumulative food RA. **COM** insisted on the objective to present as soon as possible a framework document to the CA meeting, whilst acknowledging that obviously the largest part of the work remained to be done.

The discussion on the framework approach document was then initiated, **NL** stating that the use of the veterinary medicines framework is too stringent. For investigation of metabolism, studies in target species are required and the study design requires 4 animals per time point for large animals, and 6 per time point in poultry. The OECD guideline for pesticides and biocides only needs one ruminant and 10 chickens. **EMEA** commented that if the EMEA was finally involved in MRL setting, the methodology specific to biocides would have to be refined and the current CVMP guidelines would probably not be followed by the letter. **COM** agreed that the wording on this subject in the framework document should be flexible, and while mentioning the existing guidelines, should leave room for the development of biocide-specific methods. **NL** asked whether it was now planned that EMEA would be the MRL-setting body for biocides. **COM** replied that the discussion with EMEA was not yet finalised. **COM** also stated that in order to minimise the burden on the MRL-setting body, the biocides group should focus on the decision process as to whether or not MRL setting was necessary for a given substance / PT combination, using a food RA approach. **DE** mentioned that in their comments and proposal for the framework document, a number of references to relevant existing guidelines were included, from various regulatory areas, and emphasised the need for clear guidelines which do not yet exist for biocides, so that the applicants can know the requirements, in particular in terms of metabolism and residue studies, analytical methods, etc.. Such guidelines should be kept at least as references until biocide-specific documents, if any, are made available. **COM** agreed that this was precious information. **AT** stated that the issue of MRL setting has been known for 10 years (Article 10 of BPD), and urged COM to progress further without much delay, while taking into account that the process needs some resources (people, financial resources) and procedures to be effective. **AT** also insisted that the process of MRL setting should be consistent with the existing rules for substances already regulated as PPPs or medicinal substances, and that EMEA and EFSA should both be involved as necessary, to deal with issues related to food of plant as well as of animal origin. **AT** added that the final paragraphs of the framework document should be deleted, as going into the details of MRL setting exemptions. **COM** agreed that this part should be revised, the intention being to emphasise that there are PTs or groups of uses for which an MRL or even a food RA is not needed, and this can be decided a priori. **COM** also agreed that the emphasis should not be on the details of MRL setting, but on the work to be done in steps 1 and 2, for which a number of scenarios could already be described, with the need to decide on default values, such as body weight of animals, etc.. **COM** invited the formation of working groups between MS to address Steps 1 and 2, i.e. exposure for quantitative food RA,

for the most urgent PTs, in particular PTs 3 to 5, 18 and 19, since both applicants and RMS working on the dossiers have an urgent need for clear guidance. Meanwhile, the MRL setting process itself will be further progressed by COM in co-operation with the relevant bodies. **IND** emphasised that in contrast with the PPPs or medicines, for biocidal products the actors were often at a double level, e.g. for PTs 3 and 4 a first company synthesising the ingredients and a second one formulating the product and bringing it to the market. These are often small companies and the burden in terms of data requirements should take into account the capacity of the industrial actors to generate such data. This, added to the issue of data protection ("free-rider" issue), could generate serious problems if the requests for data were made at the late, product application stage. **IND** asked for consideration of this issue at CA meeting level.

**COM** then invited a discussion limited to steps 1 and 2 of the framework document, in the light of the above comments. **SE** raised the issue of trigger values, and a discussion followed, also involving **IND**, on the differences between various regulatory frameworks. It was clear (**IND**, **COM**) that a trigger value was needed at the E.U. level to decide to go from Step 1, i.e. the worst case theoretical scenario, to step 2 where a refined exposure evaluation is performed, using additional data. **AT** supported the need for a trigger value, adding the notion that the value may need to be flexible. **NL** expressed the view that at Step 1, for animals, it should be tried to match the value of 0.1 mg/kg of dry matter feed in the livestock diet, as is used for pesticides. The 0.01 mg/kg value is a trigger value for MRL setting in the human diet. **FR** stated that the decision to go from step 2 or 3 was based on human consumption and linked to a TDI, not to a trigger value in the human diet. **NL** disagreed, stating that a trigger value is needed for the trading of food, as well as a TDI for risk assessment purposes.

**EFSA** intervened to emphasise the need to go back to the definition of MRLs, ADIs, and what they were needed for. For PPPs, the trigger value is expressed as mg/kg of dry feed because the pesticides are applied on the plants that ultimately compose the feed. Refinements in the use of this trigger value are under discussion at the moment, but the value of 0.1 mg / kg dry feed matter can be taken as starting point. This is used in the pesticides area to trigger plant metabolism studies. The nature of the residue of concern, e.g. parent or metabolite, is also taken into account. Using feeding tables, the residues in human food of animal origin are estimated. The default value of 0.01 mg/kg in animal diet is then taken as a trigger to request animal metabolism studies. A quantitative food risk assessment is then performed based on the results of these data. In the case of biocides, for which different routes of exposure of the animals are possible, a trigger value expressed in mg per kg of body weight of the animals should be more appropriate. **COM** and **NL** supported strongly the idea of an estimated exposure to the animals, relative to body weight, as a trigger value. **FR** argued that the amount absorbed was unknown, which made things difficult, and **COM** replied that because step 1 is a worst-case exposure estimation, 100 % absorption (i.e., thinking in terms of external dose) can be postulated unless information to the contrary is available. **FR** raised the issue of the choice of default values for the body weights of animals. **AT** added that the translation from the feed trigger value into an exposure relative to body weight also depends on the feed intake of the animals, and that this may or may not be linearly related to the body weight. If this was not the case, then we would not be in a position to decide on a single value for all animals. **COM**, **NL**, and **EFSA** were of the view that default values for feed intake were available, and



therefore the calculation was possible for the various animal types. Whether or not a single value was absolutely needed and could be chosen for all animals would be discussed later. **FR** agreed on the principle of estimating exposure by all relevant routes, and added that this would impose the choice or development of appropriate exposure estimation methods, for instance for the inhalation or dermal routes. **COM** agreed, mentioned also the possibility of scaling approaches for inhalation exposure, and acknowledged the urgent need for work in this direction. **PT** asked whether the reasoning should be based on ADIs or on ARfDs, and **COM** replied that for the decision to go from step 1 to step 2 this distinction was not necessary, which was agreed upon. **IND** expressed concerns about the difficulty to cover all possible PTs and situations with the proposed approach. **NL** also supported this view, saying that the current framework document approach could not be applied to a number of situations, e.g. food of plant origin. **COM** replied that the intention of the present discussion, and of the document under elaboration, should not be to cover all situations and PTs, but to focus on a few clear situations for defined PTs (e.g. PTs 3 and 18, limited to food of animal origin), in order to start building the methodology. This strategy could be defended on the ground that previous attempts to cover all situations at once had been only very partially successful. **FR** also supported a gradual approach starting with food-producing animals, as the situation of greatest immediate concern, with later developments for other situations. A short discussion on the priorities (**EMEA**, **COM**, **FR**) seemed to indicate that first priority PTs were PT 3 (veterinary hygiene), PT 4 (surface disinfectants), PT 5 (drinking water disinfectants) and PT 18 (insecticides). **AT** mentioned that the necessary exposure models were not available. **NL** agreed, added that RIVM was initiating in 2009 a project to develop such methodology for a range of biocides, and called for MS having relevant data to communicate them to RIVM in order to support the process. **COM** acknowledged the timeliness and usefulness of the RIVM project. **IND** mentioned the possibility of contacting manufacturers groups that may have relevant data. **FR** insisted that there should also be, in parallel to the RIVM project, a process of decision on default values which should take place at E.U. level. **NL** agreed with this statement. **FR** mentioned that exposure models of the Consexpo type, also developed by RIVM, incorporated many default values, and this could be a problem since these default choices were not obvious in the process. **COM** agreed with the concern that underlying defaults and assumptions should be kept in mind, and expressed the view that this could be dealt with essentially by an accurate model documentation, and that Consexpo, was (via the "fact sheets") transparent in that respect. Therefore there was the possibility to adapt the models to specific situations. **AT** stated that food of plant origin should not be left aside indefinitely, also this was relevant for some substances currently under evaluation, such as phosphides. **AT** also supported the view of **IND** that food RA should take place at the Annex I inclusion stage, and should not be left for the product authorisation stage.

**It was concluded that the following steps would be taken:**

- 1) Simple trigger values for moving from step 1 (worst case exposure estimation) to step 2 will be established, expressed in mg/kg of body weight of food-producing animal, based on a translation (as far as possible) of the 0.1 mg/kg dry matter of feed used for PPPs (action: COM with MS input).**
- 2) The framework approach document will be redrafted taking into account the discussions, and re-opened for comments. It will be clearly stated that: a) the focus is on food-producing animals, later work being required for food of plant**

**origin; b) MRL setting is the last step in the process, and if required, will be done by the appropriate body; c) PTs 2 to 5 (disinfectants), 18 and 19 (insects / arthropods control), and 20 (food / feed preservatives) will be considered in a first priority group, the detailed priorities having to be defined (action: COM with MS input).**

**3) As soon as practicable working groups should be formed to start building methodologies appropriate to the above defined objectives.**

<b>GENERAL SESSION</b>
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**JRC** welcomed the participants and opened the general session. **JRC** informed about the order of the discussions at this session and added to AOB the reports from 2 OECD meetings one on the Biocides Taskforce and one on the IUCLID 5 User Group Expert Panel. As there were no further comments or additional topics, the Agenda for the General Session had been adopted.

### **1. Update from 29<sup>th</sup> CA meeting**

**COM** reported on the last CA meeting that took place on 19-20 September in Brussels. The minutes from that meeting will be available as soon as possible. At the CA meeting, prior to the Standing Committee final discussions took place on several substances (sulfuryl fluoride, fenpropimorph, chlorophacinone and four borates). **COM** informed the meeting that there has been no vote in the Standing Committee on the Inclusion Directives presented. It was explained that the Council had blocked them because of the obligation included in Article 2 of these Directives that Member States should send to **COM** correlation tables. The Council considered this provision to go beyond the powers conferred to the Commission in the basic legal act. **COM** explained that solutions were being discussed but stressed the importance not to slow down the work in the mean time. However, the draft non inclusion decision and the draft decision setting a new deadline for submission of dossiers have been accepted unanimously by the SCB. First discussions took place on brodifacoum and nitrogen. In conjunction with the brodifacoum dossier extensive discussions were held on the issue of multiple dossiers. **COM** noted that currently legal advice is sought and that unless negative impact would be found, the CA meeting can proceed taking a decision based on the first dossier. The CA was proposed to include nitrogen into Annex I and IA, but after the discussion only the inclusion into Annex I was recommended as the product cannot be considered as a low risk biocidal product. **IND** agreed with this approach. At the CA there was also a discussion about non inclusion of diazinon. The application submitted in the framework of the review programme to support the inclusion of diazinon in Annex I for PT18 was rejected by the Portuguese CA, since the reference product in the application was a flea collar, which in PT is considered to be a veterinary medicinal product. It was concluded that it would be useful to develop a more detailed approach and additional criteria to allow greater consistency of decisions. Likewise, this applies also to teat dips and ear tags. To that end, **COM** undertook to discuss the matter further internally – in particular with the responsible service for veterinary medicinal products in DG ENTR. The proposal for "TNsG on Product Evaluation: revision of chapter 6.2 Resistance" was endorsed and will be launched for 6 month stakeholders consultation. **COM** presented the outcome of the stakeholders' consultation on creosote. The consultation was closed at the end of June and **COM** is currently revising the outcome and updating the report in view of the comments made during the CA meeting. In total 50 contributions had been received and most of them came from **IND**. The majority of the contributions were in favour of inclusion of creosote into Annex I and reported that the removal of creosote being used as PT8 from the EU market will have a significant economical impact. A document was presented on the use of market share factors during risk assessment like already provided for in several ESDs like PT18 and 21: how the use of market share

should be followed up or even enforced by the Member States. It was concluded to come back at the next meeting on this issue and await the discussions in the Technical Meeting.

**DK** referred to the borderline issues between the BPD and VMP Directives with respect to the discussion on diazinon. **DK** welcomed DG ENV's initiative to discuss this issue with DG ENTR and suggested not taking any decision on any substance in this area until this borderline issue is clarified. In addition **DK** reiterated COM's request to the MS to liaise with the national veterinary services to obtain further guidance on this matter.

## 2. Biocides-REACH Interlinkage

Two items had been communicated under this Agenda point: PBT issues and C&L.

Starting with PBT identification, **COM** informed that there is a slight delay in the whole process. ECHA informed COM that as formally PBT identification coming both from the biocides or the pesticides area is not under the remit of ECHA, ECHA needs a formal request for that task from the COM. This has to be done first and then a similar procedure as for C&L will be developed. The relevant documents on PBT and POPs identification in the context of the BPD framework will be revised.

Regarding C&L issues, ECHA is getting in place the procedures on harmonised C&L at the moment. **COM** has prepared a document that will be developed and updated further until it can be regarded as SOP. Adoption of the new Regulation on C&L will move the harmonised C&L from REACH to that new regulatory framework but still ECHA will deal with C&L proposals coming from biocides area. **IND** requested if the Applicant can be present at the Risk Assessment Committee (RAC) meetings in ECHA when the harmonised C&L proposal for their substances will be discussed. ECHA confirmed that they will be invited as so called case holders. In addition it was asked, whether the Annex XV dossier for the proposal of harmonised C&L (and also PBT identification) has to be prepared always in IUCLID5. The answer from ECHA was that in case of substances already discussed within the old framework there they will accept Annex XV dossier made completely in a format of a Word document. In case of new dossiers submitted to ECHA, all study summaries and robust studies summaries that are relevant for the C&L proposal will have to be in IUCLID5. **COM** asked to direct the MSs' opinions on this issue directly to ECHA via their RAC representatives. **DK** commented that it will be a big problem for the MSs to prepare and submit Annex XV dossier for harmonised C&L in IUCLID5. **DK** emphasised that it is in contrast to what was agreed before which was to accept dossiers from the applicants in a Word format. This means a lot of work as about 90% of all biocides dossiers are in Word format. **DK** stressed that MSs have no resources and asked who will transfer the information from Word to IUCLID5 format? **FIN** supported **DK** comment. In addition **FIN** asked if the harmonised C&L should be performed for all endpoints or only for CMRs? **COM** answered that the request of C&L for all endpoints was coming from our framework as we needed it for all endpoints. **AT** proposed that instead of asking all MS to make an intervention to ECHA separately maybe this issue could be included in the Agenda for the next CA meeting. The agreement on this issue could be reached there and a common opinion can be addressed to ECHA. **FR** supported the previous comments. It will be too much work

to develop IUCLID5 Annex XV dossier for all of the substances. All FR substances needed an Annex XV dossier on C&L. FR noted that at TM no discussion takes place on C&L, and that the time needed for preparation of a IUCLID5 would delay too much the C&L discussions of biocidal substances. Moreover FR underlined that the content of Doc III was the same as the one in IUCLID5 so it should be accepted as such. **DK** was not convinced that IUCLID5 would be massively used for the future lists. DK agreed that at the end all information would have to be in IUCLID5 but it would be a huge effort to prepare IUCLID files on the basis of Word documents. **UK**: supported all previous comments from MSs and fully agreed with **AT** initiative to discuss this issue at the next CA meeting. **IND** made an intervention about data ownership and data protection of the submitted data. **COM** stated this is indeed an issue, although there is no difference in principle between the situation under REACH and under the old legislation, where biocides were discussed in a closed session in TC C&L. **BE** remarked to make a distinction between confidentiality and data ownership as this were not the same issues. **NO** raised a question on the anticoagulants (handover substances) mentioned in the C&L documents under the section on the transitional period. Will there be a coordinated assessment of these substances also in ECHA? It is stated that the RMS must still formally submit a proposal for C&L as an Annex XV dossier to ECHA. Is there any common deadline for when these dossiers should be submitted, and will they be evaluated in a coordinated manner? **COM** stated that it would be very difficult to coordinate this process as it depends on the submission of the dossier by all RMS. **COM** will ensure that the issue of the required IUCLID5 format by ECHA is discussed at the next CA meeting.

### **3. Tracking System. Progress reports**

**DE** asked to clarify in the progress report on existing substances the remark: "COM decision to be adopted by 1<sup>st</sup> October 2008" Which COM decision it is referring to? What has to be adopted and why by this date? **COM** will check this remark.

### **4. SUBSTANCES in PT 8:**

**4a. Copper (II) oxide (RMS:FR)**

**4b. Copper (II) carbonate (RMS: FR)**

**4c. Copper (II) carbonate (RMS: FR)**

**4d. Copper (II) hydroxide (RMS: FR)**

**4e. Didecyldimethylammonium Chloride (DDAC) (RMS: IT)**

**4f. Didecyldimethylammonium Chloride (DDAC) (RMS: IT)**

**4g. Tolyfluanid (RMS: FIN)**

## **5. SUBSTANCES in PT18**

### **5a. Aluminium phosphide (RMS: DE)**

### **5b. Trimagnesium phosphide (RMS: DE)**

## **6. Application Codes PT 18/19/20**

**DE** made the introduction of the new version of the "application codes" document. The document was prepared on the basis of the comments received from **SE** and **UK**. The relevant changes had been made and a response to comments document was prepared. **DE** has asked **SE** and **UK** whether they are satisfied with the way **DE** dealt with their comments. Both **UK** and **SE** confirmed. As this document will be published on the JRC-IHCP website as a stand alone document, **COM** proposed to make a cover page including the aim of the application codes. **DE** stated some comments from **NL** had been also received. All received comments were forwarded to the relevant experts. In the first issue **NL** proposed to extend the list of pests. The answer from **DE** was that although **DE** were willing to amend the application code, the primary intention was to facilitate the process so that they wanted to include in the list some broader categories of the organisms represented by the families more then to include all potential target organisms there. In the second issue **NL** proposed to split the kill effect into two groups: into kill of individual organisms and kill of total colonies/populations. **DE** experts answered that indeed it can be useful to split the kill properties into the kill of individuals only and those that have broader effect such as killing the whole colonies. However the category 3.2 that is now in the application code refers to those effects that have only impact on the individual organisms in order to kill or to knockout them etc. And as such it refers the mode of action of the substance as a necessary item in the application document. **DE** question to the **TM** was whether the nest or colony killing should also be added to the document, and if so where it should be added in this section or in a separate one. **NL** asked to clarify the terms used in the text and they stated that as far as it is explained well it is up to **DE** to organise it in the document. **NL** asked whether the term "exterminate" would not be better and broader then the term "kill". **UK** and **IE** will check terminology. The revised document will be prepared by **DE**. **COM** stated that it could be good to have the application codes in a new version of IUCLID5.

## **7. AOB**

### **7a. OECD Meeting of the IUCLID User Group Expert Panel**

**COM** informed that the OECD Meeting of the IUCLID User Group Expert Panel took place on 23-24 September 2008 in Paris. The IUCLID 5 software was released in June 2007. The new IUCLID is the preferred tool for gathering and submitting data on properties of substances in a number of regulatory settings and voluntary programmes, including the OECD HPV Chemicals Programme. There are also the possibilities and recommendations to use IUCLID 5 tool for the data collection for the

purposes of Product Authorisation Phase within the Biocidal Products Directive (BPD) 98/8/EC. Regarding the use of IUCLID 5 within our frame, at the Paris meeting the question was posed whether the Technical Meeting for biocides would find it useful to have more specific guidance for the use of IUCLID 5 for that purpose of Biocidal framework especially for the Product Authorisation phase. Moreover TM was asked to agree to comment in the future on the content of new fields or templates possibly developed for the purpose of any biocidal activities. As the TM unanimously agreed on both issues, it will be addressed to the OECD IUCLID User Group Expert Panel.

#### **7b. SETAC Conference**

JRC informed that next year at the SETAC Conference there will be most probably a Session on Biocides. The SETAC Conference next year will take place in Göteborg on 31 May – 4 June. The abstract submission is open now and on the number of received abstracts the organizers will decide if there will be a special session devoted only to biocides.

#### **7c. Efficacy question from IT**

There was a question on efficacy from IT but as their expert could not attend the meeting other MS were asked to send their comments in writing within 3 weeks.

#### **7d. Efficacy workshop related to PT18**

The workshop took place in July in USA. The group of experts discussed the new guidance on efficacy evaluation for insecticides. If the report is finalised by December NL will present it at the next TM. A similar discussion on disinfectants took place also at the workshop. IND would be interested in having a similar guidance document. If anyone would like to be involved in this work, NL asked to inform them by email.

#### **7e. OECD Taskforce on Biocides**

AT reported on the last OECD Taskforce on Biocides meeting. The meeting was held in Dublin. Among others at the meeting, the guidance on leaching from treated wood was finalised. The final draft document will be published soon. Results from the development of efficacy test methods for disinfectants were presented. Work on the development of a guidance document on leaching of antifoulings is ongoing. In addition, it was mentioned that a vision document for the taskforce is under preparation. The OECD Taskforce will develop a new Emission Scenario Document on PT18 used for vector control. FR who took the leadership of the project invited MS interested by the project to join the steering group by contacting the OECD before November 15<sup>th</sup> or to send to FR any information relevant to this subject.

<b>ENVIRONMENT SESSION</b>
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**1. SUBSTANCES in PT 8****1a. Copper (II) carbonate, copper (II) hydroxide and copper (II) oxide (RMS: FR****1b. Groundwater assessment**

**COM** introduced the document stating that comments made at TM I 08 were taken into account and a summary was added at the end. **DK** stated that in the summary it should be clearly indicated that the adjustment of the DT50 to a temperature of 20 °C is because the FOCUS models PEARL and PELMO contain a correction for temperature and require that the DT50 value used as input value is adjusted to this temperature. In the evaluation as reported in the CAR the DT50 is adjusted to 12 °C. (as also reported in the LOEP for example). **NL** indicated that written comments will be send directly to **COM**. **NL** strongly recommended not to deviate from the already agreed guidance in the FOCUS groups. **DE** requested to include a comment in the summary indicating that the calculation of these mean values cannot be a routine calculation. In addition, **DE** requested to add to the summary the remarks at the bottom of page 5 on the application of first order kinetics for the DT50 and normalisation for organic carbon. **COM** invited **DE** to send text proposals on these additions. **UK, ES, SE** and **SI** stated that the application of these models, which are designed for the pesticides framework, within the biocides area require further work which shall be addressed in the document. **FR** stated it is too early to start preparing specific applications of these models for the biocides area as first more experience is needed. Following a question by **BE, ES, UK** and **DE** recommended to apply both models, use the outcome of PEARL being more conservative and compare these results with the PELMO outcome as supportive information.

**Conclusion:**

- **NL and DE will send written comments to COM;**
- **COM will finalise the document incorporating the comments from DK, DE and NL;**
- **There is a need for further work on the application of PEARL and PELMO within the biocides area.**

**1c. Harmonisation of application of FOCUS groundwater models PEARL and PELMO**

**DE** introduced the document, stating it is meant to be thought starter and recommended a written commenting round after which the document shall be developed further. **DE** noted that the thought starter mentions mainly the entry pathway manure application, but other pathways may be relevant (for example disinfectants ending up in sewage sludge which is applied on agricultural land). **DE** asked the other Member States to think about such other pathways. **DK** noted that, in contrast to the document where 5 cm is listed, in the TGD the soil depth for grassland is 10 cm. **DE** stated the 5 cm depth stems from the ESD. Following a question by **FR** on if all scenarios will have to lead to an acceptable risk for Annex I inclusion, **COM** noted that for PT 08 house scenario it was decided that this was not required.



**Conclusion:**

**Member States are invited to send written comments to DE before November 14.**

**2. SUBSTANCES in PT18**

**2a. Aluminium phosphide (RMS: DE)**

**2b. Trimagnesium phosphide (RMS: DE)**

**3. UK Thought Starter: Leaching Rate PT07, 09, 10**

**UK** introduced the document. Subsequently, the proposals for each PT were discussed:

- *PT 07*: it was agreed that, depending on the use, either the tonnage approach or an approach in which leaching rates to soil are calculated similar to PT 08 in a local assessment. **DE** stated the applicant has to justify the use of default emission factors, where information from efficacy tests, in-house tests etc. can likely be used. **NL** clarified that in EUSES only a local assessment is included where the regional tonnage is scaled to the local level applying for example the factor "fraction of main source". **FR** questioned the application of the tonnage approach as there are no legal instruments to obtain adequate information.
- *PT 09*: it was agreed that in general the tonnage approach will be used. There may be specific uses where a leaching rate has to be used, where **FIN** mentioned impregnation of tents;
- *PT 10*: it was agreed to use a calculated leaching rate. The time period will depend on the use pattern and the claim (for example there are applications where the product is washed off in two days). The time period used in the evaluation will have to be justified. If relevant, a difference can be made between rural and urban applications. The default number of emission days for one year will be 365 days.

**Conclusion:**

**UK, DE, DK and NL will prepare the final version of the document.**

**4. Draft Workshop Report PT 1-6**

**COM** introduced the draft workshop report. With respect to the document containing an overview of the comments on the draft PT1-6 workshop report, **COM** stated that on page 1 under Comment 3 200 m<sup>3</sup> per day at the comment by **IND**, shall be replaced by 200 liter per day. Following the discussion at the CA meeting on cumulative assessment it was decided to prepare an addendum to the workshop report highlighting the conclusions from the CA meeting on this topic. **DK** stated that the conclusion of the workshop is not adequately reflected as, in line with comments from **NO**, according to **DK** it was concluded that both the tonnage and the consumption based approaches should be performed for relevant PTs. In addition, **DK** asked the **COM** to answer their letter, in which **COM** is asked to clarify the difference between the performing cumulative risk assessment on a non-routine basis (CA meeting

conclusions as laid down in minutes 29<sup>th</sup> CA) and Article 10(1) of the BPD where it is stated that for Annex I inclusion "taking into account, where relevant, cumulation effects from the use of biocidal products containing the same active substances". **NO** stated their question at the bottom of page 8 can be removed, as the question was related to the first draft version of the report.

## 5. ESD PT13

Several questions had been received regarding the ESD for PT13:

- *Emission volume of metalworking fluids*: **DK** had identified a problem with respect to the emission volumes of metalworking fluids and posed the question whether the value used by the applicant can deviate from the default value given in the ESD. **COM** stated that it would have to be well justified. **COM** informed that the OECD is currently working on an ESD for metalworking fluids, lead by the US-EPA, of which a draft has recently been released for comments by the Task Force on Exposure Assessment. **DK** agreed and reminded that **FR** indicated in their comments that they have received 3 dossiers with 3 different values. **COM** noted the values given by **FR**, originate from the draft OECD ESD, being 3100 and 8700 L/day (total daily amounts of diluted metal working fluids assuming a maximum dilution of 2% for grinding process for both water-soluble and emulsifiable metal working fluids) for the geometric mean 90<sup>th</sup> percentile, respectively. **COM** stated that as the OECD ESD is under consultation, **COM** could circulate to the TM the relevant part of the ESD for comments. **DK** agreed and asked which value should than be used as default? **COM** proposed to use the geometric mean. **DE** stated that US EPA has derived this value based on data from small metal shops only and asked the question whether this value shall be adapted for large metal shops. **DE** suggested to look into the BREF document for the chemical sector from IPPC as there could be relevant information on metal working industry. **DK** supported **DE** but asked which value to use for Annex I inclusion: small or large metal shops? **FR** supported **DK** but could foresee complications with respect to enforcement if two different values are used. Therefore, **FR** preferred to use only one value. **COM** proposed to use the geometric mean value and will distribute this proposal to the TM.
- *Erratum ESD*: There was also a paper from **PL** highlighting some general comments on ESD for PT13 and a comment on the erratum available from the JRC-IHCP web-site. It appeared that there was an error where not the log Kow should be used but Kow value. In the EUSES 2.1 the correct formula is used. **FR** also noted that in the erratum only the first equation was corrected. However, all related equations need to be modified. This was incorrectly done in the erratum, in particular for the simplification of the terms of the equation. **COM** proposed to prepare an erratum to the erratum and indicate it there. This new version of the document will be published on the JRC-IHCP website.
- *Clarification on  $F_{conc/water}$  (comment from FR)*: in order to have a better comprehension of the equations presented in Table 7 to 9 of the ESD, it would be important to precise that  $F_{conc/water}$  represents a fraction added to an initial volume and not the fraction resulting of a dilution. **COM** will check this and add the clarification to the erratum.

- *Fraction of the metal working fluid neat solution in the final product used (comment from FR):* **FR** stated that although the applicant might be a biocide producer but not a metal working fluid manufacturer nor a user of these metal working fluid products; he has to provide a fraction of the metal working fluids neat solution in the final product used in the industry. **FR** asked whether the applicant would be able to have a clear view on how the metal working fluid containing his biocide is used? If not, the French proposal would be to use a worst-case value for  $F_{\text{conc/water}}$  (0.2) in order to cover all the metal working processes. The meeting agreed on the approach proposed by **FR**.

## 6. Penetration rate or application factor used in ESDs

The issue on penetration rate in relation to enforcement had already been discussed at the last CA meeting. The technicality of the use of the penetration rate had been referred back to the TM. On request of the COM, NL had prepared a discussion paper on the penetration factor (market share). For disinfectants the emission rate to water used for risk assessment enholds a market share of disinfectant ( $F_{\text{penetr}}$ ). By default this factor was set at 0.5. However, as part of the risk assessment for Annex I inclusion, NL proposed that the  $F_{\text{penetr}}$  should be set at 1. **COM** indicated that a similar discussion took place for antifoulings where it was decided to use a value of 90%. Moreover **COM** stated that when justified, the applicant could always deviate from the default. **FR** was not very comfortable to use different default values. **FR** would ask **IND** for statistical data on their market share. **UK** agreed that the only way on getting an acceptable value would be to perform a statistical survey. **DK** would accept as a first tier to use a value of 1 unless it can be documented otherwise by statistical data. Moreover **DK** stated that it would be important to differentiate between product authorisation and Annex I inclusion. For the Annex I inclusion statistical data for the whole EU market are needed, while for product authorisation stage a different value can be used based on statistics for a specific country. **DE** highlighted the fact that one must clearly differentiate between penetration factors used in ESDs for different product types, i.e. the use of a substance, and the equation in the ESD reflecting this use which will determine the level of the penetration factor. **IND** stated that any applicant would happy to have in practice a penetration rate of 1. However, due to competition in the market a value of one is not realistic for almost all active substances. In addition, statistical data will be very hard to obtain as these data are confidential. **COM** confirmed that this was also one of the reasons for the factors applied in the ESD, as it was considered not realistic that a certain active substance would have a 100% market share for a certain use (for example boosters used in antifouling paints). **IND** stated that as both agenda item 6 and 7 are very important for **IND**, they suggested providing the TM with written comments. Following a question by NL on the basis for the market share factors used in the ESDs, it was discussed if a default of 1 or a value between 0.5 and 1 could be used. **DK** proposed to estimate the value separately for each product type. According to **FR** it would not be possible for an individual applicant to refine the value, since the market for each substance can change over time: only default values applicable to all substance should be used. **COM** summarised that there are two options: one would be to apply the product type specific penetration factor; the other option would be to have a default market share used as a first tier for all product types. **NL** stated that there is no agreement among Member States and proposed to use a factor of 1 as a starting point and then verify it

for each product type. **DK** stressed that already accepted and agreed values in several ESDs shall not be changed, while in the remaining product types a value could be derived which is the most realistic. **IND** warned that starting with a default value of 1 the discussion will come back for each active. **DE** stated that a penetration factor of 1 seems to be unrealistic for substances in PT 1 and PT 2. Starting with a penetration factor of 1 and leaving the refinement to MS's decision during the evaluation phase of the active substance will definitely result in a variety of decisions made and will result in a case by case discussion (and decision) on penetration factors at TM level once the CARs are finalised. **DE** expressed their concern about this situation. **COM** concluded that there was no consensus on the use of a certain default value for all product types. Therefore, the already agreed market share factors in several ESDs shall be used, where justified deviation is possible. For the remaining product types a market share factor shall be agreed upon, where relevant.

## **7. PT21: outcome of e-consultation: environmental risk assessment PT21 and marina scenario development**

### *CEPE ICOMIA Marina Project Brief*

As informed at an earlier TM, CEPE together with ICOMIA started a project on the development of a marina scenario. CEPE asked COM to distribute the project brief for information to the TM. If Member States have any additional data these should be sent to CEPE by November 2008. The results will be presented to the TM in the beginning of the next year. **NL** will send comments on the project brief to **IND**.

### *Outcome Email consultation PT21*

The outcome of the e-consultation started by **NL** was discussed for each question:

- Page 1 of the document: the proposal from **NL** was agreed upon.
- Page 2 and 13-15 of the document: **NL** asked to what extent should mitigation measures for application and removal of antifouling paint be accepted? There is a Dutch study on what reduction can be achieved by using mitigation measures. The study is not yet available and as soon as **NL** will have it they will distribute it. **COM** stated it is too early, as no draft CAR has been submitted yet to the Technical Meeting for PT 21, to discuss risk mitigation measures. However, **COM** welcomed the proposal from **FR** that each Member State shall investigate which national measures exist. **NL** reported that the applicant of cybutryne has a Dutch report on the emission reduction.
- Page 3-4 of the document: **NL** questioned the fact that for all substances (even for persistent substances) for which they used MAMPEC so far, the concentration in suspended solids is higher than the one in sediment. **IND** stated they contacted the developers of MAMPEC, for which a new version will be released in a couple of months where some of the concerns are addressed, and will report back to the TM. It was decided to calculate and report for the moment both values in suspended solids and sediment.
- Page 5 of the document: the proposal from **NL** was agreed upon.
- Page 6-7: the proposal from **SE** to use the FOCUS guidance to derive DT50 values for the degradation processes was accepted. **NL** warned to avoid double

counting. Following a question from **NL** whether photolysis shall be excluded as a removal process some Member States were in favour and some not. **NL** stated the model used in MAMPEC for photolysis shall first be validated. Some Member States stated that for sediment this process can be excluded but not for the water column. **SE** stated the model used in MAMPEC takes into account the suspended matter content and the subsequent decrease of the penetration of light in the water column. **IND** proposed to contact the developers of MAMPEC and report back to the TM. **COM** concluded that photolysis cannot be excluded as a removal process in general.

- Page 8-11: average versus 95<sup>th</sup> percentile. **COM** stated that in the ESD the average is recommended. In addition, **COM** stated that in the ESD this concentration is not set equal to the PEC but regarded as the initial concentration from which a PEC shall be derived. **NL** recommended to use the 95<sup>th</sup> percentile. **IND** proposed to investigate in more detail why in the ESD the average was proposed. **COM** concluded it is too early to decide on which value to use as no draft CAR is submitted yet.
- Page 12: it was decided to not normalise the effect concentrations to a standardised organic matter content for sediment.

## **8. Outcome of e-consultation: regarding substitution of the adsorption/desorption test by QSAR for formaldehyde and lauric acid**

### **9. AOB**

#### **9a. Relevance efficacy data for environmental risk assessment**

**NL** is currently in discussion with an applicant for an insecticide in relation to the use of efficacy data in environmental risk assessment. As this is a generic issue for all PTs, **NL** prepared a document listing all pro and cons of using efficacy data in the environmental risk assessment. **NL** posed a question to the other Member States whether efficacy data on target species should be used in environmental risk assessment. **NL** stated that efficacy studies showing that target organisms (e.g. mosquitoes) are more sensitive than the most sensitive species of those taxonomic groups for which information is submitted by the applicant, triggers a request for information on non-target organisms of the same taxonomic group (e.g. insects). If these data are not sufficiently available then efficacy data should be used. **DE** stated that active substances with a specific mode of action are specifically designed to kill only target organisms and by including the efficacy data these substances will be punished. Moreover efficacy tests normally are not designed to derive ecotoxicological effect values. **DE** proposed to use this information to back up data-claims for studies with non target organisms of the same taxonomic group. **FIN** and **FR** had the same reservations on using efficacy data. In addition, **FR** stated that tests for the same pest species shall not be requested because due to resistance problems the target species may not be the most sensitive of the taxonomic group (i.e. insects).. **NL** claimed that in case the efficacy test is valid and it is possible to derive a NOEC or LC50 this should be taken into account in the assessment. If the insects are the most sensitive we should try to get more data on other insects. **COM** summarised that

information from efficacy tests can be used to define the potentially most sensitive taxonomic group, which may trigger a need for additional information. However, in principle ecotoxicological data cannot be substituted with results from efficacy tests due to the specific design of these tests.

**NL** stated that the applicant had presented a mesocosm study which did not include insects. Therefore, the question is whether this study should be used for the risk assessment? **COM** stated that in case when it can be demonstrated that the most sensitive group was not present in the mesocosm test, this questions the usefulness of this study for the PNEC derivation but it does not mean that we should use efficacy data instead. **DE** strongly advised not to use the mesocosm study in this case but to base the assessment on a single species tests. The application pattern in the mesocosm test does not fit with the biocidal use pattern, especially as the substance degraded rapidly.

#### **9b. Finalisation ESD for PT 2, 3 and 4**

**COM** informed the meeting that **DE** has kindly offered to finalise the draft ESD for PT 2, 3, 4. Comments received from other Member States on earlier versions will be incorporated. A final documents will be presented at TM IV 08<sup>2</sup>.

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<sup>2</sup> Due to delays in closing the contract with a consultant, the final draft version of the ESD for PT 2, 3, and 4 will not be available for TM IV 08. However, **DE** will inform on the progress of the revision of the ESD and on the timelines for finalisation at TM IV 08.