RAC/M/10/2010
FINAL

Minutes of the 10th meeting of the Committee for Risk Assessment (RAC)
(16-18 March 2010)

Part I Summary Record of the Proceedings

0. Welcome address

Dr Jose Tarazona, Chair of the Committee for Risk Assessment, ECHA, welcomed participants to the meeting and gave the floor to the Executive Director of ECHA for his welcome address to RAC.

The Executive Director considered the Tenth meeting of the Committee for Risk Assessment as a landmark. In his speech he expressed his satisfaction that the number of opinions adopted by RAC is increasing and that consensus had been reached for all of them. The Executive Director stressed that RAC opinions are the opinions of ECHA and are the basis for a decision-making process which guarantees the high level of protection demanded by European citizens. Furthermore, he referred to the constantly growing workload and advised RAC members to share the work as evenly as possible and to seek to ensure they receive sufficient support from their nominating Member States.

In his speech, the Executive Director also thanked the RAC regular and sector-specific stakeholder observers for their contribution to discussions but urged them to fully comply with the ECHA Code of Conduct and the other RAC procedures.

1 Welcome and apologies (cont.)

Eight advisers, two invited experts and five stakeholder representatives (from CEFIC, ECEAE, ECETOC, ECPA and Eurometaux), four observers accompanying stakeholder observers, two representatives of a Member State Competent Authority (MSCA), three representatives from the Commission and two replacements of RAC members were welcomed.

Apologies were received from eight RAC members and three regular observers (ETUC, EEB and WECF). Two members were absent. The list of attendees is given in Part III of these minutes.

Participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed after the adoption of the minutes.

2 Adoption of the Agenda

The Agenda was adopted as proposed by the Secretariat. The final Agenda and the list of all meeting documents are attached to these minutes as Annexes I and II, respectively.

3 Declarations of conflicts of interest to the Agenda

The Chair asked the members and their advisers whether there were any conflicts of interest to be declared specific to the meeting. Four members, one replacement and

one adviser declared potential conflicts of interest to different substance-related discussions in the agenda.

4 Adoption of RAC-9 Draft Minutes

The Chair introduced the revised minutes, incorporating the comments received from members.

RAC adopted the revised minutes without changes. The Secretariat was to make the final version available through the RAC CIRCA IG and publish on the ECHA website.

5 Administrative issues and information items

The administrative issues and information items were covered by the room documents RAC/10/2010/18 and RAC/10/2010/19 which had been handed out to the members. This practice was agreed previously with members. Members were informed that if there were any questions concerning the document, these would be discussed during the relevant agenda items or under any other business.

Further, the Chair informed members about the requirement of the Management Board (MB) to receive information on the support they are receiving from MSCAs and encouraged members to provide the RAC Secretariat with opinions on the support needed from Competent Authorities for the Committee members.

One member suggested preparing a general letter from ECHA to MSCAs informing them of the workload of RAC members and their required support. The Chair welcomed this proposal and also offered help from ECHA in discussing specific situations. The suggestion to inform MSCAs about the participation of the individual members in RAC activities will be considered.

5a Status report on the RAC-9 action points

The Secretariat reported that all actions from RAC-9 had been completed.

5b Outcome of written procedures

This point was covered by room document RAC/10/2010/18.

5c Report from other ECHA bodies and activities

This point was covered by room document RAC/10/2010/18.

5d Feedback on the annual survey of members

Feedback was provided from the RAC satisfaction survey 2009 in room document RAC/10/2010/19. The Chair thanked the participants for completing the annual survey and were invited to discuss the specific proposals during the meeting in May (RAC-11).

5e Update on the financial arrangements for (co-) rapporteurs for restriction dossiers

The Secretariat reported that the Commission had given agreement to the MB decision of 23-24 April 2009 on transfer of the proportion of fees to the Member States for (co-) rapporteurs' work on restriction dossiers. It was reported that at the last meeting of the MB (3-4 March 2010), an update on the current situation had been received.

Based on a co-operation agreement between ECHA and Member States, the necessary contractual basis for the transfer of funds between ECHA and the Member State Competent Authority will be established. The specific agreements and contracts would be done with each Competent Authority and possibly in addition with a mandated national institution. The contract should be concluded prior to the formal involvement of the (co-) rapporteurs in the restriction process. The model for a specific contract and other documents are under preparation and will be published in CIRCA. The decision will be published on ECHA website and the members will be provided with this document via CIRCA soon.

6 Feedback from the ECHA Management Board decision on approval of the RAC rules of procedure (RoPs)

The Chair explained that the MB had approved the RoPs subject to removing a sentence in Article 19(5) which would have meant that any minority positions were part of the RAC opinion. Nevertheless according to the remainder of Article 19(5), minority positions would still be required in writing, be recorded in the minutes and published. The Chair sought the views of RAC members on whether they would prefer minority positions to be reported and published only in the minutes or in addition to the minutes, be published in a separate document jointly with the opinion. The Chair also confirmed the right of members to either produce their own minority position or as part of a group of members, with the support, if required, of the Secretariat.

After discussion, it was agreed that minority positions should be easily accessible and readily available to the Commission, stakeholders and other interested parties. On this basis, minority positions would be provided in writing, presented in a separate document from the opinion and published at the same time as the opinion.

7 Requests according to Article 77(3) (c) of the REACH Regulation

7a The draft opinion on boric acid and borate compounds in photographic applications

The Chair introduced this item by reminding RAC members that RAC had been asked to provide an urgent opinion in relation to boric acid and borate compounds in photographic applications and by welcoming two invited experts and an expert accompanying the observer from Eurometaux.

The rapporteur and one of the invited experts presented the fifth version of the draft opinion and a summary document. The revised opinion took account of the additional

data provided by industry after RAC-9 about additional photographic products containing boron and consequently additional exposure scenarios had been derived. In addition, the recommendations were expressed more clearly and the human health aspects had been adjusted following comments received from RAC members after RAC-9. The revised opinion indicated that several worst case exposure scenarios combined with background levels of boron resulted in risk characterisation ratios (RCRs) above 1.

Members thanked the rapporteur and the members of the Ad Hoc Working Group for their efforts thus far. A discussion took place that was split over two days and included a meeting of a drafting group supported by members of the Ad Hoc Working Group and other participants interested in borates between plenary discussions. The discussion focussed on the extent to which the risk assessment should be refined, which parameters were considered to be over conservative and how to present the combined RCRs.

Some members pointed out that several elements of the risk assessment had been over estimated such as the DNEL value and several elements of the exposure worst case scenarios. Considering the toxicokinetic profile or boron and boron compounds it was considered that the 10x10 assessment factor was an over conservative approach and that there were good scientific justifications to derogate from these default values. In fact, WHO had used a 6 (intraspecies) x10 (interspecies) uncertainty factor in deriving its Guidelines for Drinking Water Quality (2003 & 2009) for boron and, based on the same data, EFSA in 2004 had also utilised a combined assessment factor of 60. However, it was also apparent that in the context of discussions arising from the Biocidal Products Directive[1] in 2009 the 10x10 default values had been used. After discussion it was agreed that a quantitative estimation of the assessment factor to be used in this opinion would require an in-depth assessment of the toxicokinetic information and the justifications indicated by WHO, EFSA and the Technical Meeting under the Biocides Directive. Due to timeline constrains of this request for and urgent opinion, it was agreed to continue to utilise the 10x10 assessment factors, but to make reference in the final opinion that there are grounds for derogating from the use of default values, and considering the overall outcome in a qualitative way. It was also agreed that the uncertainties associated with in-put parameters generally should be more clearly highlighted in the opinion to justify the use of a conservative approach.

Concerning exposure scenarios, significant discussion took place on the best way to present scenarios which included background levels of boron from food and drinking water and less likely scenarios such as those involving the tray processing of films. Members re-affirmed the need to present the effects of adding background exposure levels to those arising from the use of photographic products. However, because the data for the background contribution to exposure had not been assessed by RAC, this should be clearly indicated in the opinion. Members also expressed a clear preference to focus the conclusions of the opinion on the majority of scenarios, that result in RCRs below 1, and to make explicit reference to the exposures resulting from worst case scenarios that utilise powder formulations.

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market OJ L 123, 24.4.1998, p1-63.

During the discussion an observer from the Commission indicated that they support the additional work to finalise the opinion to ensure the Commission receives a clear message about the risk of photographic products containing boric acid and borates.

After presenting the revised exposure and RCR calculations, the discussion focused on the expressions to be used in the overall conclusion, and preliminary agreement was reached on a text subject to editorial adjustments by the rapporteur.

The Chair thanked participants for their contributions and requested the rapporteur to revise the opinion and provide it to the Secretariat by 1 April 2010. An editorial commenting round would then be arranged to finish by 9 April 2010. It was agreed this would be followed by an urgent written procedure to adopt the opinion.

7b Framework for dealing with requests according to Art 77(3)(c) of REACH

The Secretariat presented the changes introduced in the revised framework (RAC/10/2010/12). The revision had been made following the discussion at RAC-9 and subsequent written comments provided by RAC members. The major changes included the introduction of an adequacy check to be performed by the rapporteur in order to assess the adequacy of the documentation submitted with the request and the information to be generated in the process. In addition, prior to the request being issued, the Secretariat would perform a preliminary evaluation of adequacy of the documentation.

Several RAC members asked for clarification of the consequences of the adequacy check. The Chair explained that significant information gaps in the request to RAC are likely to be minimised with the preliminary evaluation performed by the Secretariat, and that the adequacy check may include negotiation between the Secretariat and the submitter of the documentation in order to guarantee that the required information is available. The Chair also confirmed that in line with the RAC Rules of Procedure, co-opted members who could be involved in the requests under Article 77(3)(c) would be appointed in the usual manner for a term of three years.

RAC agreed the revised framework with small editorial modifications. As the document is addressed to both RAC and SEAC Committees and SEAC reached preliminary agreement on the revised version of the framework during SEAC-6 meeting, the document is considered agreed by both Committees.

8 CLH

8.1 CLH Dossiers

8.1a Epoxiconazole (CAS No. 133855-98-8; EC No. 406-850-2)

The rapporteur and their adviser introduced the revised draft opinion and background document (BD) for epoxiconazole proposing the classification according to the original proposal from Sweden as follows: Repr. 1B, H360Df (CLP Regulation) and Repr. Cat 2; R61 (under Dir 67/548/EEC). Present for this item were: representatives from the Swedish Competent Authority (dossier submitter); the Danish Food Institute

as an adviser to a member; and a sector-specific stakeholder observer with another accompanying observer.

The rapporteur explained that following discussion at RAC-9, the representative from the Danish Food Institute had provided additional clarification of published studies (introduced during the public consultation) and the opinion had been strengthened accordingly. The focus of the justification for the proposed classification remained the observed post implantation loss, in particular late resorptions and cleft palates. The hazard statement H360Df was now proposed to more accurately reflect the proposed classification. RAC members thanked the rapporteur for their work and expressed their agreement with the proposed classification.

The rapporteur also drew to the attention of RAC members the provision of information from industry indicating the timetable for ongoing studies in relation to epoxiconazole. Members discussed how the take this information into account. Some members expressed the need to take all available scientific information into account when considering an opinion. Other members cautioned being open to new data all through the opinion-forming procedure since new data arriving late in the process could be difficult for (co-) rapporteurs and members to take into account. These members noted that the public consultation phase of the procedure is the appropriate time for new data to be submitted. Several members also considered that the new studies had implications for animal welfare and were not necessary.

The Chair reminded members of the difference between completely new data or studies and information that clarifies existing published studies included in the dossier or previously submitted during the public consultation, an example of the latter being the information provided by the Danish Food Institute. Concerning the new industry study programme, members noted that the studies had been initiated after RAC-9 (thus completely new studies) and in any case the final reports would not be available before RAC had a legal obligation to adopt its opinion in relation to epoxiconazole. The Chair indicated that the situation was not substance specific, and may be repeated in the future. Under these circumstances, it is up to the dossier submitter to decide on the potential relevance of the ongoing new studies, as the dossier submitter may withdraw the proposal and re-submit again the dossier incorporating the new studies when available. The representative of the dossier submitter indicated that in their view, the preliminary results confirmed the proposed classification and they did not see a need for withdrawing the proposal. The Chair mentioned that the REACH and CLP Regulations offer possibilities for updating the RAC opinions before or after the inclusion of the proposal in Annex VI of the CLP Regulation, if based on new studies, such a need is identified by Commission or Member States. It was agreed the final RAC opinion for epoxiconazole would be based on the available information, but for transparency would make reference to the ongoing industry studies.

The industry stakeholders made the following statement: BASF has a legal obligation to do studies to further assess the endocrine disrupting potential of epoxiconazole, in line with the provisions of Annex I to Commission Directive 2008/107/EC[2]. All the studies, ongoing or planned, that BASF has initiated are focussed on clarifying the

[2] Commission Directive amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances. OJ L 316 of 26/11/2008 p.4.

human relevance of endocrine-mediated findings seen in rat studies as reported in Taxvig et al or in BASF regulatory studies. BASF is performing these studies as a direct consequence of legal requirements as stipulated under the Plant Protection Directive. For animal welfare reasons, the design of the planned studies on endocrine disruption were expanded to assess also developmental toxicity (post implantation loss); there is a growing body of evidence that this effect is related to hormonal dysregulation in rats and is possibly species-specific. In any case, the studies are a direct consequence of the Annex I Inclusion Directive of Epoxiconazole under Council Directive 91/414/EEC.

Following discussion, RAC adopted by consensus the opinion for epoxiconazole as proposed by the rapporteur. The Chair thanked the rapporteur for their hard work and requested that final minor editorial changes be carried out quickly and the final version of the opinion and its annexes be sent to the Secretariat for passing onto the Commission.

8.1b Abamectin (CAS No. 71751-41-2)/Avermectin B_{1a} (CAS No. 65195-55-3)

A representative of the dossier submitter from the Dutch Competent Authority (CA) presented to RAC the original proposal for harmonised classification and labelling for abamectin explaining the reasons and the key study results led to it; in conclusion, it was clarified that on the basis of this RAC opinion, a decision for inclusion of two new entries in Annex VI is expected – one for abamectin and another one for avermectin B_{1a}.

The (co-) rapporteurs introduced to the Committee the revised draft opinion, the key comments received during the RAC consultation that led to some modifications in the draft opinion and draft BD and the responses provided to these comments. It was summarised that all comments received during the RAC consultation was in favour of the (co-) rapporteurs' draft opinion to support the dossier submitter's proposal for these substances. Furthermore, the (co-) rapporteurs suggested focusing the discussion on the consideration whether Cat 1 or 2 for acute inhalation toxicity should be proposed, specific concentration limits (SCL) for repeat dose inhalation toxicity to be set up, as well as only the most sensitive target organ (nervous system) to be mentioned in the hazard statement H372.

RAC agreed with the (co-) rapporteurs' proposal to classify this substance for acute inhalation toxicity in Cat.1 (instead of Cat.2 as it was initially suggested by the rapporteur) based on the female LC_{50} likely being lower than the cut-off value of 0.05 mg/l (3 out of 5 females died or were killed at 0.051 mg/l), as although an "overall" LC_{50} for rats would lead to Cat 2, but a higher sensitivity in females should be acknowledged (Female LC_{50} = 0.035-0.051 mg/l; Male LC_{50} = 0.051-0.21 mg/l).

RAC agreed that SCL should be of the same order/magnitude in the classification under Dir 67/548/EEC as well as under the CLP Regulation, even when guidance documents indicate somewhat otherwise. Furthermore, RAC agreed with the (co-) rapporteurs' proposal for the suggested SCL for repeat dose inhalation toxicity and the wording of the hazard statements, as follows: Cn $\geq$ 5% for T; R48/23 and STOT-RE 1; H372 (Causes damage to the nervous system through prolonged or repeated exposure); 0.5% $\leq$ Cn <5% for Xn; R48/20 and STOT-RE 2; H373 (May cause damage to the nervous system through prolonged or repeated exposure).

Finally, RAC adopted by consensus the opinion and the background document for abamectin/avermectin B1a. RAC members agreed with the view of the (co-) rapporteurs to support the proposed classification and labelling for both substances: Repr. Cat 3; R 63, T+; R26/28, T; R48/23/25, SCL: Cn ≥ 5% for T; R48/23 or 0.5% ≤ Cn <5% for Xn; R48/20, N; R50/53, SCL: Cn ≥ 0.0025% for N; R50/53, or 0.00025 % Cn < 0.0025 % for N; R51/53 or 0.000025 % Cn < 0.00025 % for N; R52/53 (under Dir 67/548/EEC) or Repr. 2; H361d, Acute Tox. 2; H300, Acute Tox. 1; H330, STOT-RE 1; H372 (Causes damage to the nervous system through prolonged or repeated exposure) for Cn ≥ 5% or 0.5% ≤ Cn <5% for STOT-RE 2; H373 (May cause damage to the nervous system through prolonged or repeated exposure), Aquatic Acute 1; H400, Aquatic Chronic 1, H410, M-factors: 10,000 (under CLP Regulation).

8.1c Gallium arsenide (GaAs) (CAS No.1303-00-0; EC No. 215-114-8)

A representative from the French Competent Authority introduced the CLH proposal which was as follows: STOT-RE 1, H372 (CLP) & T; R48/23 (under Dir 67/548/EEC); Repr. 1B, H360F (CLP) & Repr. Cat 2; R60 (under Dir 67/548/EEC) and Carc. 2, H351 (CLP) & Carc. Cat 3; R40 (under Dir 67/548/EEC).

Following the first discussion on this proposal at RAC-8, the (co-) rapporteurs and their adviser introduced their revised draft opinion, background document (BD), response to comments on the draft opinion (ORCOM) and a discussion document in relation to their proposed approach to the carcinogenicity hazard category. Their proposal was to increase category of classification for carcinogenicity to Car. 1A, H350 (CLP) & Carc. Cat. 1, R45 (under Dir 67/548/EEC).

The (co-) rapporteurs explained their approach to the carcinogenicity hazard class. Following RAC-8, they had examined the relevant available data for the carcinogenicity of GaAs with the aim of making a weight of evidence determination. In particular, this included the read across to GaAs of the substantial documentation of carcinogenicity data for arsenic and arsenic compounds as evaluated by IARC. Several RAC members noted that previously, in the absence of human data, there had not been enough data to support the category 1 classification, but with the additional work by the (co-) rapporteurs, they could in principle agree to the classification. A member highlighted the link between CLP and the IARC classification criterias by referring to the CLP guidance section 3.6.2.3.1. Other members queried whether the read across from IARC is acceptable as a basis for the work of RAC and an EU harmonised classification. Following discussion it was agreed that IARC information should be referred to, but a better basis for read across would be data for arsenic compounds already classified as carcinogenic category 1A and listed in Annex VI of the CLP Regulation. A member suggested the (co-) rapporteurs to review and include a few key studies on human data in the BD. A member questioned why not other endpoints as well should be assessed by using read-across. A member answered that read-across limited to carcinogenicity in this case was relevant, because it is known that animal models are not suitable for testing of this hazard class for GaAs.

Other issues were also discussed. One RAC member suggesting rephrasing to be more precise regarding effects in tissues concerning fertility, as fertility itself were not investigated and he noted that the justification for repeated dose toxicity could be

strengthened. Members supported the proposal of the (co-) rapporteurs not to apply the classification of acute toxicity from the group entry for arsenic compounds to GaAs; but to apply the group entry for the environmental classification as no specific information on environmental hazards was provided in the dossier. Another member noted that EFSA has prepared a recent opinion on arsenic which would be valuable to the (co-) rapporteurs.

The Chair thanked members for their contributions and invited the (co-) rapporteurs to revise their draft opinion and its annexes by 7 April. The SECR would then arrange a round of editorial comments and depending on the comments received may organise adoption of the opinion by written procedure or at RAC-11.

8.1d Tetrahydrofuran (THF) (CAS number: 109-99-9; EC Number: 203-726-8)

The dossier submitter's representative from the French Competent Authority presented to RAC the proposal for classification of THF as Flam.Liq.2,H225; EUH 019; Eye Irrit. 2,H319; STOT SE 3,H335; Carc. 2,H351 (under CLP Regulation) or as F; R11-19; Carc. Cat.3, R40; Xi, R36/37; S-phrases: S(2-) (13) S16- S29- S33-S36 - S37 S(46) (based on the Dir 67/548/EEC).

The (co-) rapporteurs for THF introduced to RAC the first draft opinion and draft BD. They proposed to focus the discussion on carcinogenicity. Mutagenicity was evaluated as part of the assessment for carcinogenicity. Reproductive toxicity and respiratory irritation were not evaluated due to lack of data.

The (co-) rapporteurs suggested classifying THF as Carc.2 – H351 (under CLP Regulation) or Carc. Cat. 3; R40 (in accordance with the Directive 67/548/EEC) based on increased incidents of renal tumours in male rats and mammary gland tumours in female rats and of liver tumours observed in female mice.

A possible mechanism of carcinogenicity for kidney tumours in male rats was discussed and the (co-) rapporteurs concluded that there was no evidence of a male rat specific mechanism. During the discussion one RAC member asked whether in general, when the criteria for evaluation of chronic progressive nephropathy (CNP) as a possible mechanism to explain renal tumours in rats are fulfilled, these tumours are to be considered not of relevance for humans (just like kidney tumours in male rats induced by alpha-2-u-globulin related nephropathy).

RAC agreed with the view of the (co-) rapporteurs and supported the proposed classification for THF as Carc. 2,H351 (under CLP Regulation) or Carc. Cat. 3, R40 (under Dir 67/548/EEC).

The Chair thanked the members and reminded that the commenting round had ended just before the meeting (on 15th March) and invited any final editorial comments on the draft opinion and draft BD by 29 March 2010. Depending on comments received the adoption may take place during the next RAC meeting or by written procedure before the meeting.

8.1e TDCP (Tris[2-chloro-1-chloromethyl)ethyl] phosphate) (CAS Number:13674-87-8; EC Number: 237-159-2)
The Chair invited the representative of the dossier submitter from the Irish Competent Authority (MSCA) to introduce the CLH proposal for TDCP to the members for a first discussion.

The proposal for classification was: Carc. 2, H351 (CLP Regulation) or Carc. Cat 3; R40 (Dir 67/548/EEC). The representative of the dossier submitter also informed RAC that during the public consultation two MSCAs had proposed an additional classification of Repr. 2, H361f (CLP) or Repr. Cat 3; R62 (Dir 67/548/EEC).

The (co-) rapporteurs then introduced their first draft opinion. They proposed to agree with the proposed classification and labelling from the Irish MSCA and, on the basis of comments received in the public consultation, had also made a provisional proposal for the additional classification of Repr. 2, H361f (CLP) or Repr. Cat 3; R60 (Dir 67/548/EEC).

Concerning the proposed classification for the carcinogenicity hazard class, RAC reached preliminary agreement, without significant discussion, on the harmonised classification for TDCP as Carc. 2, H351 (CLP) or Carc. Cat 3, R40 (Dir 67/548/EEC).

Members considered that further discussions were needed on the proposed additional hazard class for reproductive toxicity. The (co-) rapporteurs explained their proposal had been based upon an analysis of the time sequence in the repeated dose toxicity and the two year carcinogenicity study, where it appeared that the testicular toxicity cannot be totally attributed to Leydig-cell tumours. By way of support to this, a closely related substance, TCEP[3], is classified as Repr. Cat 2; R60; and in November 2005 TC C&L had provisionally agreed to classify TDCP as Repr. Cat.3; R62. RAC members in principle acknowledged the grounds for a classification for reproductive toxicity (fertility) on the basis of testicular toxicity. However, in the discussion a number of weaknesses in the evidence available for TDCP were indicated. For example the symptoms were found at an age of 24 months, which may not be likely to contribute to fertility effects, against a high incidence of similar effects in the controls (~70%) while there was no information about testicular toxicity at a relevant age (as usually assessed in 90 day or 1-generation studies). The read-across was not regarded as a suitable approach in this case, because another closely related substance – TCPP[4] – was not toxic to reproduction. Further supporting information on TCEP, e.g. and whether there was a similar pattern of late findings, was not available.

In summary, the preliminary view seemed to predominate, that the data are insufficient to justify a classification for reproductive toxicity.

The Chair thanked the (co-) rapporteurs and invited RAC to provide any comments or responses to the questions raised by the (co-) rapporteurs in their presentation in relation to the reproductive toxicity proposal by 26 March in the RAC CIRCA newsgroup. The (co-) rapporteurs were then to revise their draft opinion and BD

[3] Tris(2-chloroethyl) phosphate
[4] Tris(2-chloro-1-methylethyl) phosphate

accordingly by 12 April. A revised version would then be distributed to RAC for possible adoption at RAC-11.

8.1f Leucomalachite Green (CAS No. 129-73-7) – accordance check

The RAC rapporteur for Leucomalachite Green, the first submitted dossier from the group of 87 substances with agreed classification and labelling at TC C&L, was invited to provide feedback from the ongoing accordance check and to express its view on the way of dealing forwards. The rapporteur shared his concerns related to this dossier's accordance check and further processing. Although a quick and smooth process for these 87 substances was considered by RAC at their latest plenary meetings, it seemed impossible to lighten the procedure, as RAC should make an opinion on the basis of comparison with the CLP criteria that leads to difficulties due to insufficient data transparency in the submitted dossier. Therefore, the rapporteur suggested the opinion for these substances to be formulated on the basis of an accelerated procedure for the 87 substances with full utilisation of previous TC C&L work and without preparing of a BD.

The Commission representatives clarified that although the classification and labelling of this substance was discussed and agreed by TC C&L, it was done under the provisions of Directive 67/548/EEC and now RAC is expected to adopt an opinion with a CLP criteria as a starting point that is sufficiently justified in a BD as a part of the opinion.

Following the Chair's proposal to have more detailed discussion on the processing of the 87 substances under agenda item 8.3b, RAC agreed that the normal procedure for processing of this substance should be applied. In addition, the rapporteur for Leucomalachite Green was requested to finalise the accordance check report according to this outcome of the discussion.

8.2 Appointment of RAC (co-) rapporteurs for CLH dossiers

Room document RAC/10/2010/20 was introduced by the Chair who explained that two new intentions for CLH dossiers (both biocide active substances) had been received and rapporteurs and co-rapporteurs were required. By the end of the meeting one member had volunteered and RAC agreed to appoint this member as a rapporteur for one of the substances. RAC members were invited to come forward for the other three vacant places. The revised status document was to be uploaded to the RAC CIRCA IG after the meeting to reflect the changes.

8.3 General CLH issues

8.3a Templates for the CLH opinion and BD and Commission´s feedback on RAC request

Following the RAC request asking for clarification on the scope and the content of the RAC opinion and BD on CLH proposals and the Secretariat's letter to the Commission in this regard, the Commission representatives presented their initial answers (see room document RAC/10/2010/22) embedded in the Secretariat's letter and indicated that the Commission will send a formal answer to ECHA and RAC in the following weeks.

The Commission observers acknowledged the improvements in the format of the CLH RAC opinions adopted after RAC-7 and indicated further suggestions for facilitating the use of the RAC opinions in the Commission decision-making process.

It was pointed out that during the opinion-forming process, RAC should assess whether the proposed harmonised classification and labelling for a substance meets the criteria under the CLP Regulation as a starting point. RAC agreed to modify the opinion template according to the Commission indications.

During the following discussion, RAC agreed that (co-) rapporteurs should consider preparing a relatively concise opinion that includes summary of the key elements of the argumentation, as this will allow the opinion to be a stand-alone document. Furthermore, the BD should contain the more detailed information and the full supportive scientific documentation for the opinion, which could be seen as an executive summary of the BD.

The Commission representatives reminded of the importance to keep the right balance of the information provided in the two documents, as mainly the opinion will be used in the decision-making process and BD will be consulted when needed only.

In addition, the Secretariat recalled that in the near future the CLH report, used as a basis for BD, should be also considered as a summary of the available information, as the robust study summaries should be submitted in the IUCLID 5 dossiers only.

Regarding the Commission request to receive a track-change version of the first and last BD versions in order to see the difference between the original and the final versions, it was clarified that RAC considered it as unpractical to try to keep track changes in the different drafts during the opinion-forming process. If there is a need for highlighting the changes in different versions when RAC considers a controversial dossier, after the adoption of the RAC opinion, the Secretariat should prepare such document on the basis of comparison between the revised CLH report submitted by the dossier submitter after the public consultation and the final BD annexed to the adopted RAC opinion.

8.3b Substances already agreed at TC C&L

The Commission representatives informed RAC that as there are no transitional measures foreseen in the legislation and the Commission could take a decision only after receiving a RAC opinion, when a dossier for any of these 87 substances is submitted, RAC should formulate an opinion supported by BD with clear argumentation on the basis of the comparison with the CLP criteria as a starting point, as in all regular cases. In addition, it was clarified that RAC has freedom to decide how to organise the process (e.g. grouping the proposals, where relevant, discussion in batches, etc.). However, the Commission pointed out that Annex VII translation tables should not be used when RAC formulates an opinion, as the opinion and BD should clearly state the reasons behind RAC consideration on why the substance should be classified or not for the hazard classes in the proposal.

Furthermore, it was clarified that if an Annex VI entry of a substance covers several hazard classes, but a new proposal is submitted for CLH of an additional or modified hazard class(es), RAC should compare only the information for the proposed class(es) with CLP criteria (and DSD criteria). The Commission also confirmed the need for providing a specific justification for non-CMR/RS hazard classes in the CLH dossier and report for the TC C&L agreed substances.

Several members expressed their concerns regarding the additional burden this will bring to the MS dossier submitters who should put together the old and new information in one more complex set of data in a IUCLID 5 dossier (apart from the Robust Study Summaries Requirement according to the guidance), as this may lead to reconsidering the situation for non-CMR substances from dossier submitter's point of view and to a decision not to submit dossiers for all 87 substances that will reflect to the expected CLH for these substances. In addition, it will be a challenge also for RAC, as part of the RAC opinion should be built on the previous TC C&L conclusions.

The regular CEFIC observer underlined to the importance for RAC consideration of all practical aspects and pleaded on industry's behalf the Committee to find a real pragmatic solution for these 87 substances.

Finally, RAC agreed that the normal CLH procedures for handling these dossiers (for both accordance check and opinion-forming processes) should be applied, as the accordance check needs to clarify whether the information provided in the dossier is sufficient to allow opinion-forming; however, following the public consultation, preferably written procedures for adoption of the RAC opinions will be applied, and only more controversial cases, different approaches with plenary discussions will be considered.

8.3c Note H, hazard statements on reprotoxicity, justification for non-CMR&RS proposals

The Commission representatives confirmed that the RAC approaches regarding the use of Note H (requirement to self-classify other hazard classes than those included in Annex VI) and the indication of the hazard statements on reprotoxicity with the possible specification with note F, f, D, d are acceptable for the Commission. The issues on how to implement these hazard statements, as well as the usefulness of Note H are still under discussion within the Commission services. RAC was also invited if it finds inconsistency between the guidance and the legal text, to follow the legal text and to provide suggestions for further guidance updates.

RAC agreed with the editorial modification of the footnote related to Note H proposed by the Commission.

Regarding the provided justifications for Community level harmonisation in the CLH proposals, the Commission clarified that RAC should not assess the appropriateness of the justification provided by the dossier submitter on the need for action at Community level for the harmonisation of other effects than carcinogenicity, mutagenicity, reprotoxicity and respiratory sensitisation. According to Article 37(5) of Regulation (EC) No 1272/2008, the Commission will evaluate the sufficiency of the provided justification during the decision-making process. RAC should focus its resources and only assess whether the proposed harmonised classification meets the criteria in Annex VI to Regulation (EC) No 1272/2008.

In addition, the Commission informed RAC that the guidance on development of CLH dossier should explain to the dossier submitters the provision of justification; it also contains an example on justifications for Community harmonisation for non-CMR/RS hazard classes. The Commission informed participants that they will

provide further examples on acceptable justifications for inclusion in the CLH guidance.

Furthermore, RAC agreed that it should not evaluate the justifications for non-CMRs; the opinion, BD and accordance check templates will be modified accordingly. However, RAC expressed concerns for their workload in case a proposal for non-CMRs would be rejected by the Commission only after the RAC opinion. Therefore, members asked the Secretariat to consult with the Commission and CARACAL options on how and when the justification for Community level harmonisation should be evaluated in order to avoid unnecessary workload to RAC.

8.3d State of play of the submitted CLH dossiers

RAC was informed that an update of the state of play of the submitted CLH dossiers is provided in document RAC/10/2010/23 (distributed as a room document). Members were invited to contact the Secretariat if they need further clarification.

8.3e Feedback from the Ad hoc meeting for exchanging experience on accordance check for CLH dossiers

The Chair presented the room document RAC/10/2010/13 to RAC where the discussions from the ad hoc meeting were compiled in a table. Members were invited to submit their comments on the document via RAC CIRCA IG after the meeting. The document would be a part of the RAC-9 minutes after the agreement by RAC.

8.3f Handling a group of substances

The Chair introduced RAC with the need for clarifying the number of the required RAC opinions when handling CLH dossiers for a group of substances and suggested the number of the opinions to be considered in order to facilitate the discussions by RAC and in the light of the number of expected entries in Annex VI of the CLP Regulation.

Some members pointed out that RAC starting position should be to have different opinions for each of the substances in the group, as the classification should be substance-specific. However, the importance to keep flexibility was underlined in case there is a special reason for combining the individual substance opinions in one opinion for the whole or part of the group with very clear justification for it. Therefore, in conclusion, RAC agreed that (co-) rapporteurs should consider the possibility of formulating one opinion or the need of formulating several opinions in the cases when a group of substances is handled and decide on a case-by-case basis.

9 Restrictions

9.1 Report from the meeting of RAC and SEAC (co-) rapporteurs and ECHA Secretariat

The Chair of RAC briefly reported from the informal meeting of the RAC and SEAC (co-) rapporteurs and the ECHA Secretariat for the first two restriction dossiers that was held the day prior the RAC plenary meeting. During that meeting, the (co-) rapporteurs were provided with opportunities to meet their SEAC counterparts and the allocated Scientific Dossier Managers (SDMs) and the contact persons from the RAC and SEAC Secretariats and to discuss the dossier timelines, the ways for

communication among all actors in the process, in particular when confidential information should be considered, as well as the expected exchange of deliverables and expertise between RAC and SEAC (co-) rapporteurs during the conformity check and later on in the opinion-forming process. The (co-) rapporteurs also agreed to have their first dialogues as face-to-face meetings preliminary scheduled for the 3rd and 4th weeks of June 2010.

9.2 General restriction issues

The Secretariat informed RAC that the first two Annex XV dossiers proposing restrictions on DMF and Lead and its compounds in jewellery are expected to be submitted in mid-April 2010; furthermore, both dossier submitters Norway (for the Annex XV restriction dossier on phenyl-mercury compounds) and ECHA (for the Annex XV restriction dossier for mercury in measuring devises) are planning to submit their dossiers in mid-June 2010. It was clarified that there is a change in the scope of the Norwegian dossier, as one more phenyl-mercury compound is included in the dossier.

Furthermore, the Secretariat was requested to provide the (co-) rapporteurs with the expected restriction dossiers as soon as they are submitted.

10 RAC manual of conclusions and recommendations (MoCR)

The Secretariat presented the revised version of the RAC Manual of conclusions and recommendations (Document RAC/10/2010/14) and the key changes on the basis of the comments received (Document RAC/10/2010/15), such as only fully finalised cases to be included as entries in the MoCR, indexing system to be created, etc. In addition, the Secretariat clarified that the current version of the RAC MoCR is designed as an on-line document accessible only for the RAC CIRCA Users. However, for the future, RAC may reconsider the format and the content of the document and to suggest modifications, if needed.

Finally, RAC agreed on the outline of the MoCR with two minor changes.

11 Authorisation

11a Working procedure for the appointment of (co-) rapporteurs for applications for authorisations

The Chair explained that the first draft procedure for the appointment of (co-) rapporteurs for authorisation applications had been presented to RAC at the RAC-9 meeting. After that meeting, a CIRCA newsgroup had been opened for RAC members to provide comments on the document. SEAC had had a commenting round on the same document in CIRCA at the same time. Based on the comments which had been received from the Committees, RAC and SEAC proceeded with slightly different draft procedures. The Chair briefly introduced the revised draft working procedure for the appointment of (co-) rapporteurs by RAC for authorisation applications (meeting document RAC/10/2010/16). The Chair added that the comments which had been received from the RAC members via CIRCA had been compiled and responded in the meeting document RAC/10/2010/17.

One RAC member questioned the timing of the formal agreement on the appointment of rapporteur, referring to the SEAC draft procedure for the appointment of (co-)

rapporteurs, which had been changed to have this formal agreement at the end of the process; the member was interested why it was not possible for RAC to have the formal agreement at the end of the process. The Chair responded that it is up each Committee to decide on the procedure, and that the only difference was that RAC opted for an informal consultation and SEAC for a formal appointment. A possible explanation is that for RAC it was logical to take a substance as a basis for the establishment of the pool of rapporteurs. For SEAC, however, other parameters might be important, e.g. the use, which would make the establishment of the pool and the appointment of (co-) rapporteurs prior to the submission of applications complicated.

Another member proposed to indicate that the first and the preferred option should be to have both a rapporteur and a co-rapporteur for an authorisation application, while keeping the possibility not to have a co-rapporteur. The member suggested the following wording to be included in the Section 2.1 of the document RAC/10/2010/16: "Usually a co-rapporteur is appointed, even though the need for a co-rapporteur is considered case-by-case". In addition, the member proposed to indicate that the selection criteria listed in the Section 2.2 of the document was not exhaustive and some other arguments might be considered depending on the case.

RAC agreed the proposed procedure and the Secretariat would introduce the few editorial modifications in the procedure based on the suggestions expressed at the meeting.

11b RAC role in the authorisation process

The Chair informed that a Power Point presentation describing the ongoing steps related to the preparations for authorisation applications will be uploaded to CIRCA IG. Documents for discussions are expected at the May and September meetings.

12 Guidance issues

12a Feedback from the guidance update on the DNEL/DMEL derivation from human data

The member participating in the partner expert group (PEG) for this guidance update presented a status report on developments. He explained that whilst there are no issues of current concern, clarification discussions were taking place on topics of interest such as the application of assessment factors and the selection of the leading health effect and critical DNEL/DMEL once all DNEL/DMELs have been derived. A potential issue that might arise was the lack of guidance on the use of non-epidemiological human data and human 'experience', for example in relation to irritation or corrosion. RAC was expected to be consulted on the post-PEG draft at the end of April 2010.

12b Feedback from the RAC consultation on the update of the guidance for preparing a CLH dossier

The Secretariat summarised the comments received from RAC members thus far and explained the remaining stages of the procedure for updating the guidance document.

Comments received from RAC members included instructions to dossier submitters to avoid submitting dossiers for no classification (except active substances of biocides and plant protection products); how to deal with substances that are also part of a

group entry; the need to provide a full history of previous discussions on the hazard of the substance; that the CLH report should be stand alone; dealing with substances with classification already agreed at TC C&L; substance identification and issues relating to the CLH report template. There was some discussion on the legal requirements in the CLP Regulation for substance identification (ID). It was agreed that the rapporteur should focus on the substance ID issues relevant for RAC discussions, while the legal requirements not relevant for RAC discussions will be directly addressed by the Secretariat.

As next steps, the Secretariat explained that any further comments to clarify the Secretariat proposal for addressing the RAC comments should be sent through the CIRCA IG by 23 March 2010. Following consolidation of the various comments, the guidance was to be revised and sent to CARACAL for discussion. The aim was to publish the final guidance update on 19 May 2010. Following consultation with RAC on the guidance and the discussions, the templates for the CLH report format and accordance check were to be modified and provided to RAC after the meeting.

12c Other guidance activities

The Secretariat presented an overview of the ongoing and planned guidance activities relevant to RAC. These included a further guidance document on the application of the CLP criteria (PEG in May 2010); ongoing updates of the guidance for occupational and consumer exposure; scope of exposure assessment (currently with PEG); DNEL/DMELs (see 12a above); update of guidance for preparing a CLH dossier (see 12b above); and guidance on safety data sheets (PEG in mid April).

RAC members thanked the Secretariat for the update. Several members pointed out that the time for commenting on guidance documents was often too short to make an adequate contribution to the development of the guidance documents. The Chair agreed that the time allowed for RAC consultations had been shortened and explained that all the guidance development timelines had been compressed with the aim of being ready for registrants meeting the first registration deadline in Q4 2010.

13 Any other business

13a RAC STO participation in the work of RAC

Following the Chair's proposal, a closed session was organised for discussion and decision on the stakeholder participation in the work of RAC. In the light of the policy of transparency and openness, RAC took the following procedural decisions: members agreed that the full text of the draft minutes from the plenary meetings may be consulted with sector-specific STO observers; regular and sector-specific STO observers are allowed to observe the RAC discussions via RAC CIRCA Newsgroups; sector-specific STO observers and observers accompanying regular or sector-specific observers are allowed to observe the plenary item on conclusions and action points when practically possible. The names of RAC (co-) rapporteurs remain confidential until the adopted opinions are published on the ECHA website. These decisions were taken on the basis that RAC stakeholders comply with the confidentiality provisions of the ECHA Code of Conduct for Stakeholders.

The Chair briefly reported the outcome of the closed session to the stakeholder observers when the open plenary session was reconvened.

The RAC secretariat informed the members that REACH-IT will not be used by RAC members. A RAC member requested clarifications on IUCLID 5 and an ad hoc meeting was organised after RAC-10 for interested members and observers.

14 Main conclusions and Action Points of RAC-10

The Secretariat presented the main conclusions and action points of the RAC-10 plenary meeting for final comments and agreement by the Committee. All suggestions were reflected accordingly and RAC agreed the document. The main conclusions and action points are attached as Part II of these meeting minutes.

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18 March 2010

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
(Adopted at the Tenth meeting of RAC)
(16-18 March 2010)

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
2 Adoption of the Agenda	
The revised Agenda (RAC/A/10/2010_rev.1) was adopted. Four members, one replacement and one adviser have declared potential conflict of interest to different substance-related discussions under one Agenda item.	**SECR** to upload the adopted Agenda to the RAC CIRCA IG as a part of the RAC-10 minutes.
4. Adoption of RAC-9 Draft Minutes	
The minutes of RAC-9 (RAC/M/09/2010 draft final) was adopted without changes.	**SECR** to upload to the RAC CIRCA IG and the ECHA website the adopted minutes
5. Administrative issues and informal items	
5e Update on the financial arrangements for (co-) rapporteurs for restriction dossiers	
-	**SECR** to upload to RAC CIRCA IG relevant documents concerning the cooperation agreement between ECHA and MSCA after the meeting
6. Feedback from the MB decision on approval of RAC Rules of procedure	
Minority positions will be recorded in the minutes and in a separate document and made public at the same time with the opinion. Members with minority positions should provide them in writing to SECR.	
7. Requests according to Article 77(3)(c) of REACH	
7a. Final draft opinion on boric acid and its compounds in photographic applications	
RAC achieved a preliminary agreement on the text to reflect the conclusion of the opinion.	**Rapporteur and invited experts** to modify the draft opinion and BD according to the agreed conclusions by 1 April 2010

	SECR to organise an editorial round to end by 9 April 2010 followed by urgent written procedure for the adoption of the final draft opinion
7b. Framework for dealing with requests according to Article 77(3)(c) of REACH	
RAC agreed the revised Framework for dealing with requests according to Article 77(3) (c) of REACH with small modifications.	**SECR** to upload the final Framework to RAC CIRCA IG after the meeting.
8. CLH	
8.1 CLH Dossiers	
8.1a. Epoxiconazole	
RAC adopted by consensus the opinion for epoxiconazole subject to some editorial changes in the opinion and its annexes. RAC members agreed with the view of the rapporteurs on the harmonised classification on developmental toxicity: **Repr. Cat 2, R 61** (under Dir 67/548/EEC) or **Repr. 1B, H360Df** (under CLP Regulation). RAC also agreed on the approach for handling new studies received after the public consultation.	**Rapporteur** to include minor editorial changes in the adopted opinion and its annexes as soon as possible and to provide to SECR. **SECR** to upload the adopted opinion and its annexes to the RAC CIRCA IG and publish them on the ECHA web site after the meeting. **SECR** then to forward the adopted opinion and its annexes to COM without delay.
8.1b. Abamectin/Avermectin B1a	
RAC adopted by consensus the opinion and the background document for abamectin/avermectin B1a. RAC members agreed with the view of the rapporteurs to support the proposed classification and labelling for both substances: **Repr. Cat 3, R 63; T+, R26/28; T, R48/23/25; N; R50/53** (under Dir 67/548/EEC) or **Repr. 2; H361d; Acute Tox. 2, H300; Acute Tox. 1, H330; STOT-RE 1, H372** ("Causes damage to the nervous system through prolonged or repeated exposure")**, Aquatic Acute 1, H400; Aquatic Chronic 1, H410, M-factors: 10,000** (under CLP Regulation). RAC also agreed to include **Specific concentration limits,** as follows: **Cn ≥ 5%** for **T; R48/23** and **STOT-RE 1; H372** (Causes damage to the nervous system through prolonged or repeated exposure)**; 0.5% ≤ Cn <5%** for **Xn; R48/20** and **STOT-RE 2; H373** (May cause damage to the nervous system through prolonged or repeated exposure).	**SECR** to upload the adopted opinion and its annexes to the RAC CIRCA IG and publish them on the ECHA web site after the meeting. **SECR** to forward to COM the adopted opinion and its annexes after the meeting.

8.1c. Gallium arsenide	
RAC agreed to investigate the possibility for read across from the listed entries of arsenic compounds classified as carcinogenic category 1A in Annex VI of the CLP Regulation to GaAs.	**Rapporteurs** to revise the draft opinion and its annexes and send to SECR by 7 April 2010. **SECR** to organise a round of editorial comments after receiving the revised draft opinion from the rapporteurs and if possible to organise the adoption of the final draft opinion by written procedure or at RAC-11.
8.1d. Tetrahydrofuran	
Preliminary agreement was reached on the opinion and its annexes and on the harmonised classification as follows: **Carc. Cat 3, R40** (under Dir 67/548/EEC) **or Carc. 2, H351** (under CLP Regulation).	**Members** to provide any final editorial comments by 29 March 2010 in the existing CIRCA newsgroup. **Rapporteurs** to make a final edit of the documents **SECR** to organise the adoption of the final draft opinion by written procedure or at RAC-11.
8.1e. TDCP	
RAC reached preliminary agreement on the harmonised classification as follows: **Carc. Cat 3, R40** (under Dir 67/548/EEC) **or Carc. 2, H351** (under CLP Regulation). The rapporteurs' proposal, triggered by a comment in the public consultation (PC), for a harmonised classification of Repr. Cat 3, R60 (under Dir 67/548/EEC) or Repr. 2, H361f (under CLP Regulation) required further consideration. RAC acknowledged the concern for reprotox, but indicated a number of weaknesses in the evidence presented which may not be sufficient to support this C&L. A short reflection on the comment made in the public consultation will be included in the RCOM and/or BD.	**SECR** to upload presentation by the rapporteurs after the meeting. **Members** to provide any additional responses to the questions in the presentation by 26 March in the existing CIRCA newsgroup. **Rapporteurs** to revise the draft opinion and its annexes and complete the ORCOM by 12 April 2010. **SECR** to distribute the revised draft opinion and its annexes to RAC members for further discussion and possible adoption at RAC-11.
8.1f Leucomalachite Green – accordance check	
RAC took note on the feedback from the rapporteur's accordance check of this substance and agreed that the normal procedure should be applied also for Leucomalachite Green, one of the 87 substances with agreed classification by TC C&L.	**Rapporteur** to finalise the accordance check report for Leucomalachite Green by 26 March 2010 **SECR** to communicate the outcome of the accordance check to the dossier submitter after the receipt of the final accordance check report

8.2 Appointment of (co-) rapporteurs for CLH dossiers	
RAC agreed to appoint the volunteers as (co-) rapporteurs for the newly registered CLH intentions (see document RAC/10/2010/20)	**SECR** to upload in RAC CIRCA IG the updated status document to reflect RAC appointments for CLH proposals after the meeting. **Members** are requested to come forward for the remaining positions. **SECR** to identify potential (co-)rapporteurs and encourage them to fill the vacant positions.
8.3 General CLH Issues	
8.3a Templates for the CLH opinion and BD and Commission's feedback on RAC request	
RAC agreed that rapporteurs should consider having relatively concise opinions with provided summary of the argumentation and the detailed information provided in BD. However, differences may be needed on case-by-case basis. RAC considered that it is unpractical to try to keep track changes during the opinion-forming process. If there is a need for highlighting the changes in different versions this should be done by SECR.	**SECR** to upload the formal COM answer to RAC CIRCA IG, when received **SECR** to revise the templates for the CLH opinion and BD in the light of the received COM feedback after the meeting
8.3b Substances already agreed at TC C&L	
RAC took note on the COM need to have BD for each of these substances when submitted with clear argumentation in the opinion on the basis of the comparison with the CLP criteria as a starting point. Therefore, the normal CLH procedures for handling the dossier should be applied. However, RAC pointed out to the additional burden this will bring to RAC and the MS dossier submitters.	
8.3c Note H, hazard statements on reprotoxicity, justification for non-CMR&RS proposals	
RAC agreed with the editorial modification of the footnote related to Note H proposed by COM. RAC agreed that it should not evaluate the justifications for non-CMRs. However, RAC expressed concerns for their workload in case a proposal for non-CMRs would be rejected by COM only after the RAC opinion.	**SECR** to revise the accordance check report template to be in line with the received COM feedback after the meeting **SECR** to consult with COM on how and when the justification should be evaluated
8.3e Feedback from the Ad Hoc meeting for exchanging experience on accordance check for CLH dossiers	
	Members to provide their comments on the document RAC/10/2010/13 by 9 April 2010.

	SECR to revise the document and to organise a written procedure for its adoption by end of April 2010.
8.3f Handling a group of substances	
RAC agreed that rapporteurs should consider the need of formulating several opinions in the cases when a group of substances is handled and decide on it on case-by-case basis.	
9 Restrictions	
9.1 Report from the meeting of RAC and SEAC (co-)rapporteurs and ECHA Secretariat	
	SECR to upload to the RAC CIRCA IG the presentations and the documents relevant for processing of all future restriction Annex XV dossiers after the meeting
9.2. General restriction issues	
	SECR to provide the RAC restriction (co-) rapporteurs with their Annex XV dossiers as soon as they are submitted
10. RAC Manual of conclusions and recommendations	
RAC approved the outline of the RAC MoCR.	**SECR** to upload the RAC MoCR in the non-confidential section of the RAC CIRCA IG after the meeting.
11. Authorisation	
11a. Working procedure for the appointment of rapporteurs for applications for authorisations	
RAC agreed the revised Working procedure for the appointment of rapporteurs for applications for authorisations with a small modification.	**SECR** to upload the final WP in RAC CIRCA IG after the meeting
12. Guidance issues	
12b. Feedback from the RAC consultation on the CLH guidance document	
RAC supported the revised draft document subject to some editorial modifications. RAC also supported that SECR would perform the formal substance ID checking in parallel to the accordance check.	**Members** to send any final comments via the existing CIRCA newsgroup by 23 March. **SECR** to check the legal requirements for substance ID according to the CLP Regulation and revise the text accordingly **SECR** to upload the revised CLH report format

	to RAC CIRCA IG in due course **SECR** to modify the accordance check template after the meeting.
13 Any other business	
13a. RAC STO participation in the work of RAC	
RAC agreed that the full text of the draft minutes may be consulted with sector-specific STO observers according to the provisions of the Code of conduct for STO observers. RAC agreed that the regular and sector-specific STO observers are allowed to observe the RAC discussions via RAC CIRCA Newsgroups. RAC agreed that the sector-specific STO observers and observers accompanying regular or sector-specific observers are allowed to observe the plenary item on conclusions and action points when practically possible. RAC agreed to have the closed session minuted in the general publicly available RAC-10 minutes.	**SECR** to follow the RAC decisions when organising the STO observers' participation in the work of RAC.
GENERAL	
-	**SECR** to upload all presentations, room documents and the RAC-10 Main conclusions and action points (i.e. this doc) to RAC CIRCA IG by 22 March 2010.

Part III. List of Attendees

2. List of Attendees of the RAC-10 meeting (16-18 March 2010)

Members		**ECHA staff**
ANDERSSON Alicja		DANCET Geert
BARANSKI Boguslaw		DE BRUIJN Jack
BORGES Maria Teresa		FUHRMANN Anna
DI PROSPERO FANGHELLA Paola		HAUTAMÄKI Anne
DUNAUSKIENE Lina		HOLLINS Steve
DUNGEY Stephen		KARHU Elina
GREIM Helmut		KOKKOLA Leila
GRUIZ Katalin		KULJUKKA-RABB Terhi
HALKOVA Zhivka		LIPKOVA Adriana
JENSEN Frank		LUOTAMO Marita
KADIKIS Normunds		LUSCHÜTZKY Evita
LARSEN Poul Bo		NOUWEN Johan
LE CURIEUX-BELFOND Olivier		NYLUND Lars
LEINONEN Riitta		PEDERSEN Finn
LOSERT Annemarie		RÖCKE Timo
LUND Bert-Ove		SADAM Diana
NUNES Céu		SCHÖNING Gabriele
PICHARD Annick		TARAZONA Jose
POLAKOVICOVA Helena		VASILEVA Katya
PRONK Marja		YLÄ-MONONEN Leena
RUPPRICH Norbert		
SCHULTE Agnes		**Representatives of the Commission**
SMITH Andrew		GRODZKI Karola (DG ENTR)
STOLZENBERG Hans-Christian		ROZWADOWSKI Jacek (DG ENTR)
SULG Helen		WISTUBA Christine (DG ENV)
TADEO LLUCH José L.		
Van der HAGEN Marianne		**Stakeholder observers**
VAN MALDEREN Karen		ANNYS Erwin (CEFIC)
VILANOVA Eugenio		GELBKE Heinz-Peter (ECPA) (industry expert for epoxiconazole)
		MEISTERS Marie-Louise (ECETOC)
Replacements		TAYLOR Katy (ECEAE)
BREEN Alan (replacement of Thomasina Barron)		WAETERSCHOOT, Hugo (Eurometaux)
CONWAY Louise (replacement of Yvonne Mullooly)		
		Other observers
Advisers to the RAC members		BALL, Wayne (an observer accompanying the nominated observer representing Eurometaux for borates)
		LLOYD Sara (an observer accompanying the nominated observer representing ECPA
ALESSANDRELLI Maria (adviser to Paola DI PROSPERO)		

		for abamectin/avermectin B1a)
CRACZYK Anna (adviser to Boguslaw Baranski)		MICHEL Cécile (the representative of the French CA, the dossier submitter for THF and GaAs
DUSSART Aurélie (adviser to Karen van Malderen)		OHLSSON Agneta (the representative of the Swedish CA, the dossier submitter for epoxiconazole)
HASS Ulla (adviser to Poul Bo LARSEN)		STINCHCOMBE Stefan (BASF) (an observer accompanying the nominated observer representing ECPA for epoxiconazole)
HERREMANS Joke (adviser to Marja Pronk)		WETERINGS Peter (an observer accompanying the nominated observer representing CEFIC for TDCP)
LINDEMAN Birgitte (adviser to Marianne van der Hagen)		
MYÖHÄNEN Kirsi (adviser to Riitta Leinonen)		**Invited experts**
PASQUIER Elodie (adviser to Annick Pichard)		KINZL Max (invited expert for borates)
		NEISEL Friederike (invited expert for borates)

Part IV. LIST OF ANNEXES

ANNEX I. Final Agenda of the RAC-10 meeting

ANNEX II. List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-10 meeting

ANNEX I

16 March 2010
RAC/A/10/2010

Final Agenda

Tenth meeting of the Committee for Risk Assessment

16 – 18 March 2010

Helsinki, Finland

16 March: starts at 9:00
18 March: ends at 15:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/10/2010
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of RAC-9

- Adoption of the draft minutes

RAC/M/09/2010 draft final
For adoption

Item 5 – Administrative issues and information items

a. Status report on the RAC - 9 action points
b. Outcome of written procedures
c. Report from other ECHA bodies and activities

RAC/10/2010/18
ROOM DOCUMENT
For information

d. Feedback on the annual survey of members

RAC/10/2010/19
ROOM DOCUMENT

For information

e. Update on the financial arrangements for (co-) rapporteurs for restriction dossiers

For information

Item 6 – Feedback from the MB decision on approval of RAC Rules of procedure

- Handling minority positions

For discussion and decision

Item 7 – Requests according to Art 77(3)(c) of REACH

a. Final draft opinion on boric acid and its compounds in photographic applications

For adoption

b. Framework for dealing with requests according to Art 77(3)(c) of REACH

RAC/10/2010/12
For agreement

Item 8 – CLH

8.1 CLH Dossiers

a. Epoxiconazole

For adoption

b. Abamectin/Avermectin B1a

For discussion and possible adoption

c. Gallium arsenide

For discussion and possible adoption

d. Tetrahydrofuran

For discussion

e. TDCP

For discussion

f. Leucomalachite Green – accordance check

For discussion

8.2 Appointment of RAC (co-) rapporteurs for CLH dossiers

- Appointment of RAC (co-) rapporteurs for CLH dossiers

RAC/10/2010/20
ROOM DOCUMENT
For agreement

8.3 General CLH issues

a. Templates for the CLH opinion and BD and Commission's feedback on RAC request

b. Substances already agreed at TC C&L

c. Note H, hazard statements on reprotoxicity, justification for non-CMR&RS proposals

RAC/10/2010/22
ROOM DOCUMENT
For discussion

d. State of play of the submitted CLH dossiers

RAC/10/2010/21
ROOM DOCUMENT
For information

e. Feedback from the Ad Hoc meeting for exchanging experience on accordance check for CLH dossiers

RAC/10/2010/13
For discussion

f. Handling a group of substances

For discussion

Item 9 – Restrictions

9.1 Report from the meeting of RAC and SEAC (co-)rapporteurs and ECHA Secretariat

For information

9.2 General restriction issues

- Update on intended restriction dossiers

For information

Item 10 – RAC manual of conclusions and recommendations

- Revised RAC manual of conclusions and recommendations

RAC/10/2010/14& RAC/10/2010/15
For discussion and possible outline approval

Item 11 – Authorisation

a. Working procedure for the appointment of rapporteurs for applications for authorisations

RAC/10/2010/16&RAC/10/2010/17
For agreement

b. RAC role in the authorisation process

For information

Item 12 – Guidance issues

a. Feedback from the guidance update on the DNEL/DMEL derivation from human data

b. Feedback from the RAC consultation on the CLH guidance document

RAC/10/2010/23
ROOM DOCUMENT
For information

c. Report on other guidance activities

For information

Item 13 – Any other business

- STO participation in the work of RAC

For agreement

Item 14 – Main conclusions and Action Points of RAC-10

- Table with main conclusions and action points from RAC- 10

For adoption

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ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-10 meeting.

RAC/A/10/2010_rev1	Revised Draft Agenda – Tenth meeting of the Committee for Risk Assessment
RAC/M/09/2010	Minutes of the 9th meeting of the Committee for Risk Assessment – draft final
RAC/10/2010/18	Administrative issues and information items
RAC/10/2010/19	Feedback on the annual survey of members
RAC/09/2010/01	Framework for dealing with requests for opinions according to Article (77)(3)(c) of REACH
RAC/10/2010/12	Outline of the discussion on the classification of epoxiconazole for developmental toxicity at RAC-9
RAC/10/2010/20	Appointment of RAC (co-) rapporteurs for CLH dossiers
RAC/10/2010/22	Commission feedback on RAC requests related to general CLH issues
RAC/10/2010/21	Status report on submitted proposals for harmonised CLH
RAC/10/2010/13	Feedback from the Ad Hoc meeting for exchanging experience on accordance check for CLH dossiers
RAC/10/2010/14	Revised RAC manual of conclusions and recommendations
RAC/10/2010/15	ECHA Secretariat responses to RAC comments on proposed draft RAC manual of conclusions and recommendations (received orally at RAC-9 or in writing by 12 February 2010)
RAC/10/2010/16	Revised draft working procedure for the appointment of rapporteurs and co-rapporteurs by RAC for authorisation applications
RAC/10/2010/17	ECHA Secretariat responses to RAC comments on proposed draft working procedure for the appointment of rapporteurs and co-rapporteurs by RAC and SEAC for authorisation applications
RAC/10/2010/23	Feedback from the RAC consultation on the CLH guidance document

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