RAC/M/08/2009
FINAL

Minutes of the 8th meeting of the Committee for Risk Assessment (RAC)
(24 – 26 November 2009)

Part I Summary Record of the Proceedings

1. Welcome and apologies

Dr Jose Tarazona, Chair of the Committee for Risk Assessment, ECHA, welcomed participants to the meeting and introduced the new member of RAC from Czech Republic Marian Rucki.

Five advisers and five stakeholder representatives (from EEB, EUROMETAUX, CEFIC, ECPA and ETUC), representatives from the Commission (COM) and invited expert replacing the RAC member Paola Di Prospero were welcomed.

Apologies were received from four RAC members and four regular observers (from BUAV, ECETOC, HEAL and OECD). Two RAC members were absent. The list of attendees is given in Part III of these minutes.

Leila Kokkola, a new scientific assistant of the RAC secretariat, was introduced by the Chair.

RAC was informed of the resignation of two members (Roberto Mezzanotte and Jose Tarazona) since the 7th plenary meeting.

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

Revision 1 of 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. None were declared.

4 Outcome of written procedures and status report on the RAC-7 minutes

4a Outcome of written procedures and consultations

The Secretariat informed RAC of the outcomes of the launched written procedures, organised RAC consultations and calls for expression of interest launched in the period between RAC-7 and RAC-8 meetings. It was clarified that RAC had agreed 14 decisions via written procedures for appointment of RAC (co-) rapporteurs for submitted or intended dossiers proposing harmonised classification and labelling (CLH) or restriction; as well as for a request in relation to boric acid and its compounds according to Article 77(3)(c) of REACH; the establishment and agreement of the mandate of an *ad hoc* working group, supporting the rapporteur for this specific request; the appointment of RAC members in a Partner Expert Group to consider the draft updated guidance for the preparation of a CLH dossier and the adoption of the RAC-7 minutes.

Furthermore, RAC was informed of the written consultations that had been organised for the rapporteurs' draft opinions on five CLH proposals (on di-tert-butyl peroxide, indium phosphide, epoxiconazole, trixylyl phosphate and gallium arsenide) and some other consultations, including *inter alia*, access to confidential information of the Committee members, their advisers and invited experts; admission of new STO observers in the RAC work; admission of an industry expert to the RAC-8 discussion on epoxiconazole; the draft Rules of Procedures (RoPs) between ECHA, the Advisory Committee on the Safety, Hygiene and Health Protection at Work (ACSH) and the

Scientific Committee on Occupational Exposure Limits (SCOEL) and ECHA and European Food Safety Authority (EFSA).

The Secretariat reminded RAC of the ongoing consultation on the updated guidance on information requirements and chemical safety assessment (Chapter R.12) with the deadline of 4 December 2009.

The Secretariat also reported on the outcomes of the two calls for expression of interest for (co-) rapporteurship for the first three registered restriction intentions and for five new registered CLH intentions. Since further CLH intentions had been registered in the Registry of intentions after the initial preparation of the meeting document, the Secretariat presented them in the room document RAC/08/2009/55 and requested the members to consider possible (co-)rapporteurship and indicate their interest during the meeting.

4b Status report on the RAC-7 and SEAC-4 Action points and RAC-7 Action points (Parts I & II)

The Secretariat reported that all action points from RAC-7 and SEAC-4 joint session had been completed. The action points from the separate RAC-7 session had also been completed, with the exception of two outstanding issues that were in progress.

It was further clarified that due to some technical problems with the CIRCA newsgroups, the Secretariat did not consider it appropriate to establish such groups for collection of stakeholder comments for the ongoing RAC work. Therefore, the RAC stakeholder observers are recommended to provide their comments via the RAC functional mailbox.

5 Risk management options at Community level (Joint Session with SEAC)

The session was initiated with a presentation given by the Secretariat for the purpose of assessing Risk Management Options (RMO) (justification of restriction as most appropriate Community wide measure). Future tasks of members of RAC and SEAC with regards to reviewing the justification that a restriction was the most appropriate risk management solution were explained. An introduction was also given to explain which RMOs could be considered in such a review and on what basis the RMOs could be assessed. During the session two presentations on specific legislative areas with high relevance for risk reduction of chemicals were given to explain them in more detail and to illustrate their links to REACH: waste legislation was presented by Christine Wistuba (Directorate-General Environment, COM) and occupational health legislation (OHL) was presented by Christine Northage (Health and Safety Executive, UK). Commentaries to these presentations were provided by Cees Luttikhuizen (SEAC member) and Boguslaw Baranski (RAC member), respectively. It was emphasized that the description of RMOs in Annex XV needs to allow comparisons of the identified options in the light of their effectiveness, practicality and monitorability, and conclusions to be drawn about the proposed restriction (with defined scope and conditions) as the most appropriate Community wide measure.

6 Draft opinions for CLH dossiers

6a Epoxiconazole (CAS No. 133855-98-8; EC No. 406-850-2)

The dossier submitter proposes the following classification for epoxiconazole: reproductive toxicity category 1B – H360D (CLP Regulation) and Repr. Cat 2; R61 (Dangerous Substances Directive (DSD)).

The Chair welcomed for the discussion on epoxiconazole a representative from the European Crop Protection Association (ECPA) and an industry expert from BASF accompanying the ECPA and CEFIC representatives. RAC was also informed that the two representatives of the dossier submitter of this CLH proposal were prevented from participation in the discussion and sent their

apologies. Two documents from the industry representatives were distributed on an exceptional basis (and subsequently uploaded to the RAC CIRCA IG). However, the Chair emphasised that industry representatives, like other stakeholders, should in general, make their data and documents available during the public consultation, rather than at this late stage.

The rapporteur and their adviser presented an overview of the state of play and of the comments received from RAC members on the first draft opinion. The rapporteur stated that new studies had been received after the discussions at the Technical Committee for Classification and Labelling (TC C&L). However, in their view these new studies did not provide sufficient evidence to merit the classification proposed by the dossier submitter. The first draft opinion and background document (BD) had been prepared on this basis.

Comments from RAC members had focused on several aspects: the mechanism of action related to endocrine disruptor effects; the impact of the new studies on the foetotoxicity and teratogenicity; the question of the dystocia in relation to developmental toxicity and fertility; the comparison of the classification criteria under Directive 67/548/EEC and the CLP Regulation; and the lack of in depth evaluation of the new studies by previous groups. The rapporteur noted that the opinion, response to comments table and a supplementary note had been circulated in which each of these issues had been addressed.

The Chair summarised the proceedings thus far. A procedural discussion had taken place in a restricted session at RAC-7 in which it had been concluded that particular attention should be paid to the new studies that had occurred since the discussions at TC C&L. Subsequently, the comments on the rapporteur's first draft opinion had indicated a difference in the views of RAC members on whether to have an in depth evaluation of all of the available data for toxic to reproduction, the appropriate classification and the extent of the association between developmental and maternal toxicity. Given these differences, it was appropriate to discuss the way forward.

Several RAC Members reaffirmed the need to focus future discussions on the new studies, but a number of others highlighted the importance of considering the new studies together with the other data on reproductive toxicity presented in the dossier in a weight of evidence approach. The discussion then moved onto the most suitable way to consider all of the data, either in plenary, or first in a working group of RAC. A number of members supported the idea of establishing a working group to consider in depth the reproductive toxicity aspects outside of the RAC plenary. Others pointed out that because the discussion was likely to involve fundamental issues of interpretation, all RAC members would benefit from the discussion.

The Chair explained that a working group discussion would not replace a RAC plenary discussion but it might be useful to have an in depth consideration of the reproductive toxicity aspects and the classification criteria using epoxiconazole as case study, and allocating sufficient time for these discussions, e.g. outside of the plenary because of time constraints. After further discussion, it was agreed that an analysis of the reproductive toxicity data should take place in an *ad hoc* meeting associated to RAC-9. The *ad hoc* meeting would be open to all RAC members that wished to attend, their advisers, representatives of the dossier submitter, RAC stakeholders and their industry experts. It was also agreed the Secretariat would facilitate the organisation of the *ad hoc* meeting and it would take place alongside of the RAC-9 meeting. Members were to be invited to submit their questions and suggestions for discussion and any further comments on the interpretation of the available data by 14 December 2009. Documentation for the meeting, including an agenda, would be prepared jointly by the rapporteur and Secretariat and provided to participants by 11 January 2010.

6b Di-tert-butyl-peroxide (DTBP) (CAS No. 110-05-4; EC No. 203-733-6)

A representative of the dossier submitter from the French Competent Authority (CA) presented to RAC the original proposal for harmonised classification and labelling for DTBP explaining the reasons and the key study results led to it.

The rapporteurs for DTBP introduced to the committee the revised draft opinion, the rapporteurs' grounds for it, the comments received during the RAC consultation and the responses provided to these comments.

RAC agreed by consensus with the view of the rapporteurs to support the proposed classification and labelling for DTBP as **Muta. Cat 3, R68** (under Dir 67/548/EEC) and **Muta. 2, H341** (under CLP Regulation).

It was agreed that the Secretariat will organise a written procedure for adoption of the RAC opinion on the CLH proposal for DTBP after the meeting.

6c Indium phosphide (CAS No. 22398-80-7; EC No. 244-959-5)

A representative from the French CA introduced their CLH proposal of indium phosphide. The proposal was for specific target organ toxicity (STOT) repeated exposure category 1 – H372 (CLP) & T; R48/23 (DSD); reproductive toxicity category 2 – H361f (CLP) & Repr. Cat.3; R62 (DSD) and carcinogenicity 1B – H350 (CLP) & Carc. Cat.2; R45 (DSD) with a specific concentration limit (SCL) of 0.01%.

The rapporteurs introduced the first draft of their opinion and the comments from RAC members received thus far. They reported that there was a need for discussing the justifications for the proposed specific concentration limits (SCLs) for carcinogenicity and for STOT repeated exposure cat. 1.

Two general issues to be clarified were also noted by the rapporteurs. One was the use of either the hazard statement H361 or H361f. The other issue was the use of note H and whether this should appear in the RAC opinion. Note H had originally been proposed by the dossier submitter but then initially deleted by the rapporteurs for the purposes of the RAC opinion.

Members discussed the various issues raised by the rapporteurs. Concerning the SCL for carcinogenicity, some members expressed concerns for deriving a T25 value if a dose-response relationship is lacking. The rapporteur responded that unexpected high toxicity led to early discontinuation of dosing at the two highest doses, preventing the establishment of a dose-response, even though tumours were noted in all exposed dose groups. Other members proposed a weight of evidence approach in the BD to document that indium phosphide is a high potency carcinogen, but drawing attention to the limitations of the T25 values. After discussion it was agreed that the latter approach was agreed upon and the (co-) rapporteurs would incorporate the available evidence in the justification for a SCL of 0.01%. A discussion was also held on the SCL for STOT Rep. 1; the evidence was discussed and after several options had been considered, a proposal for the derivation of the SCL was agreed. The rapporteur agreed to revise the draft opinion and BD according to these discussions.

Concerning the hazard statement for reproductive toxicity, following the same arguments employed for other substances it was agreed to include the use of the hazard statement H361f in the opinion.

Concerning note H, it was pointed out there are a lot of substances in Annex VI that have this note already, but since RAC now has specific hazard classes to consider, it is for COM rather than for RAC to consider if and when note H should be applied. Some members suggested that it would be better to continue to include note H otherwise this may give a misleading signal to industry who may question whether its provisions still need to be applied. After discussion, it was agreed not to

include note H in the RAC opinion at this stage and that the Secretariat would clarify its usage with COM.

One member queried whether the hazard statement for STOT RE.1, H372, should refer to more organs than the main target organ, which is the lung in this case. It was mentioned that more guidance may be needed on how to select the organs that should be mentioned in the hazard statement. Also, the rapporteurs pointed out that their preference was to specify inhalation as the route of exposure as this would assist in the protection of the lung following inhalation exposure. The Secretariat explained that according to the CLP guidance, the route of exposure should be stated where *it is conclusively proven* that no other routes of exposure cause the hazard. But since there are no data for the oral or dermal route, it may not be conclusively proven that other routes of exposure do not cause the hazard (Toxicokinetic data in the BD indicated accumulation in the lung and liver after intraperitoneal administration). The rapporteur agreed to consider this matter further.

It was noted that the rapporteur(s) cannot modify the CLH dossier, as it is owned by the dossier submitter, although obviously the rapporteur may consider which information is relevant and should be included in the BD. In the end it would be up to the Commission to decide if the justification for classification proposals other hazard classes than CMR and respiratory sensitisation is sufficient. It was discussed however, whether the rapporteur(s) should or could revise the justification for harmonised classifications for hazard classes other than CMR and respiratory sensitisation. Additional information on this issue is required before a final decision could be taken. For the time being, it was suggested that for indium phosphide, the rapporteur together with the French CA, should revise the justification for a harmonised classification for repeated dose toxicity to include a reference to the substance being a "handover" compound from TC C&L.

The Chair thanked members for their useful input and asked the rapporteurs to revise their opinion and BD and to submit to the RAC Secretariat by 14 December 2009.

6d Trixylyl phosphate (TXP) (CAS No. 25155-23-1; EC No. 246-677-8)

The Chair invited the representative of the dossier submitter from the Dutch CA to introduce the members with the proposal for harmonised classification and labelling for TXP as an introduction to the discussion on this substance.

The rapporteur for TXP was asked to present their draft opinion and the considerations behind it. It was pointed out that although, the proposal is based on one combined study on repeated dose toxicity and reproduction/developmental toxicity only; the evidences for the adverse effects to the fertility are obvious. Instead, the data does not allow definite conclusion on developmental effects, but the rapporteurs' draft opinion is in favour of the proposed classification by the dossier submitter. RAC members agreed by consensus with the view of the rapporteurs to support the proposed classification for TXP, as **Repr Cat 2, R 60** (under Dir 67/548/EEC) and **Repr 1B** (under CLP Regulation).

The main discussion related to TXP was focused on the selection of the most appropriate hazard statement under the CLP Regulation: H360 (as suggested by the dossier submitter) or H360F (proposed by one of the rapporteurs) due to the clear need to communicate the hazards/ risks on fertility.

After clarification provided by the Secretariat on the way of interpretation of the criteria in the CLP Regulation and the Guidance on the application of the CLP criteria and a short discussion, RAC agreed to propose in the RAC opinion at this stage that TXP should be labelled with the hazard statement: **H360F** (under CLP Regulation) in order to highlight the observed effects on fertility. Considering the need for a general view on the implications of this labelling in line to the CLP criteria, some members and observers suggested the need for a clarification on this issue from

COM. It was agreed that for the time being, the Committee will include the letter when considered relevant, and will re-discuss this general issue if additional clarifications from the ECHA Secretariat and COM are provided.

The rapporteurs were requested to revise the opinion and the BD according to the discussion, and to include a justification for the proposed hazard statement according to the discussion.

The Secretariat agreed to consult COM about the issue of the use of hazard statements for reproductive toxicity and organize an informal consultation within RAC after having got clarity on the issue.

The Secretariat agreed to communicate the message to the relevant colleagues for a possible need for modification of the guidance on the application of the CLP criteria for clarification, consistency and better understanding of the interpretation of the CLP criteria in the CLP Regulation and the Guidance document with respect to the hazard statements for reproductive toxicity.

Furthermore, RAC agreed that the Secretariat will organise a written procedure for adoption of the RAC opinion on the CLH proposal for TXP after the opinion's revision.

6e Gallium arsenide (GaAs) (CAS No.1303-00-0; EC No. 215-114-8)

The rapporteurs introduced their first draft opinion in relation to the proposal from France for the CLH of GaAs. The proposed CLH was as follows: STOT Rep. 1 – H372 (CLP) & T; R48/23 (DSD); toxic for reproduction 1B – H360F (CLP) & Repr. Cat 2; R60 (DSD) and carcinogenicity 2 – H351 (CLP) & Carc. Cat 3 R40 (DSD).

On the basis of the first review of the dossier and comments received from RAC members several outstanding issues remained to be further clarified. Concerning the proposal for STOT Rep. 1, more detailed information on dose levels inducing organ toxicity was to be included and compared to the guidance values for assigning the correct classification. The rapporteur noted that the effects on fertility as presented in the dossier were considered to be a primary, rather than a secondary effect. In addition, further text was to be provided in the BD on general systemic toxicity.

The proposal for H351 had received particular attention from the rapporteurs and RAC members. The rapporteurs reported that the International Agency for Research on Cancer (IARC) had concluded that GaAs is carcinogenic to humans (Group 1) based upon the release of gallium (Ga) and arsenic (As) moieties. However, the limited data presented in the dossier was in animals and the relevance of the arsenic moiety to the carcinogenicity of GaAs remained unclear. Data in the dossier indicated low solubility of GaAs in water, but following *in vivo* exposure of test animals to GaAs, both Ga and As had been detected in blood and urine. It was also reported that the presence of testicular effects from Ga is an indication for the bioavailability of the As moiety and hence possible carcinogenic effects in humans. The rapporteurs also noted that a group entry for arsenic compounds exists in Annex VI and it was unclear whether the other hazard classes should be included in the classification for GaAs.

RAC members discussed the first proposals from the rapporteurs. Members shared the concerns of the rapporteurs about uncertainties associated with the basis for carcinogenicity in humans and whether an upgrading of 1B could be assigned to GaAs. Some members noted that all of the available data should be considered. Others argued that read across from human data must be based upon GaAs data rather than the arsenic moiety and extrapolation to humans from the reported animal toxicokinetics was unsound. RAC agreed that more information was necessary before a classification of the carcinogenicity hazard class could be performed.

Concerning the group entry for arsenic compounds, one member noted that the current group entry does not contain the carcinogenicity hazard class. In general it was agreed to further explore questions relating to the group and specific entries with the dossier submitter.

Another interesting question discussed by RAC was to what extent the rapporteurs should amend and change the BD, as assessing the carcinogenicity of GaAs using read-across to arsenic and other arsenic compounds should not be rapporteurs' task, as this would require a huge workload and also probably a second public consultation.

The Chair thanked the rapporteurs for their presentation and concluded that the Secretariat should approach the dossier submitter to determine whether RAC should continue to process the dossier in its current form, or whether they would like to modify the proposal to include additional information on the possible effects of GaAs in relation to human carcinogenicity. In the light of proceedings at CARACAL-3, the Secretariat would also clarify the view of the dossier submitter in relation to the additional hazard classes specified for the group entry for arsenic compounds and inform the rapporteurs about the outcome of this enquiry. The rapporteurs would then continue with the preparation of a revised opinion and an opinion response to comments document (ORCOM), when appropriate.

7 General CLH issues

7a Feedback from the Commission on the DAT opinion

The Chair informed RAC of some details of COM's note with feedback on the DAT CLH opinion, relevant for the work of the Committee. It was clarified that the note was not related to the RAC conclusion but to the information submitted by ECHA to COM after the adoption of the RAC opinion. However, in order to facilitate the COM's decision-making process, the Secretariat suggested some additions to the structure of the CLH opinion template, with a summary of the justification with scientific grounds to be provided with the opinion, as well as with the BD. In addition, it was mentioned about the Secretariat's problems with the RCOM, as during the public consultations, the parties concerned instead of using the web form for commenting, attach their comments in pdf documents that create a lot of additional work for the Secretariat.

Some members also expressed their views on the structure and content of the CLH opinion template and the BD, the focus of the rapporteurs' work, as comparison of the data with the criteria and assessment of the evidences in a CLH proposal and the amount of the additional work for the rapporteurs, in particular in developing the BD as a tracking document.

The Secretariat confirmed that different views are possible on the type of the BD, but in next few years, when full IUCLID-5 dossiers are provided and robust study summaries are available, the size of the CLH report and rapporteurs' work will be reduced. It was agreed to distribute the revised opinion template to the rapporteurs for their consideration when revising the opinions.

Some rapporteurs raised the issue of the importance of the whole RAC participation in the opinion consultation at an early stage and the need for common approach on the late coming data submitted by parties concerned after the public consultation. RAC agreed on the way of dealing with the late comments, as RAC has no obligation to consider them- it was agreed that the Secretariat will consult with the rapporteurs and the rapporteurs and will only distribute the late coming data to RAC if the rapporteur considers that this is needed. The Chair requested the RAC stakeholder observers to remind once more to the organisations they are representing, the need for submitting all relevant information exclusively during the public consultation period.

7b Feedback from the last CARACAL meeting

The Secretariat presented feedback from the third meeting of the competent authorities for REACH and CLP held on 13 October 2009. The main discussion issues were related to COM's document on the

scope of the harmonised classification and labelling when CLH proposals are based on the impurities or not proposing classification and the need for group entries in Annex VI. Some of the important conclusions of these discussions were that substances with classification on the basis of constituents should be included in the C&L inventory, including the reasons for the inventory; priority in the CLH process should be given to the substances that fulfil the criteria in Annex I for carcinogenicity, mutagenicity and reproductive toxicity and respiratory sensitisation (CMR & RS), i.e. not to substances classified due to presence of CMR constituents; C&L of group entries should be checked for each entry separately.

Furthermore, COM has been requested to continue the further development of the aspects on classification of mixtures and substances with unknown or variable composition or with biological origin (UVCB), on the classification and labelling of individual entries covered by a group entry.

7c Standard phrases for opinions relating to biocide and PPP dossiers

The Chair presented to the Committee document RAC/08/2009/48 with the Secretariat's proposal for standard phrases in RAC opinions on the proposed harmonised classification of active substances used in biocidal products and plant protection products clarifying that the idea is to facilitate the work of rapporteurs, as for Plant Protection Products (PPP) and Biocide Directive Products (BDP) RAC should produce opinion based on all hazard classes. After a short discussion, RAC agreed that this information should come from the Member State dossier submitter as part of the argumentation of their proposals and recommended to the Secretariat to communicate this need to the Member State Competent Authorities (MSCAs).

7d RAC statement for the public consultation of TC C&L substances

The Secretariat presented document RAC/08/2009/49 explaining that based upon the RAC decision taken at RAC-7 on the way of dealing with the 87 substances with previously agreed classification and labelling from the TC C&L, a RAC statement for the purposes of the public consultation was developed with a clarification that only new data for these substances will be considered by RAC. The document had been consulted with RAC and the comments received taken into account and reflected in the text.

RAC agreed the document with minor modifications and recommended the Secretariat uses the statement when launching a public consultation for any of the TC C&L substances, when appropriate.

7e State of play of the submitted CLH dossiers

The Secretariat reported on the state of play of the submitted CLH dossiers and registered intentions by the date of the meeting, including new information which has become available since the status report (document RAC/08/2009/50) had been distributed.

Following comments received from some rapporteurs for the submitted dossiers, members were queried whether they consider a need for discussion and revision of the accordance check procedure in the light of the lessons learnt with the accordance checks performed.

Most of the RAC active rapporteurs responded in principle positively on the question, some indicating a need for collecting more experience with the accordance checks before having such a discussion.

The Secretariat pointed out that the members will be provided with the most recent information after the meeting via RAC CIRCA IG in an update of the status document referred to under item 10b of the Agenda.

8 Working groups

Discussion paper on the potential establishment of RAC working groups in the field of human health hazard assessment

The Secretariat introduced RAC with the document RAC/08/2009/51 explaining that the purpose of the discussion is to collect first members' views on the need, the type and the timeframe for potential establishment of RAC working groups (WG) in the field of the human health hazard assessment in the light of the anticipated workload coming from the three main REACH processes where RAC is involved and potential requests from the Executive Director (ED). It was clarified that according to the legal requirements, a RAC WG is not an independent group of experts and could not be established without RAC members' participation. Moreover, there is no opportunity for delegating the adoption of RAC opinions to any WG. The mandate and composition of the WGs must be adopted by RAC; subgroups within the WG can also be established when needed.

One RAC member asked the Secretariat to collect preliminary information on the proportion of the total number of the expected CLH proposals and expected CMR dossiers and to inform the Committee of the estimations at RAC-9.

Some other members expressed the view that it is much more important for RAC as a scientific committee to find a way to share the work more equally in-between the members or to consider how to expand the expertise of the current committee, instead of searching for other more complex options. The alternative for *ad hoc* WGs, to be established according to the RAC Rules of Procedure, was considered sufficient for the current work load. Based on current experiences, the issue can be re-opened in the future when appropriate and needs appear.

COM also expressed the view that they were in favour of establishing, when needed and if appropriate, of *ad hoc* WGs on case-by-case basis.

Finally, it was considered that that there are no current needs for considering the establishment of generic RAC WGs or sub-WGs on this issue. Depending on the workload, the creation of *ad hoc* groups will be considered whenever needed and the discussion on more generic WG may be re-opened, when appropriate.

9 Request according to Art 77(3) (c) in relation to boric acid and borates

The Secretariat presented the background to the Article 77(3)(c) request. Following the adoption of the 1st ATP to the CLP Regulation, some 500 substances were newly classified as CMR (Cat 1A and B) substances. COM is currently preparing an amendment to Annex XVII of REACH to restrict the placing on the market of these substances for supply to the general public. The proposed amendment includes derogation for boric acid and some of its compounds for use in developers, fixers, bleaches and ancillary chemicals for use in wet processing of sensitised photographic films, plates, papers and related media. This derogation was based on data provided by industry at a late stage of the process and had been qualitatively evaluated by the Member State responsible for the risk assessment review under the Existing Substances Regulation[1].

To get an additional and urgent opinion, COM had asked ECHA (20 October 2009) to review and evaluate whether the consumer use of boric compounds in photographic applications poses a risk to consumers that is not adequately controlled. If a risk is identified, RAC was to indicate additional measures to reduce the possible risk to consumers.

[1] Council Regulation EEC No. 793/93 on the evaluation and control of the risks of existing substances; OJ L84/1 of 5.4.93.

The Secretariat introduced the RAC Work Plan (room document RAC/08/2009/54) which has been drawn up following the request to RAC ('the RAC mandate') by the ED of ECHA on 28 October 2009 to prepare an opinion to respond to the Commission's request. It was explained that in the absence of RAC working procedures to handle such requests, the most relevant elements of existing working procedures had been applied. Accordingly, one of the RAC members had been appointed as a rapporteur and an *ad hoc* working group had been established to provide drafting support to the rapporteur. The mandate of the *ad hoc* working group specified the composition, terms of reference and timeline for its activities. A draft opinion template had also been prepared that was under discussion with the Commission. The Work Plan foresaw the adoption of the RAC opinion at RAC-9 and for ECHA to respond to COM in early February 2010.

A RAC invited expert that was a member of the *ad hoc* working group presented a first appraisal of the exposure to consumers from boron via photographic applications. The presentation included additional data that had been provided by industry based on a questionnaire prepared by the rapporteur and the invited expert.

Members discussed the presentations and noted the need to consider in the exposure assessment the possibility of repeated and cumulative exposure which would include exposure, other than during the preparation of the solution. It was also underlined that the exposure assessment should also be based on the *reasonable worst case scenario*, rather than accidental exposure. In order to be ready to consider the rapporteur's draft opinion, RAC members requested that the first appraisal of the exposure data be uploaded to the RAC CIRCA IG. Several members indicated the Commission had proposed a very tight time frame for a response from ECHA. The Secretariat agreed and hence had proposed to the Commission that RAC would provide its opinion in a more workable timeframe i.e. by 1 February 2010.

Three further RAC members expressed an interest to participate in the *ad hoc* working group and another member proposed an additional invited expert. RAC agreed to their inclusion and agreed to the Work Plan, as revised, to include the additional participants. The Secretariat was to upload the revised work plan to the RAC CIRCA IG after the meeting.

10 Agreement of RAC (co-) rapporteurs for intended restriction and CLH dossiers

10a Recommendation to RAC on the appointment of (co-) rapporteurs for Annex XV restriction dossiers: phenylmercury compounds, dimethylfumarate and lead and its compounds in jewellery

The Secretariat introduced document RAC/08/2009/52 which included the first three intentions for restriction dossiers, their expected submission dates as notified to the Agency and recorded in the registry of intentions and the recommendation of the Chair for (co-) rapporteurs. RAC agreed the document and the recommended (co-) rapporteurs were appointed.

The Secretariat undertook to upload to the RAC CIRCA IG a status document to reflect the appointments after the meeting.

10b Recommendation to RAC on the appointment of (co-) rapporteurs for CLH dossiers

The Secretariat introduced document RAC/08/2009/55 (distributed as a room document) including new intentions for CLH proposals with expected submission dates as registered in the Registry of intentions (RoI) and provided more details on the expected CLH hazard classes. Members were requested to volunteer for (co-) rapporteurship.

RAC agreed to appoint as rapporteurs and co-rapporteurs for these new intentions identified candidates who expressed their interest prior to or during the meeting.

As two vacant positions for a rapporteur and for a co-rapporteur remained, the Secretariat was requested to identify the appropriate members with expertise in the human health field and to encourage them to volunteer these positions.

The Secretariat undertook to update and upload to the RAC CIRCA IG the status document, listing the appointed rapporteurs and co-rapporteurs for all submitted and intended dossiers.

11 Authorisation

11a Introduction to authorisation process

The Secretariat presented an overview of the authorisation procedure, authorisation applications and decisions and introduced the preparations needed to process authorisation applications.

RAC and SEAC were to be involved at the application for authorisation phase of the procedure and it was recalled that authorisations were substance, use and supply chain-specific. Applications for authorisations must include a chemical safety report, an analysis of the alternatives and a substitution plan where the analysis of alternatives shows that suitable alternatives are available and may include Socio-economic analysis and justification for not covering certain risks. RAC has ten months to prepare its draft opinion from the date of receipt of the application and the clock did not stop, once started. During this period RAC was required to assess the risks to health and/or environment from use(s) of the substance, including the appropriateness and effectiveness of the risk management measures and, if relevant, of risks arising from possible alternatives. The opinion must provide a solid basis for COM to decide whether or not to grant an authorisation for the use(s) applied for and to set a time-limited review period and, where necessary, conditions.

It was further explained that applications for authorisation may arrive as early as mid 2010 (i.e. once the first update of Annex XIV of REACH is adopted by COM and published in the Official Journal) and up to mid 2012 (i.e. the first application date as proposed by ECHA in its first Annex XIV recommendation to COM). It was therefore the Secretariat's target to have procedures and supporting documents in place by mid 2010. In discussion after the presentation, one of the RAC stakeholder observers indicated that EU based (chemical) industry may submit applications for up to five substances, out of the seven which were recommended by ECHA to COM and that may potentially be listed in the first Annex XIV, by mid 2010; however, given the restricted number of uses and companies involved, the total number of applications was likely to be limited.

11b Preparation for handling authorisation applications

The Secretariat presented document RAC/08/2009/53 which elaborated on the preparations for handling applications for authorisation by RAC and SEAC. It was explained that these preparations were likely to include: a working procedure for appointing a rapporteur; rapporteur's terms of reference; the procedure for conformity checks; the procedure for developing the RAC and SEAC opinions; and the format of the RAC and SEAC opinions. Discussions on these procedural aspects were likely to commence at RAC-9.

12 RAC consultations on guidance documents

12a Process for updating the guidance document for the preparation of a CLH dossier

The process and state of play of the update of the guidance for the preparation of CLH dossiers was described by the Secretariat. The update of the draft guidance was currently being considered in the Partner Expert Group (PEG). This is the first step of the consultation process and preceding the formal consultation of RAC which is likely to take place in January 2010. Publication of the updated guidance is expected in April 2010, assuming a favourable opinion by CARACAL in March 2010.

RAC is considered a key customer of this guidance document, since CLH dossiers would be received and opinions drawn up on the basis of the guidance and the suggestions therein. The Secretariat explained that where possible, issues that had already arisen during earlier RAC discussions on CLH dossiers had already been included during the drafting stage of the guidance document.

Two RAC members participated in the ongoing PEG consultation. One of these members gave a short presentation and the other member provided a summary document of the issues arising from this work. One of these members sought clarification of how and when to exchange ideas with other RAC members whilst they were participating in the PEG. Both members set out a number of specific issues in the draft guidance for the consideration of RAC.

A discussion followed in which RAC supported the participation of RAC-members in the consultation of the PEG to identify issues of potential concern, in order to be ready for the formal RAC consultation step of the procedure. The Chair thanked the two members for their work thus far. He confirmed that RAC participants in the PEG are not acting as representatives of the whole Committee, but as individual experts nominated through RAC. They are expected to share two roles, one as independent experts acting in their own capacity and second for detecting issues particularly relevant to RAC in order to facilitate the future consultation of the Committee on the draft guidance. Regarding this second role, the main activity is to inform other RAC members on the key issues with potential relevance for RAC arsing in the draft guidance, in order to facilitate the formal RAC consultation. In exceptional circumstances, RAC members participating in a PEG may inform the RAC Secretariat of issues of high potential concern; then the Secretariat will clarify these issues prior to the formal RAC consultation.

12b Future consultations on other guidance documents

Forthcoming consultations for other guidance documents and their likely timings were presented by the Secretariat. Of particular interest were the guidance documents on open issues in relation to the CLP Regulation (PEG consultation Q2, 2010); the update to the guidance on Annex V (exemptions from registration obligations in accordance with Article 2(7)(b) of REACH (Q4, 2009/Q1, 2010); the guidance on waste and recovered substances (PEG consultation Q1, 2010); and various updates to the guidance on the chemical safety assessment and information requirements (CSA & IR), including the use descriptor system (see section 12c) (PEG consultation Q4, 2009 – Q1, 2010).

12c Update of the CSA & IR guidance (chapter 12 – use descriptor system)

The Secretariat presented an overview of the draft updated Chapter 12 to the ECHA guidance on CSA & IR. It was explained that under REACH, each manufacturer and importer of substances which require an exposure assessment would have to develop, assess and communicate the exposure scenario covering the life cycle of their substances. For this purpose uses of the substance needed to be mapped out and the use descriptor system standardised the description of the use of substances.

The updated guidance now included, *inter alia*, an environmental descriptor, a systematic explanation of the six different ways employed in the guidance for listing uses, an explanation of the application of the use descriptor system in particular situations and some modifications to the use descriptor system itself. The update was to take into account experience through use since its first publication in spring 2008 and to align it with ECHA's CSA tool, Chesar (Chemical Safety Assessment and Reporting tool). Chesar was to include a use description module, which provided a standard life-cycle tree structure to map the uses of a substance. It was currently in the testing phase and a first version was expected to be released in February 2010.

RAC members had received the draft updated guidance and were invited to send any comments to the RAC CIRCA IG newsgroup by 4 December.

13 Report from other ECHA bodies

Report from meetings of the Management Board, SEAC, Forum and MSC

The Secretariat briefly reported from the last meeting of the ECHA Management Board (MB) held in September 2009. In its meeting, the MB discussed the ECHA REACH-IT security policy, in the light of the MSCA access to confidential information and agreed on it by written procedure. The ED had reported on the ongoing ECHA activities, including the Committees' activities. The Work Programme for 2010 was adopted and published after the meeting on the ECHA website. The MB agreed with an Amendment of the ECHA Reimbursement Guide having direct influence to the Committees members' practical arrangements for their meeting participation.

The Chair of the MSC gave a report from the MSC-9 meeting held in October 2009 and informed RAC of the ongoing preparation for the MSC-10 meeting scheduled for the beginning of December 2009. During the last meeting, MSC had a discussion on the second set of 15 Annex XV dossiers proposing substances for identification as substances of very high concern (SVHC). For all dossiers the public consultation has been completed, as one substance goes to the candidate list directly, as there are no comments received for it. Furthermore, MSC should take decisions with unanimous agreement on the other 14 substances based on their intrinsic properties. When unanimous agreement is reached ECHA shall include the substances in the Candidate List. If MSC fails to find unanimous agreement the issue is transferred to the Commission which will make a proposal for the REACH Committee on inclusion of a substance on the Candidate List. In addition, at their December meeting, MSC is expected to seek unanimous agreement on the first ECHA's draft decision on a testing proposal included in a registration dossier.

A brief report was provided from the 3rd CARACAL meeting held in October 09. The Secretariat informed RAC of COM's explanation on their Work plan for restrictions in transitional phase, clarifying that recently ECHA has been requested to prepare an Annex XV dossier proposing restriction of mercury in the measuring devices and to review the current restriction on phthalates. It was mentioned also that in the beginning of 2010, COM may ask ECHA to prepare an Annex XV restriction dossier for PFOA. RAC had already been requested to formulate an opinion on the use of boric acid and borates in the photographic applications, according to Article 77 (3)(c) of the REACH Regulation.

The Chair of the SEAC provided RAC with feedback from the semi-parallel SEAC-5 meeting. During its meeting, SEAC agreed to appoint rapporteurs and co-rapporteurs for the three intended restriction dossiers, as for the new intention on mercury in measuring devices, a call for expression of interest for (co-) rapporteurship will be organised. The Committee agreed also the revised SEAC Rules of Procedure with a key modification - a provision for establishing of joint RAC & SEAC WGs. A discussion on the framework for dealing with request for Art.77 (3) was taken place. SEAC was also informed of the outcome of the consultation on the document of the Committees' access to the confidential information. An authorisation session was organised for SEAC, similar to the RAC's one, with discussions on the authorisation process and on the assessment of the exposure for potential applications per use.

Finally, after brief introduction of herself, the new team leader and the former Forum Chair reported on the last Forum activities, relevant for the work of RAC. The established Working Group on restriction had its first meeting in mid-October where it had discussed the Forum working procedures for providing advice on a restriction proposal. Although there are no proposals submitted yet, the WG preparation is ongoing, as the first Annex XV dossiers proposing restrictions are expected in mid-April 2010.

14 Co-operation with other Community bodies

14a Report of the fifth meeting of the Chairs of EU bodies involved in risk assessment (18-19 November 2009)

The Chair presented to RAC feedback from the 5th meeting of the Chairs and the Secretariats of Scientific Committees and Panels involved in risk assessment. Key issues that were addressed at this meeting were a review of emerging risks with sessions in nanomaterials and synthetic biology, as well as a separate session on alternative methods and the ongoing projects of the European Center for the Validation of Alternative Methods (ECVAM) as the coordinator body for these activities at the EU level. RAC was informed of the Secretariat's intention to investigate further the possibility for involving RAC members in these activities, and particularly on the three inter-session preparatory working groups.

14b Report on the issues arising during the consultation on the draft rules of procedure for co-operation between ECHA and EFSA and ACSH and SCOEL

The Secretariat reminded members that at the Joint Session of RAC-7, an overview had been given of the REACH requirements for rules of procedure (RoPs) to establish the lines of co-operation between ECHA and EFSA, ACSH and with SCOEL. In particular, these RoPs were aimed at sharing information between these EU bodies, avoiding conflicts of opinions and to put in place a resolution mechanism where a conflict of opinion had been identified.

The Secretariat had drafted the RoPs and RAC had been consulted on them in October 2009. Several comments had been received and these were to be passed onto the drafting team for their consideration. It was reported that the ECHA/EFSA RoPs were to be considered for approval at the December meeting of the ECHA MB, but the other RoPs were likely to progress over a longer time period and in a more stepwise approach.

15 Any other business

15a Admission of experts supporting RAC stakeholders

The Chair informed the Committee that the admission of experts supporting RAC stakeholders will be covered with the revision of the procedure for the stakeholder participation in the work of RAC scheduled for RAC-9.

15b Revision of the rules for reimbursement

The Secretariat introduced to RAC the most recent changes to the revised ECHA Rules for Reimbursement which had an impact on the members' meeting participation. Members were reminded that the deadlines for their practical arrangements must be respected.

15c Annual survey

The Secretariat provided a preview to the meeting participants of a forthcoming annual survey and highlighted its importance as an indicator for measuring the members' satisfaction with the Secretariat's support and for identifying the key elements requiring improvement in the services provided by the Secretariat.

16 Main conclusions and Action points of RAC-8

The Secretariat presented the main conclusions and action points of the RAC-8 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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Part III. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
(Adopted at the eighth meeting of RAC)
(24-26 November 2009)

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The Agenda (RAC/A/08/2009_rev.1) was adopted without any changes. No declarations of conflict of interest declared.	**SECR** to upload the adopted Agenda to the RAC CIRCA IG as a part of the RAC-8 minutes.
5. Risk management options at Community level (Joint Session with SEAC)	
Discussion on the Occupational Health Legislation at the EU level is planned for the RAC-9 meeting.	**SECR** to upload to the RAC CIRCA IG the CARACAL document on waste and recovered substances after the meeting and other relevant RMO documents in due course
6. Draft opinions for CLH dossiers	
6a. Epoxiconazole	
After discussion, RAC concluded that there is a need for more detailed re-evaluation on the provided data on reprotoxicity and developmental effects with focus on the new studies but also considering the previous ones. For this purpose, RAC agreed to have a one day informal meeting back-to-back to RAC-9 on 25 January 2010 for more detailed discussion. RAC agreed that the informal meeting is open also to the interested advisers and observers.	**Members** to send to the SECR their questions and suggestions for discussion on the CLH proposal for epoxiconazole by 14 December 2009. **Members** to provide specific comments on interpretation of the data to the rapporteur by 14 December 2009. **SECR** to compile the questions and to forward the table to the rapporteur for response and structuring the discussion by 18 December 2009. **SECR** to distribute to all members the documents provided by the rapporteur relevant for this substance-related discussion by 11 January 2010. **SECR\RAPP** to prepare the Agenda for the January meeting on epoxiconazole.
6b. Trixylyl phosphate	
RAC members agreed by consensus with the view of the rapporteurs to support the proposed	**Rapporteurs** to revise the draft RAC opinion and the BD, following the conclusions of the

classification for trixylyl phosphate, as **Repr. Cat 2, R 60** (under Dir 67/548/EEC) **or Repr 1B** (under CLP Regulation). RAC agreed to propose the substance to be in addition labelled with the following hazard statement: **H360F** (under CLP Regulation).	RAC discussion and to submit them to the SECR by **7 December 2009** **SECR** to organise informal RAC consultation for final editorial comments by **10 December 2009** **SECR** to organise a written procedure for adoption of the CLH opinion on trixylyl phosphate by **18 December 2009** **Members** to respond **within the deadline specified with the written procedure** (NB: quorum of at least 60% required – minimum 22 members to respond)
6c. Indium phosphide	
RAC members agreed by consensus with the view of the rapporteurs to support the proposed classification for indium phosphide, as **Carc. Cat2, R45; Repr. Cat 3, R 62; T, R48/23** (under Dir 67/548/EEC) **or Carc. 1B, H350; Repr 2; H361f; STOT Rep.1, H372** (under CLP Regulation) with appropriate specific concentration limits.	**SECR** to clarify with the Commission the use of Note H and to inform RAC of this in due course. **Rapporteurs** to revise the draft RAC opinion and draft BD, following the RAC discussion and to submit them to the SECR by **14 December 2009.**
6d. Di-tert-butyl peroxide (DTBP)	
RAC members agreed by consensus with the view of the rapporteurs to support the proposed classification and labelling for DTBP, as **Muta. Cat 3, R68** (under Dir 67/548/EEC) **or Muta. 2, H341** (under CLP Regulation).	**SECR** to organise a written procedure for adoption of the CLH opinion on DTBP by **8 December 2009** **Members** to respond **within the deadline specified with the written procedure**.
6e. Gallium arsenide	
RAC discussed if the current CLH report contains enough information for read-across of the human data as presented in the IARC Monograph on gallium arsenide. RAC concluded that the dossier did not include all the available data pertinent to the carcinogenicity classification RAC concluded that the CARACAL document related to the group entries is also relevant for this dossier	**SECR** to approach the dossier submitter for their intention to continue or modify the present dossier. **SECR** to inform the rapporteurs after the response of the dossier submitter. **Rapporteurs** will provide revised opinion, BD and also the ORCOM depending on the outcome of the dialogue with the dossier submitter.
7. General CLH issues	
7a. Feedback from the Commission on the DAT opinion	
Rapporteurs have been recommended to use the revised template for a CLH opinion modified according to the Commission's recommendations.	**SECR** to consult the revised template for a RAC CLH opinion and the BD with the relevant Commission services after the

RAC agreed on the way of dealing with the late comments submitted by parties concerned after the public consultation; RAC is not obliged to consider them; however the rapporteur may decide how to deal with them.	meeting.
7c. Standard phrases for opinions relating to biocide and PPP dossiers	
-	**SECR** to inform the MSCA that a justification for non-classification (lack of data or data do not require classification) to be included in the dossier
7d. RAC statement for the public consultation of TC C&L substances	
RAC agreed on the statement in document RAC/08/2009/49 with minor changes for the public consultation of the 87 substances which were previously agreed C&L by TC C&L.	**SECR** to upload the final version of the RAC statement after the meeting; the statement will be used when launching a public consultation for any of the TC C&L substances, when appropriate.
8. Working groups	
After discussion, RAC concluded that there are no current needs and this discussion may be re-opened, when appropriate	-
9. Request according to Art 77(3)(c) in relation to boric acid and borates	
RAC agreed the Work Plan (room document RAC/08/2009/54), as proposed by the Secretariat. RAC agreed that the opinion needs to justify the exposure assessment and demonstrate that the reasonable worst case scenario is considered in the opinion. RAC agreed to invite Dr. Frederike Neisel to join the *Ad hoc* WG as an invited expert. RAC members were invited to join the *Ad hoc* WG in addition to those who already had been identified. Olivier Le Curieux-Belfond and Maria Teresa Borges volunteered and RAC agreed their participation.	**Members** to provide comments to the rapporteur and the SECR immediately due to the urgency of the case. **SECR** to invite Dr. Neisel as an invited expert to participate in the *Ad hoc* WG **SECR** to provide the members with exposure data provided by the Rapporteur as upload them to the RAC CIRCA IG.
10. Appointment of RAC (co-) rapporteurs for intended restriction and CLH dossiers	
10a. Recommendation to RAC on the appointment of (co-) rapporteurs for Annex XV restriction dossiers: phenylmercury compounds, dimethylfumarate and lead and its compounds in jewellery	
RAC took note on the document RAC/08/2009/52 and agreed to appoint the volunteering RAC members as RAC rapporteurs for the expected Annex XV restriction dossiers.	**SECR** to upload in the RAC CIRCA IG a status document to reflect RAC appointments for restriction dossiers after the meeting.

10b. Appointment of (co-) rapporteurs for intended CLH dossiers	
RAC agreed to appoint the rapporteurs for all newly registered CLH intentions and co-rapporteurs for some of them (see document RAC/08/2009/55_rev1)	**SECR** to upload in RAC CIRCA IG the updated status document to reflect RAC appointments for CLH proposals after the meeting. **SECR** to identify potential rapporteurs and encourage them to fill the vacant positions.
12. RAC consultations on guidance documents	
12c. Update of the CSA and IR Guidance (Chapter 12)	
-	**Members** are requested to provide their comments on the revised guidance document by 04 December 2009
14. Co-operation with other Community bodies	
14a. Report of the fifth meeting of the Chairs of EU bodies involved in risk assessment (18-19 November 2009)	
-	SECR to investigate further the possibility for involving RAC members in these activities
GENERAL	
-	**SECR** to upload all presentations, room documents and RAC-8 Main conclusions and action points (i.e. this doc) to RAC CIRCA IG by 30 November.

Part IV. Lists of Attendees

List of Attendees of the RAC-8 meeting (24-26 November 2009)

Members		**ECHA staff**
ANDERSSON Alicja		AHRENS Andreas
BARANSKI Boguslaw		DE BRUIJN Jack
BARRON Thomasina		HOLLINS Steve
BORGES Maria Teresa		ERICSSON Gunilla
DUNAUSKIENE Lina		FUHRMANN Anna
DUNGEY Stephen		KARHU Elina
GREIM Helmut		KOWALSKI Urlike
GRUIZ Katalin		KOKKOLA Leila
JENSEN Frank		KULJUKKA-RABB Terhi
KADIKIS Normunds		LEFEVRE Remi
KREUZER Paul		LIPKOVA Adriana
LARSEN Poul Bo		LOGTMEIJER, Christiaan
LE CURIEUX-BELFOND Olivier		LUOTAMO Marita
LEINONEN Riitta		LUSCHÜTZKY Evita
LOSERT Annemarie		NOUVEN Johan
LUND Bert-Ove		NYLUND Lars
MULLOOLY Yvonne		PEDERSEN Finn
NUNES Céu		ROGGEMAN Maarten
PICHARD Annick		SADAM Diana
POLAKOVICOVA Helena		SPJUTH Linda
POSPISCHIL Erich		SUNDQUIST Anna-Liisa
PRONK Marja		TARAZONA Jose V.
RUCKI Marian		THUVANDER Ann
RUPPRICH Norbert		VAHTERISTO Liisa
SCHULTE Agnes		VASILEVA Katya
SMITH Andrew		YLÄ-MONONEN Leena
STOLZENBERG Hans-Christian		
SULG Helen		**Representatives of the Commission**
VAN DER HAGEN Marianne		GRODZKI Karola (DG ENT)
VAN MALDEREN Karen		WISTUBA Christine (DG ENV)
VILANOVA Eugenio		LUVARA Giuseppina (DG ENT)
Invited experts replacing a member		**Stakeholder observers**
ALESSANDRELLI Maria (replacement of Paola DI PROSPERO)		ANNYS Erwin (CEFIC)
		LEENAERS, Joeri (Eurometaux)
Advisers to the RAC members		GELBKE Heinz-Peter (ECPA) (industry expert for epoxiconazole)
DUSSART Aurelie (adviser to Karen VAN MALDEREN)		WEFFERS, Heribert (EEB)
GRACZYK Anna (adviser to Boguslaw BARANSKI)		SANTOS Tatiana (ETUC)
LINDEMAN Brigitte (adviser to Marianne VAN DER HAGEN)		STINCHCOMBE Stefan (BASF) (industry expert for epoxiconazole)
MYÖHÄNE Kirsi (adviser to Paul Kreuzer)		MULLER Andre (the representative of the

		Dutch CA, the dossier submitter for trixylyl phosphate)
PASQUIER Elodie (adviser to Annick Pichard)		
		Invited expert
		KINZL Max (Umweltbundesamt, Austria)

Part V. LIST OF ANNEXES

ANNEX I. Final Agenda of the RAC-8 meeting

ANNEX II. Lists of documents submitted to the Members of the Committee for Risk Assessment for the RAC-8 meeting

ANNEX I

24 November 2009
RAC/A/08/2009

Final Agenda
Eighth meeting of the Committee for Risk Assessment

24 November – 26 November 2009
Helsinki, Finland
24 November: starts at 9:00
26 November: ends at 16:00

Item 1 – Welcome & apologies

Item 2 – Adoption of the agenda

RAC/A/08/2009
For adoption

Item 3 – Declarations of conflicts of interest to the agenda

Item 4 – Outcome of written procedures and status report on the RAC-7 minutes

a. Outcome of written procedures and consultations
b. Status report on the RAC - 7 (Parts I & II) action points

Item 5 – Risk management options at Community level (Joint Session with SEAC)

a. Overview of relevant Community legislation
b. Assessment of RMOs
c. Examples

Item 6 – Draft opinions for CLH dossiers

a. Epoxiconazole
b. Di-tert-butyl-peroxide
c. Indium phosphide
d. Trixylyl phosphate
e. Gallium arsenide

For discussion

Item 7 – General CLH issues

a. Feedback from the Commission on the DAT opinion

For information

b. Feedback from the last CARACAL meeting

For information and discussion

c. Standard phrases for opinions relating to biocide and PPP dossiers

RAC/08/2009/48
For agreement

d. RAC statement for the public consultation of TC C&L substances

RAC/08/2009/49
For agreement

e. State of play of the submitted CLH dossiers

RAC/08/2009/50
For information

Item 8 - Working groups

- Discussion paper on the potential establishment of RAC working groups in the field of human health hazard assessment

RAC/08/2009/51
For discussion

Item 9 – Request according to Art 77(3)(c) in relation to boric acid and borates

- Discussion following request to evaluate newly available scientific evidence on the use of boric acid and borates in photographic applications.

RAC/08/2009/54 & RAC/08/2009/56 (Room documents)
For discussion

Item 10 – Appointment of RAC (co-) rapporteurs for intended restriction and CLH dossiers

a. Appointment of (co-) rapporteurs for Annex XV restriction dossiers: phenylmercury compounds, dimethylfumarate and lead and its compounds in jewellery

RAC/08/2009/52
For agreement

b. Appointment of (co-) rapporteurs for intended CLH dossiers

RAC/08/2009/55 (Room document)
For agreement

Item 11 – Authorisation

a. Introduction to authorisation process

For information

b. Preparation for handling authorisation applications

RAC/08/2009/53
For information

Item 12 – RAC consultations on guidance documents

- Process for updating the guidance document for the preparation of a CLH dossier

- Future consultations on other guidance documents

For information

- Update of the CSA and IR Guidance (Chapter 12)

For consultation

3 – Report from other ECHA bodies

- Report from meetings of the Management Board, SEAC, Forum and MSC

For information

Item 14 – Co-operation with other Community bodies

a. Report of the fifth meeting of the Chairs of EU bodies involved in risk assessment (18-19 November 2009)

For information

b. Report on the issues arising during the consultation on the draft rules of procedure for co-operation between ECHA and EFSA and ACSH and SCOEL

For information

Item 15 – Any other business

a. Admission of experts supporting RAC stakeholders
b. Revision of the rules for reimbursement
c. Annual survey of RAC members

For information

Item 16 – Action Points and main conclusions of RAC-8

- Table with action points and main conclusions from RAC- 8

For adoption

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ANNEX II

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-8 meeting

RAC/08/2009/48	Standard phrases for no classification of biocides and PPPs
RAC/08/2009/49	TC C&L substances feedback
RAC/08/2009/50	State of play of the submitted CLH dossiers
RAC/08/2009/51	Paper on RAC Working Groups (CMR, RS, *Ad hoc* subgroups)
RAC/08/2009/52	Appointment of restriction rapporteurs
RAC/08/2009/53	Preparation for handling authorisation applications - Outline of RAC & SEAC workplan
RAC/08/2009/54	Work plan for Art 77(3)(c) request for boric acid and its compounds (room doc)
RAC/08/2009/55	Appointment of CLH rapporteurs for intended dossiers (room doc)
RAC/08/2009/56	Opinion template for borates (room doc)