Helsinki, 22 March 2010
RAC/M/09/2010
FINAL

Minutes of the 9th meeting of the Committee for Risk Assessment (RAC)
(26 - 28 January 2010)

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 and welcomed the new RAC member José L. Tadeo Lluch nominated by Spain.

Eight advisers, two invited experts and five stakeholder observers (CEFIC, ECETOC, ECPA, Environmental Bureau, Eurometaux), two observers accompanying nominated stakeholder observers, two representatives of a Member State Competent Authority (CLH dossier submitter), an observer from the OECD, three representatives from the Commission and a replacement replacing one of the RAC members were welcomed.

Apologies were received from seven RAC members and three regular observers (from BUAV, ETUC and Business Europe). Two members were absent. The list of attendees is given in Part IV 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

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. A member declared that the member is working for the competent authority that submitted the epoxiconazole dossier.

4 Adoption of RAC-8 Draft Minutes

The Chair introduced the revised minutes, incorporating the comments received from four members and the RAC observer from ETUC. RAC rejected the proposed addition by the ETUC observer, as it concerns the work of the Member State Committee (provided information on classification and labelling of CMR substances) and is not relevant for RAC.

Furthermore, one member requested for inclusion of more information about the plenary discussions and the reached conclusions in a relatively short and well-structured minutes. The Secretariat agreed with the proposal and clarified that the key elements for the discussions and the main conclusions will be recorded in the table with Main conclusions and Action Points from each plenary meeting (attached as part III of meeting minutes) and adopted by RAC at the end of the meeting. More details of the substance-related scientific discussions should be provided with the Background document (Annex 1 to the RAC opinions).

Following this clarification and few editorial changes, RAC adopted the revised minutes. The Secretariat would make the final version available through the RAC CIRCA IG and the ECHA website.

5 Administrative issues and information items

The Chair indicated that following the suggestions received from the members, the administrative issues and information items were covered by the room document RAC/09/2010/10 which had been handed out to the members. Members were informed that if there were any questions from the document, these may be discussed during the relevant agenda items or under any other business. This practice will be used in the future whenever possible.

The Chair acknowledged the participation in the survey and the received comments. The Chair also indicated that a summary and follow up of the received comments will be presented at the March meeting.

6 Requests according to Art 77(3) (c) of the REACH Regulation

6a 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. This request is related to the Commission proposal to include a derogation for these application in the 'standard' restriction on the consumer uses of CMR (cat 1A and 1B) substances as such or in mixtures above the concentration limits defined in the CLP Regulation. He also welcomed two invited experts and an expert accompanying the observer from Eurometaux. The rapporteur and one of the invited experts gave presentations based upon the data and findings presented in the fourth version of the draft opinion that had previously been provided to members via the RAC CIRCA IG.

A long discussion took place that was split over three days and included a meeting of the Ad Hoc Working Group between plenary discussions and which included other RAC participants interested in borates. The discussion focussed on two key aspects: the human health effects (toxicological profile and toxicokinetics) of boric acid and borates; and the choice of exposure scenarios to be utilised in the risk characterisation.

Following discussion, a consensus was reached that development & fertility are the leading health hazards. On the basis of the available studies, for fertility, a NOAEL of 17.5 mg B/kg bw/day was agreed and for developmental toxicity a NOAEL of 9.6 mg B/kg bw/day. Assessment factors were not considered necessary for dose-response uncertainty and the quality of the whole database was considered sufficient for the assessment. Using the default assessment factors of 10 and 10 for intra- and interspecies uncertainty, these NOAELs would yield DNELs of $DNEL_{fertility}$ of 0.175 mg B/kg bw/day and $DNEL_{development}$ of 0.096 mg B/kg bw/day. The possibility for refining the interspecies factor was also considered, based on the available metabolic

and toxicokinetic information. Finally, a refinement was not justified in this particular case and it was decided not to deviate from the default factor which was considered to be a conservative approach. After significant discussion concerning dermal absorption and the uncertainty associated with the available data, the value of 0.5% was considered as the most proper figure based on the available data. Some members considered that an additional uncertainty factor should be added. It was agreed that a range of between 0.5 and 1.0% should be utilised with an explanation about the uncertainty in the final opinion.

Concerning the choice of exposure scenarios, the following were agreed to be utilised: preparation of solutions from liquid concentrates; tank development of films; film development in basins and the preparation of solutions from powder formulations. It is assumed that preparation and use of solution may occur in the same day. The Committee has no information indicating if consumers develop films simultaneously in tanks and basins. Some members noted that due to lack of better information most of the assumptions where conservative; when all these conservative assumptions are used together it results in potentially very conservative exposure estimation. After discussion, it was agreed that reasonable worst case scenarios would be derived for all of these exposure scenarios and there would also be a cumulative scenario assuming the preparation of the solution from powder and development of films both in tank and basin in one day. Furthermore, the cumulative exposures arising from food and drink would also be included. Some members and the rapporteur noted the uncertainty associated with the exposure scenarios on account of incomplete market and use data for boric acid and borate substances in photographic applications. It was also noted that the COM derogation was with respect to developers, fixers, bleaches and ancillary chemicals in wet processing of photographic films, plates, papers and related media and RAC's mandate was to determine the risk to the general public from such exposure. It was agreed the opinion will address the uncertainties of in-put parameters and discuss probabilities of the scenarios.

Risk characterisation ratios (RCRs) were then calculated and scenarios assuming foreseeable typical use conditions, yielded RCRs below one indicating acceptable risk from photographic applications, also when combined with exposure from food and drink. For reasonable worse case scenarios, some RCRs were above one, when combined with exposure from food and drink.

Industry observers indicated that boron substances are not present in paper developers and for fixing solutions the level of boron is below 1% and therefore should not be included in the exposure scenarios. RAC agreed that this information would be noted in the final opinion, subject to adequate written confirmation.

During the discussion observers from the Commission indicated that on account of the unexpected complexity in preparing the opinion and the late arrival or incomplete provision of information from industry it was acceptable to extend the deadline for receiving the opinion from RAC. The rapporteur was asked to revise the opinion as soon as possible and to provide to RAC, via the Secretariat, for comments before finalisation.

6b Framework for dealing with requests according to Art 77(3)(c) of REACH

The Secretariat introduced document RAC/09/2010/01 which was addressed to both RAC and SEAC Committees. SEAC had already considered the document and had provided comments on it that had been taken into account in the current version. The emphasis of the proposed approach was to provide sufficient flexibility to deal with future requests according to Article 77(3)(c) which may vary according to urgency and type.

In general, RAC members appreciated the approach and considered the document to be well constructed. However, in the light of experience with the boric acid request from the Commission to ECHA, a number of members highlighted the need to ensure that sufficient preparatory work was done prior to the request coming to RAC. Suggestions included better provision of all relevant data from industry in advance of submitting a petition to the Commission; ECHA's active involvement in safeguarding the interests of the Committees especially with regard to the documentation for the case; the need for clarifying the nature of the consultation of third parties; and the introduction of an accordance check into the process. Some members also indicated that, where relevant, SEAC should be involved with future requests and questioned the notion of an urgent request. Members also suggested that for heavy workload requests, additional resources should be considered, for example including the use of co-opted members, in addition to invited experts.

The Chair thanked members for their comments and agreed to establish a RAC CIRCA IG newsgroup for any additional comments by 9 February 2010. Following this further consultation, the Secretariat would discuss with the Commission and revise the framework for possible agreement at RAC-10.

7 CLH Dossiers

7a Epoxiconazole (CAS No. 133855-98-8; EC No. 406-850-2)

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

The Chair introduced the discussion by explaining that following RAC-8, a number of members had asked for an in depth discussion to be held at RAC-9 to consider the scientific evidence related to epoxiconazole and developmental toxicity. The aim of the discussion was to form a clear RAC view on the interpretation of the available data for the CLH proposal relating to epoxiconazole and to seek RAC agreement on its classification and labelling. Document RAC/09/2010/02 had been circulated in advance of the meeting to structure the discussion.

Representatives from the Swedish Competent Authority (dossier submitter), the rapporteur and her advisers, the ECHA Secretariat, the Danish Food Institute, an adviser to a member and industry gave presentations to assist RAC members to interpret the scientific data relating to developmental toxicity.

A long discussion took place over parts of two days interspaced by an ad hoc meeting of members and observers interested in epoxiconazole to discuss the data and to attempt to draw a conclusion. The plenary discussion focussed on two main aspects: post implantation loss and observed malformations (cleft palates).

During the discussion on post implantation loss, emphasis was placed on the significantly higher frequency of very late resorptions observed in certain epoxiconazole studies, which is a very rare developmental toxicity effect. The rapporteur highlighted three studies in particular which had been described by the representative from the Danish Food Institute that were relevant to exposure during late gestation: Schneider (2002) where late resorptions with overt maternal toxicity had been recorded and Taxvig (2007 & 2008) in which statistically significant effects on late and very late resorptions are observed without maternal toxicity. The rapporteur explained that these findings pointed to a classification for reproductive toxicity in category 1B (CLP Regulation).

Concerning cleft palates, the rapporteur described a high incidence had been recorded in the data from Hellwig (1989), but a low incidence in Schneider (2002) at the same dose, but increased duration of treatment and increased post- implantation losses, that may have masked teratogenicity. The rapporteur summarised that observed cleft palates cannot be considered as secondary to maternal toxicity.

During the discussion observers from industry explained that further studies were being carried out to fulfil the requirements of Commission Directive 2008/107/EC[1] to assess potential endocrine disrupting properties that were considered highly relevant for the discussion on classification of epoxiconazole. The Chair noted the potential relevance of the ongoing studies, but explained that the regulatory deadline for delivering a RAC opinion would not allow the results to be taken into account.

After discussion, there was a consensus amongst members that the weight of evidence from the available scientific data allowed a conclusion to be reached for a classification of reproductive toxicity in category 1B (CLP). However, to provide a robust justification for this, RAC requested the representative from the Danish Food Institute to provide the rapporteur with additional written information on hormones and post implantation losses for the purposes of presenting the final opinion. As soon as the supporting documentation had been received, the rapporteur was to revise the opinion and its annexes and provide them to the Secretariat for circulation for final comments.

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

The rapporteur summarised the outcome of discussions at RAC-8 and subsequent consultation on the draft opinion relating to the CLH proposal for indium phosphide.

The opinion now included the addition to the hazard statement “causes damage to lungs through prolonged or repeated inhalation exposure” for STOT RE.1 - H372 and for STOT RE.2 - H373. Concerning the carcinogenicity hazard class, the limitations

[1] 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.

of the T25 model had been noted, but nevertheless the use of the approach was still considered to be justified. For reproductive toxicity, the hazard statement H361f was considered the most appropriate hazard statement, but it was recognised that H361 could be applied if the available criteria are applied strictly. A footnote explaining this circumstance was included in the opinion. It was agreed to use the same footnote in other similar cases.

The labelling according to the CLP Regulation had also been added as follows: GHS08; Dgr; H350, H361f and H372. Concerning the use of note H, a footnote and an explanatory sentence had been added to the revised opinion, prior to a clear steer from the Commission on how to use note H.

RAC adopted the opinion and agreed the proposed approach for the use of note H. It was agreed that a similar approach should be applied to other relevant RAC opinions, pending advice from the Commission.

The Chair thanked the (co-)rapporteurs and all others involved in the development of the opinion.

7.1c Di-tert-butyl-peroxide (DTBP) (CAS No. 110-05-4; EC No. 203-733-6)

The Chair reminded the members that at RAC-8, 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) and then invited the RAC rapporteurs for this substance to make brief final remarks in relation to their draft opinion. The DTBP co-rapporteur presented the final modification in the draft opinion related to the included S-phrases in the proposal and suggested only those S-phrases that are relevant for the proposed for harmonisation endpoint to be considered by RAC.

RAC agreed with rapporteurs' proposal that S-phrases should only be discussed as far as related to the actual proposal and decided to include S23 but not S33 in their opinion on DTBP.

With this clarification, RAC adopted the CLH opinion with its annexes for DTBP.

The Chair thanked the (co-)rapporteurs and all others involved in the development of the opinion.

7.1d Trixylyl phosphate (TXP) (CAS No. 25155-23-1; EC No. 246-677-8)

The Chair recalled that at RAC-8, RAC members agreed with the view of the rapporteurs to support the proposed classification **Repr. Cat 2, R 60** (under Dir 67/548/EEC) **or Repr 1B, H360F** (under CLP Regulation) and invited the RAC rapporteur for this substance to make brief final remarks in relation to the draft opinion.

Furthermore, RAC agreed to include the footnote related to the hazard statement H360. With this small modification, RAC adopted the CLH opinion and its annexes for TXP.

The Chair thanked the (co-)rapporteurs and all others involved in the development of the opinion.

7.1e Abamectin (CAS No. 71751-41-2)/Avermectin B1a (CAS No. 65195-55-3)

The RAC rapporteur for this substance presented the key elements of the rapporteurs' first draft opinion on the CLH proposal for abamectin/avermectin B1a and few other issues for RAC consideration. It was specified that abamectin, included as an active substance in the regulatory programmes for Plant Protection Products and Biocidal Products Directive, is without current harmonised classification and labelling and, therefore, information on all endpoints is provided in the CLH dossier. Both rapporteurs considered that the proposed classification for this substance, as **Repr. Cat.3; R63; T+; R26/28; T ; R48/23/25; N; R50/53** (under Directive 67/548/EEC) and **Repr. 2, H361d; Acute Tox. 2, H300; Acute Tox. 2 H330; STOT-RE 1, H372; Aquatic Acute 1, H400; Aquatic Chronic 1, H410** (under the CLP Regulation) as relevant, because the provided information has sufficiently justified it. However, as the RAC consultation on the first draft opinion for abamectin/avermectin B1a is ongoing, the rapporteurs requested for members' comments on the draft opinion and their views on the need to set up a specific concentration limit (SCL).

One member suggested to the rapporteurs to consider whether acute and repeated dose toxicity are mediated via the same mechanism (neurotoxicity caused by GABA-antagonism) and that classification for repeated dose toxicity therefore is not relevant.

The Chair concluded that following the RAC consultation, the rapporteurs will be requested to provide the revised draft opinion and BD on abamectin and the opinion responses to the comments (ORCOM) and these documents will be distributed for discussion and possible adoption of the CLH opinion for this substance at RAC-10.

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

RAC agreed to appoint the volunteering RAC members for (co-)rapporteurship of intended CLH dossiers, as indicated in document RAC/09/2010/03_rev.2. The Secretariat was requested to identify potential co-rapporteurs and encourage them to fill the vacant position.

RAC also agreed to modify its decision dated 14 December 2009 for the appointment of Paola Di Prospero, as instead of a co-rapporteur, she should be considered as a second RAC rapporteur for the intended group submission of five CLH dossiers.

7.3 General CLH issues

7.3a Comments on the templates for the CLH opinion and background document (BD)

Following the RAC-8 discussion on the revised templates for CLH opinion and BD and the Commission's intervention on the issue, two RAC members provided RAC and the Secretariat with their general comments. Therefore, the Chair invited them to summarise their concerns which to be further explored at RAC-10.

The invited member, supported by some members, pointed out that due to the existing confusion after the Commission's intervention on the justification provided in the BD, there is a need for clarification on the required documentation for the Commission's decision-making process. Some other key elements also need urgent clarification, such as the use of the CLH report as the basis for developing a BD where the rapporteurs should provide their written justification on the harmonised and non-harmonised endpoints covered in the proposal, in particular for those cases when the draft opinion does not support the dossier submitter's proposal and/or new data are

submitted during the public consultation that the rapporteurs should consider in the draft opinion.

In conclusion, RAC agreed on the need to have clarity on the issue and requested the Secretariat to consider and ensure the Commission's active involvement in this pending for clarification essential issues. The Chair confirmed that a specific discussion point will be included in the Draft Agenda for RAC-10 in March, as the Secretariat will organise a discussion on the CLH issues identified during RAC-8 and RAC-9 and will invite the Commission to actively take part in this discussion and clarify its view on the necessary documents and on the way forward.

7.3b Substances already agreed at TC C&L

The Chair informed RAC of the on-going conversations with the Commission. It was explained that a solid scientific justification comparing the data with the classification criteria is required for legal purposes. As a consequence, RAC recommendation for the use of the agreed classification is not sufficient, as RAC must also agree with the justification (comparison of data with criteria). It should be also noted that the TC C&L agreements only cover the criteria under Directive 67/548/EEC (DSD). However, the comparison of the data with the CLP criteria has been never discussed and must be discussed by RAC. Therefore, RAC opinion needs to include all scientific justifications and comparison of data with criteria.

Taking into account the huge amount of expected additional work for RAC and need to keep the highest scientific expertise of RAC, instead of creating additional work for the members with these 87 substances, one member asked for involvement of MSCA and ECHA in all administrative tasks of this process. The Secretariat confirmed that the clarification on administrative roles is also one of the pending issues in the ongoing conversations with COM and the translation table under the CLP Regulation might be useful in this regard.

The Chair invited the RAC rapporteur for the only submitted dossier from the group of 87 substances proposing harmonised classification and labelling for Leucomalachite Green (CAS No. 129-73-7, EC No.204-961-9), as agreed at TC C&L, to provide feedback from the ongoing accordance check. The rapporteur shared his concerns related to this dossier's accordance check that although a good scientific justification provided in the proposal, there are difficulties in the comparison of the data with the CLP criteria due to not sufficient data transparency in the submitted dossier.

A member suggested also this issue to be re-opened for discussion in CARACAL, as when the first discussion was held, it was concluded that accordance check for such dossier will be needed just for purpose of the substance identification. However, in the light of the late discussions, when all requirements should be met, this will require more work from the MS submitting the dossier. The Secretariat agreed to report to next CARACAL meeting of the RAC concerns related to these substances, as MSCAs originally submitted these substance dossiers are concerned parties.

Furthermore, some members underlined that although a quick and smooth process was asked, it seems that the normal CLH process should be applied for these 87 substances that leads to wasting of time, high level of scientific expertise of RAC members and other resources across Europe for already examined substances.

Therefore, RAC asked the Secretariat to prepare and provide COM and CARACAL with the resource estimations for the necessary work hours and expertise required by RAC in order to cover this additional workload in parallel with the routine work of the Committee.

The Secretariat also reminded to the members that those substances for which new data have not been provided with the CLH proposals or during the public consultations, could be processed faster as the expected scientific discussion might be lighter. There is no clarity as well on the number of the CLH dossiers that will be submitted in reality.

In conclusion, the Chair thanked the members for their comments and suggested a discussion on this issue to be organised during RAC-10, as this will allow also the Commission's active participation and agreement on the way of dealing forward with these substances.

RAC agreed to postpone this discussion for RAC-10 and asked the Commission's observers at the meeting to transfer the message to the relevant Commission services to consider alternative ways for handling these substances and to inform RAC of the alternative solutions at RAC-10.

7.3c State of play of the submitted CLH dossiers

The Secretariat explained that the updated information of the state of play of the submitted CLH dossiers was provided with room document RAC/09/2010/11. Members were informed that the recently (re-)submitted CLH dossiers will be uploaded to RAC CIRCA IG according to the security provisions for providing confidential information referred to under item 9b of the Agenda.

8 Restrictions

8.1 Appointment of RAC (co-) rapporteurs for restrictions dossiers

The Secretariat introduced document RAC/09/2010/04 which summarised the intention for a restriction dossier for mercury in measuring devices, from ECHA on request from the Commission and the recommendation of the Chair for a rapporteur and co-rapporteur. RAC agreed the document and the recommended (co-) rapporteurs were appointed.

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

8.2 General restriction issues

The Chair noted there were no new issues to report.

9 Procedure for the admission of stakeholder observers and their experts and information on confidentiality rules (Closed Session)

9a Procedure for the admission of stakeholder observers and their experts and information on confidentiality rules

The Secretariat introduced the members with the draft procedure for admission of stakeholder observers and their experts in the work of RAC (see document

RAC/09/2010/05). It was explained that a need was identified for procedural description of the steps that should be followed when RAC considers the involvement of additional stakeholder organisations (STO) in their work as regular or sector-specific observers (incl. the meeting participation of sector-specific observers and the experts accompanying RAC regular or sector-specific STO observers for a specific substance-related discussion. Therefore, the proposed draft was developed on the basis of general principles agreed by RAC at their 3rd meeting and the established good working practises in this regard.

RAC supported the draft procedure without changes.

Furthermore, RAC agreed to admit the participation of Women in Europe for a Common Future (WECF), Eurogroup for Animals (EUROGROUP), the European Mine, Chemical and Energy Workers' Federation (EMCEF) and the European Society of Toxicology In Vitro (ESTIV) that have expressed their interest in the RAC work as regular observers. The Secretariat was requested to invite these four additional stakeholder organisations to nominate representatives to be involved in the RAC routine work.

RAC took a decision to invite European Aerosol Federation (FEA), Association of European Candle Manufacturers (AECM), European Council of producers and importers of paints, printing inks and artists' colours (CEPE), The European Container Glass Federation (FEVE) and Standing Committee of the European Glass Industries (CPIV) to participate in the work of RAC as sector-specific observers on case-by-case basis. Following this decision, the Secretariat was requested to update the list of RAC-agreed sector-specific STO observers and to publish it on the ECHA website after the meeting.

Finally, RAC agreed to have this sub-item of the closed session minuted in the general publicly available RAC-9 minutes.

9b Information on confidentiality rules

The Secretariat introduced the members with the new security provisions regarding the access to confidential information of Committees' members, their advisers and invited experts explaining that the relevant documents are uploaded to the confidential section of RAC CIRCA IG. RAC members were informed of the need to provide the Secretariat with their signed acknowledgements of receipt of the *Notice on security provisions regarding access to confidential information uploaded to CIRCA under REACH and CLP* either during RAC-9 or by 5 February 2010. Following this date, the access to the confidential section of RAC CIRCA IG of the members whose acknowledgements have not been received, will be revoked until receiving the required document.

In addition, the Secretariat explained to the members the practical requirements for granting or modifying the access of their advisers to both confidential and/or non-confidential sections of RAC CIRCA IG and asked those members who want to provide advisers with such access to submit their requests and the required documentation by 5 February 2010 or later on when such a need appears. Following this date, the Secretariat will update the list of registered advisers as RAC CIRCA users in both confidential and non-confidential sections.

One member requested and the Secretariat agreed to prepare and provide a template for registering a member's adviser for granting/modifying access to RAC CIRCA IG after the meeting.

It was highlighted that it is members' responsibility to ensure non-disclosure of confidential information in all cases when requesting access for advisers or download dossiers in IUCLID 5 format. One member indicated that when an institution has local IUCLID 5 installation available for all users in the institution, the RAC member working for this institution should use it when downloads and works with the IUCLID 5 dossiers relevant for his/her work. The Secretariat recommended to the members to consider the real need for downloading an IUCLID 5 dossier first, as in most of the cases the important information for formulating the RAC opinion is provided in the CLH report. However, if such downloading is really needed, the member should take the necessary measures for ensure the non-disclosure of confidential information at the institutional level, to download and keep the dossier there until needed and as soon as the dossier is completed, to remove it from the institutional IUCLID system.

Finally, RAC agreed to have this sub-item of the closed session minuted in the general publicly available RAC-9 minutes.

10 Revision of the RAC rules of procedure

The Secretariat introduced document RAC/09/2010/07 pointing out the key changes over its predecessor. The document was agreed subject to the inclusion of a minor modification proposed by a member to include the word 'notification' in Article 5(3)(b). The Secretariat was requested to forward the modified document to the Management Board for approval at its meeting scheduled for 4-5 March 2010.

11 RAC Manual of conclusions and recommendations (MoCR)

The Secretariat presented to the members its proposal for setting up and maintaining of a RAC Manual of conclusions and recommendations (Doc RAC/09/2010/08). It was pointed out that although there is no a legal requirement for such document, it might be a useful tool for avoiding duplication of the work or any other unnecessary efforts for RAC members when considering issues similar to those already reflected in the MoCR, as this on-line document will keep records of the identified solutions for the key cases of general interest for the use of RAC members, their advisers, RAC regular observers and the ECHA Secretariat.

RAC responded positively on the Secretariat's proposal to have such a document and agreed with the proposed approach.

Some members came with initial comments on the content and the structure of the draft MoCR (provided as an annex to the document RAC/09/2010/08) suggesting the Secretariat to consider the inclusion of generic explanation in the entry and active hyperlinks to the specific cases, the use of content indexing, the option for searching via key words, etc.

In addition, the Secretariat was requested to organise RAC written consultation for providing additional comments on the structure and the content of the RAC MoCR. The Secretariat confirmed that a CIRCA Newsgroup will be created for collecting members' comments/suggestions and the revised version of the RAC MoCR will be distributed as a RAC-10 meeting document for possible outline approval.

12 Authorisation – working procedure for the appointment of rapporteurs for applications for authorisations

The Secretariat introduced the main steps in appointing of rapporteur and co-rapporteur for authorisation applications and compared the proposed appointment procedure with those agreed for handling CLH and restriction dossiers.

The Secretariat proposed to start the appointment process already after COM has initiated "regulatory procedure with scrutiny" to include substances in Annex XIV of REACH.

For each substance (or group of substances) to be included in Annex XIV, RAC members would be asked to express interest to become rapporteur for authorisation applications. Based on expressions of interest received, the Secretariat would create a pool of potential rapporteurs for each substance (or group of substances) and seek for RAC agreement on the pool via written procedure or, if applicable, at the next available plenary meeting and propose to consider this agreement as the appointment of rapporteurs. As soon as an application arrives to ECHA, the Secretariat will contact the rapporteurs from the pool for this particular substance (or group of substances) to clarify availability of the members and the Chair will then select rapporteurs among those members who confirmed their availability, taking into account the individual expertise and work load.

The Secretariat informed participants that SEAC was discussing the same document via CIRCA newsgroup, as there were no SEAC meetings foreseen before March (consultation open until 8 February). After a short discussion it was proposed to open a similar newsgroup for receiving further comments for RAC.

Based on RAC and SEAC comments the draft procedure would be revised and the document would be presented to both Committees at their March meetings for possible adoption.

13 Guidance issues

13a Presentation of issues arising from the PEG on the update of the guidance document for the preparation of a CLH dossier

The Secretariat explained the procedure for updating the guidance document and the role and composition of the PEG within this procedure. The structure of the updated guidance document was described with particular reference to the CLH report format. It was pointed out that the revised draft guidance document (following the PEG), the RCOM table and comments from the two RAC members that had participated in the PEG had already been provided to RAC in the RAC CIRCA IG.

A brief discussion followed in which one member underlined the need to give clear instructions in the guidance on the expectations from RAC in order to be able to process the dossier efficiently. The dossier submitter should provide adequate contextual information about the history of the substance in other EU institutions and should follow the dossier through the RAC process and respond to queries arising from rapporteurs. The guidance should also clarify what options are available to RAC

and the dossier submitter in the event that significant new data arises during the public consultation. Sufficient flexibility should also be built into the CLH report template to allow rapporteurs to present the justification for an opinion in the most appropriate way when preparing the background document. Another member noted the need to strengthen section 4.9 of the guidance document concerned with the justification demonstrating the need for action at Community level by adding some options for consideration to help not only the dossier submitter to decide and justify proposals, but also RAC rapporteurs to assess this justification during the accordance check. An environmental endpoint was used as an example: what is the minimum number of necessary Member States, or the minimum produced tonnages, to consider the European level as relevant? Can long range transport or PBT/vPvB properties be sufficient arguments to justify the European level harmonised classification?

The Chair thanked the two RAC members that had participated in the PEG for their efforts and invited any further comments by 19 February 2010 in the RAC CIRCA newsgroup that had been established. The back-to-back meeting to be held after RAC-9 was also expected to provide useful comments for updating this guidance.

13b Presentation of the guidance update on the DNEL/DMEL derivation from human data

The Secretariat gave an introduction to the ongoing update of the guidance document for the characterisation of a dose-response for human health: the derivation of derived no-effect levels (DNELs) and derived minimal effect levels (DMELs), chapter R8 of the CSA and IR guidance.

RAC was to be consulted on the draft update following the PEG discussion which was expected to take place early Feb-mid March 2010. Key discussion points anticipated were: the intraspecies assessment factor; how to deal with negative data from studies in humans and data which was found to be inconsistent in animal and human studies.

13c Report on other guidance activities

Within the context of the CSA & IR guidance, the Secretariat introduced the ongoing update to chapters R14 and R15, concerned with occupational and consumer exposure estimation, respectively. The two documents had been considered at a PEG convened at the end of 2009. RAC was expected to be consulted on the revised versions of the documents around the end March or early April.

The Chair also noted that RAC was expected to be consulted on an update to the guidance on environmental exposure estimation (R16) soon after RAC-9.

14 Co-operation with other bodies

14a Recent activities in the revision of the OECD existing chemicals programme

The OECD representative presented the recent activities in the revision of the OECD existing chemicals program.

SIDS Initial Assessment Meeting (SIAM) assessed about 860 chemicals. In the lat two years the number of submitted dossiers and assessed chemicals decrees which correlate with REACH implementation in Europe.

The revised program is addressed to the High Production Volume (HPV) and non HPV chemicals. The 44th Joint Meeting recommended to continue producing the full Screening Information Data Sheet (SIDS) initial hazard assessments, elaborate targeted hazard assessments, exposure information and Integrated Approaches to Testing and Assessment which aim reducing testing in concrete hazard. The program has also to develop a simple system to keep track of national, regional and international assessment activities to avoid duplication of work and improve access to information on national and regional GHS classifications, e.g. via eChemPortal. OECD is interested to link this portal to other national or regional data bases.

Additionally the speaker brief RAC on experiences in 2009 with CLH dossiers (TXP, considered in the electronic discussion groups) and SVHC (Antracene discussed in SIAM 29th and the conclusion were adopted).

OECD was seeking for cooperation with EU countries and ECHA. There were differences in frequency of meetings (SIAM meets twice per year, RAC up to 6 times per year) and also deadlines for commenting in OECD and RAC were different.

The Chair thanked the OECD observer and expressed the importance of receiving information from OECD. RAC will be informed about possible future co-operation with the OECD.

14b The work of SCOEL, occupational exposure limits and risk management options

The SCOEL Scientific Secretariat presented the Committee and described the legal basis of the work of the Committee as well as their role in the establishment of EU Occupational Exposure Limits. She also outlined the areas of common interest to both Committees, SCOEL and RAC.

The Chair thanked the speaker and mentioned that two members of RAC were also SCOEL members, a situation that will facilitate common understanding among the role of the Committees.

A RAC member asked how many substances are considered on average within one meeting. The speaker replied that currently more than 20 substances are being debated during one meeting. In the future the number of substances would be lower to insure high level of scientific discussion.

Another member inquired how long was the process for one substance. It was explained that the duration of procedure for one substance depends on the substance and last from 3-4 meetings up to few years.

The relation between an OEL and DNEL (required in the registration dossier) was also discussed. It was clarified that if it is possible to assess on scientific basis the exposure limit, the role of SCOEL is to asses the available information and suggest an

OEL. In uncertain cases the REACH procedure is recommended, the DNEL is derived in a tiered approach, requesting additional information for refinement only when the acceptability of the risk cannot be granted. The guide agreed between DG EMPL and social partners, which might clarify this subject; it would be approved by Advisers Committee in the upcoming weeks.

The RAC members questioned also the collaboration between ECHA and SCOEL regarding prioritisation of chemicals for examination by SCOEL, and how to use the work of other scientific committees in the work of RAC.

The chair informed that the co-operation procedure was already under discussion. The Secretariat will further discuss how to use the synergy of both Committees to maximum extend. The Chair added that the main cooperation partner among the scientific committees for RAC will be SCOEL.

15 Any other business

The Chair reported the outcome of the closed session to the stakeholder observers and stressed on the following key decisions: the agreed RAC procedure on admission of stakeholder observers and their experts in the work of RAC, the agreed RAC decision on involvement of additional stakeholder organisations as RAC permanent or sector-specific observers and implementation of ECHA confidentiality rules for members, their advisers and invited experts.

In addition, the Chair encouraged the STO early involvement and active contributions to the RAC work during and after the public consultation. RAC was informed as well that due to a need for consultation on draft RAC documents with the parties concerned, a disclaimer will be included in the drafts for clarification purposes.

16 Main conclusions and Action Points of RAC-9

The Secretariat presented the main conclusions and action points of the RAC-9 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.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
(Adopted at the Ninth meeting of RAC)
(26-28 January 2010)

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
1. Adoption of the Agenda	
The Agenda (RAC/A/09/2010_rev.1) was adopted without any changes. One member has declared potential conflict of interest to one Agenda sub-item.	**SECR** to upload the adopted Agenda to the RAC CIRCA IG as a part of the RAC-9 minutes.
4. Adoption of RAC-8 Draft Minutes	
The minutes of RAC-8 (RAC/M/08/2009 draft final) was adopted with few editorial changes.	**SECR** to upload to the RAC CIRCA IG and the ECHA website the adopted minutes
6. Requests according to Article 77(3)(c)	
6a. Discussion and adoption of draft opinion on boric acid and its compounds in photographic applications	
In scenarios assuming foreseeable typical use conditions we arrive at RCRs below one indicating acceptable risk from photochemical applications, also when combined with exposure from food and drink. For reasonable worse case scenarios we have some RCRs above one, when combined with exposure from food and drink. The opinion will address the uncertainties of in-put parameters and discuss probabilities of the scenarios.	**Rapporteur** to revise the draft opinion as soon as possible and send it to SECR **SECR** to distribute the revised draft opinion for comments, as soon as received **Rapporteur** to consider the comments and modify the opinion, if needed **SECR** to organise the adoption of the final draft opinion by urgent written procedure
6b. Framework for requests according to Article 77(3)(c)	
RAC agreed to provide written comments to the draft Framework for requests according to Article 77(3)(c).	**SECR** to create a newsgroup for collecting members' additional comments on the draft framework after the meeting **Members** to post their comments in the respective newsgroup by 9 February 2010 **SECR** to revise the draft framework, consult with COM and distribute it as a meeting

	document for RAC-10
7. CLH dossiers	
7.1a. Epoxiconazole	
Preliminary agreement was reached on the classification for epoxiconazole of **Repr. Cat 2; R61** (under Dir 67/548/EEC) **or Repr 1B** (under CLP Regulation) subject to the provision of additional information on hormones and post-implantation losses for the purposes of presenting the final opinion.	**Dr. Ulla Hass** to provide the rapporteur with an additional supporting paper on hormones and post-implantation losses by 20 February 2010 **Rapporteur** to revise the opinion and BD as soon as possible after receiving the additional paper and to provide to the SECR the revised draft opinion. **SECR** then to provide revised opinion and BD to RAC for final comments.
7.1b. Indium phosphide	
RAC adopted the opinion and the background document for indium phosphide. RAC members agreed with the view of the rapporteurs to support the proposed classification and labelling: **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). RAC also agreed to include a footnote and text in the scientific justification concerning note H. This would be applied to all substances with non harmonised hazard classes. RAC also agreed on the footnote to be included in relation to the hazard statements H360 and H361, when appropriate.	**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.
7.1c. Di-tert-butyl peroxide (DTBP)	
RAC adopted the opinion and the background document for DTBP. RAC members agreed with the view of the rapporteurs to support the proposed classification and labelling: **Muta. Cat 3, R68** (under Dir 67/548/EEC) **or Muta. Cat. 2, H341** (under CLP Regulation)**.** RAC decided to include S23 but not S33 in their opinion. RAC agreed that S-phrases should only be discussed as far as related to the actual proposal.	**SECR** to upload the adopted opinion and its annexes to the RAC CIRCA IG and published them on the ECHA web site after the meeting **SECR** to forward to COM the adopted opinion and its annexes after the meeting
7.1d. Trixylyl phosphate (TXP)	

RAC adopted the opinion and the background document for TXP. RAC members agreed with the view of the rapporteurs to support the proposed classification **Repr. Cat 2, R 60** (under Dir 67/548/EEC) **or Repr 1B, H360F** (under CLP Regulation). RAC agreed to include the footnote related to the hazard statement H360.	**SECR** to upload the adopted opinion and its annexes to the RAC CIRCA IG and published them on the ECHA web site after the meeting **SECR** to forward to COM the adopted opinion and its annexes after the meeting
7.1e. Abamectin/Avermectin B1a	
-	**Members** to provide their comments on the 1st rapporteurs' draft opinion and its annexes by 12 February 2010 via the respective RAC CIRCA Newsgroup **Rapporteurs** to provide revised draft opinion, BD and also ORCOM depending on the comments received by 03 March 2010. **SECR** to distribute the revised draft opinion and its annexes to RAC members for further discussion and possible adoption at RAC-10, as soon as the documents are received.
7.2 Appointment of (co-) rapporteurs for CLH dossiers	
RAC agreed to appoint the rapporteurs for the newly registered CLH intentions and co-rapporteurs for some of them (see document RAC/09/2010/03_rev.2)	**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 co-rapporteurs and encourage them to fill the vacant position.
7.3 General CLH Issues **Comments on the templates for the CLH opinion and BD**	
RAC agreed on the need to have clarity on the issue and requested SECR to consider and ensure COM active involvement in this pending for clarification essential issue.	**SECR** to organise a discussion on the CLH issues identified during RAC-8 and RAC-9 for which a view of COM has been requested during RAC-10 and to invite COM to actively take part in this discussion for further clarification on the way forward
7.3a Substances already agreed at TC C&L	
RAC agreed to postpone this discussion for RAC-10 and asked COM to consider alternative ways for handling these substances. RAC asked SECR to prepare and provide COM and CARACAL with the resource estimations	**SECR** to organise a discussion on this issue during RAC-10 and to ask for the COM's active participation in the discussion in order to agree on the way of dealing forward with these substances.

for the necessary work hours and expertise required by RAC in order to cover this additional workload in parallel with the routine work of the Committee.	**SECR** to report to next CARACAL meeting of the RAC concerns related to these substances, as MSCAs originally submitted these substance dossiers are concerned parties.
8 Restrictions	
8.1 Appointment of (co-) rapporteurs for Hg in measuring devices	
RAC took note of the document RAC/09/2010/04 and agreed to appoint the volunteering RAC members as a RAC rapporteur and a co-rapporteur for the expected Annex XV restriction dossier.	**SECR** to upload in the RAC CIRCA IG the updated status document to reflect RAC appointments for this restriction dossier after the meeting.
9. Procedure for the admission of stakeholder observers and their experts and information on confidentiality rules	
9a Procedure for the admission of stakeholder observers and their experts	
RAC agreed on WP (doc RAC/09/2010/05_rev.1). RAC agreed to admit the participation of Women in Europe for a Common Future (WECF), EMCEF, Eurogroup for Animals and European Society of Toxicology In Vitro (ESTIV) in the RAC work as regular observers. RAC agreed to invite European Aerosol Federation – FEA, Association of European Candle Manufacturers, CEPE, FEVE and CPIV (Standing Committee of the European Glass Industries) to participate in the work of RAC as sector-specific observers on case-by-case basis. RAC agreed to have this sub-item of the closed session minuted in the general publicly available RAC-9 minutes.	**SECR** to upload the agreed procedure to the RAC CIRCA IG and publish it on ECHA web site (after the meeting). **SECR** to invite Women in Europe for a Common Future (WECF), EMCEF, Eurogroup for Animals and European Society of Toxicology In Vitro (ESTIV) to nominate their permanent representatives and to involve them to the Committee's work (after the meeting). **SECR** to update the list of RAC-agreed sector-specific STO observers and to publish it on the ECHA website (after the meeting).
9b Information on confidentiality rules	
RAC took note on the security provisions regarding the access to confidential information uploaded to RAC CIRCA IG. RAC agreed to have this sub-item of the closed session minuted in the general publicly available RAC-9 minutes.	**Members** who did not sign the collective acknowledgement of receipt of the *Notice on security provisions regarding access to confidential information uploaded to CIRCA under REACH and CLP* to sign and send to the Secretariat their individual acknowledgements **by 5 February 2010**

	SECR to prepare a template for registering a member's adviser for granting/modifying access to RAC CIRCA IG (after the meeting). **RAC members** to inform the Secretariat if they want to grant any CIRCA access to some of their advisers providing the required information in this regard **by 5 February 2010** or later on when such a need appears. **SECR** to update the list of RAC CIRCA users in both confidential and non-confidential sections **after 5 February 2010**
10. RAC Rules of procedure	
RAC agreed on the proposed revision of the RAC RoPs with a minor modification.	**SECR** to forward the revised RAC RoPs for approval at the Management Board meeting in March 2010
11. RAC Manual of conclusions and recommendations	
RAC agreed with the Secretariat's proposal to have a MoCR.	**SECR** to create a newsgroup for collecting members' additional comments on the structure and content of the draft RAC MoCR after the meeting. **Members** to post their comments by 12 February 2010. **SECR** to revise the structure and content of the draft RAC MoCR and distribute it as a meeting document for RAC-10
12. Authorisation **Working procedure for the appointment of rapporteurs for applications for authorisations**	
RAC agreed to provide written comments to the draft procedure for appointment of rapporteurs for authorisation applications.	**SECR** to create a newsgroup for collecting members' comments on the draft procedure after the meeting **Members** to post their comments in the respective newsgroup by 9 February 2010 **SECR** to revise the draft procedure and distribute it as a meeting document for RAC-10
GENERAL	
	SECR to upload all presentations, room documents and RAC-9 Main conclusions and action points (i.e. this doc) to RAC CIRCA IG by 02 February 2010.

Part III. Lists of Attendees

Members		**ECHA staff**
BARANSKI Boguslaw		DE BRUIJN Jack
BARRON Thomasina		HOLLINS Steve
BORGES Maria Teresa		ERICSSON Gunilla
DI PROSPERO FANGHELLA Paola		FUHRMANN Anna
DUNAUSKIENE Lina		HONKANEN Jani
GREIM Helmut		HUUSKONEN Hannele
JENSEN Frank		KARHU Elina
KADIKIS Normunds		KARJALAINEN Antti
KREUZER Paul		KOKKOLA Leila
LARSEN Poul Bo		KULJUKKA-RABB Terhi
LE CURIEUX-BELFOND Olivier		LEFEVRE Remi
LEINONEN Riitta		LIPKOVA Adriana
LOSERT Annemarie		LOUEKARI Kimmo
LUND Bert-Ove		LUOTAMO Marita
MULLOOLY Yvonne		NYLUND Lars
NAKOPOULOU Chrysanthi		PEDERSEN Finn
NUNES Céu		RIALA Riitta
ORPHANOU Maria		RÖCKE Timo
PICHARD Annick		SADAM Diana
POLAKOVICOVA Helena		SCHÖNING Gabriele
PRONK Marja		SUNDQUIST Anna-Liisa
RUCKI Marian		TARAZONA Jose V.
RUPPRICH Norbert		VASILEVA Katya
SCHULTE Agnes		YLÄ-MONONEN Leena
SMITH Andrew		
STOLZENBERG Hans-Christian		**Representatives of the Commission**
SULG Helen		HUICI-MONTAGUD Alicia (DG EMPL, SECR SCHOEL)
TADEO LLUCH José L.		LUVARA Giuseppina (DG ENT)
VAN MALDEREN Karen		WISTUBA Christine (DG ENV)
VILANOVA Eugenio		
		Representative of OECD
Replacements		GOURMELON, Anne (OECD)
BJØRGE Christine (replacement of Marianne VAN DER HAGEN)		
		Stakeholder Observers
Advisers to the RAC members		GELBKE Heinz-Peter (ECPA) (RAC Sector-specific stakeholder observer)
FASTIER Anthony (adviser to Annick Pichard)		MEISTERS Marie-Louise (ECETOC)
GRACZYK Anna (adviser to Boguslaw BARANSKI)		VIÑAS, Mercedes (CEFIC)
HASS Ulla (adviser to Poul Bo LARSEN)		WAETERSCHOOT, Hugo (Eurometaux)
MYÖHÄNEN Kirsi (adviser to Paul Kreuzer)		WEFERS, Heribert (EEB)
PASQUIER Elodie (adviser to Annick Pichard)		

REUTER Ulrike (adviser to Helmut GREIM)		
VAN ELSACKER Paul (adviser to Karen VAN MALDEREN)		**Other Observers**
		BALL, Wayne (an observer accompanying the nominated observer representing Eurometaux for borates)
Invited experts		DANIELSSON Bengt (the representative of the Swedish CA, the dossier submitter for epoxiconazole)
KINZL Max (invited expert for borates)		OHLSSON Agneta (the representative of the Swedish CA, the dossier submitter for epoxiconazole)
NEISEL Frederike (invited expert for borates)		STINCHCOMBE Stefan (BASF) (observer accompanying the stakeholder observer representing ECPA)

Part IV. LIST OF ANNEXES

ANNEX I. Final Agenda of the RAC-9 meeting

ANNEX II. Lists of documents submitted to the Members of the Committee for Risk Assessment for the RAC-9 meeting

ANNEX I

26 January 2010
RAC/A/09/2010

Final Agenda

Ninth meeting of the Committee for Risk Assessment

26 January – 28 January 2010

Helsinki, Finland

26 January: starts at 9:00
28 January: ends at 12:30

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/09/2010
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of RAC-8

- Adoption of the draft minutes

RAC/M/08/2009 draft final
For adoption

Item 5 – Administrative issues and information items

a. Status report on the RAC - 8 action points
b. Outcome of written procedures
c. Feedback on the annual survey of members
d. Report from other ECHA bodies and activities

RAC/09/2010/10 (Room document)
For information

Item 6 – Requests according to Art 77(3)(c) of REACH

a. Discussion and adoption of the 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/09/2010/01
For discussion

Item 7 – CLH

7.1 CLH Dossiers

a. Epoxiconazole **RAC/09/2010/02**
For discussion

b. Indium phosphide

For adoption

c. DTBP

For adoption

d. Trixylyl phosphate

For adoption

e. Abamectin

For discussion

7.2 Appointment of RAC (co-) rapporteurs for CLH dossiers (if relevant)

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

RAC/09/2010/03_rev1 (Room document)
For agreement

7.3 General CLH issues

a. Substances already agreed at TC C&L

For discussion

b. State of play of the submitted CLH dossiers

RAC/09/2010/11 (Room document)
For information

Item 8 – Restrictions

8.1 Appointment of RAC (co-) rapporteurs for restriction dossiers

- Appointment of RAC (co-) rapporteurs for the mercury in measuring devices restriction dossier

RAC/09/2010/04
For agreement

8.2 General restriction issues

- Update on intended restriction dossiers

For information

Item 9 – Procedure for the admission of stakeholder observers and their experts and information on confidentiality rules (Closed Session)

RAC/09/2010/05 & RAC/09/2010/06
For agreement

Item 10 – Revision of the RAC rules of procedure

- Second revision of the RAC rules of procedure

RAC/09/2010/07
For agreement

Item 11 – RAC manual of conclusions and recommendations

- RAC manual of conclusions and recommendations

RAC/09/2010/08
For discussion and possible agreement

Item 12 – Authorisation

- First discussion of the working procedure for the appointment of rapporteurs for applications for authorisations

RAC/09/2010/09
For discussion and possible agreement

Item 13 – Guidance issues

a. Presentation of issues arising from the PEG on the update of the guidance document for the preparation of a CLH dossier
b. Presentation of the guidance update on the DNEL/DMEL derivation from human data
c. Report on other guidance activities

For information

Item 14 – Co-operation with other bodies

- Recent activities in the revision of the OECD existing chemicals programme
- The work of SCOEL, occupational exposure limits and risk management options

For information

Item 15 – Any other business

- Report back from the closed session

Item 16 – Action Points and main conclusions of RAC-9

- Table with action points and decisions from RAC- 9

For adoption

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ANNEX II

Documents submitted to the Members of the Committee for Risk Assessment for the RAC-9 meeting.

RAC/A/09/2010_rev1	Final Draft Agenda – Ninth meeting of the Committee for Risk Assessment
RAC/M/08/2009	Minutes of the 8th meeting of the Committee for Risk Assessment – draft final
RAC/09/2010/10	Administrative issues and information items
RAC/09/2010/01	Framework for dealing with requests for opinions according to Article (77)(3)(c) of REACH Regulation
RAC/09/2010/02	Outline of the discussion on the classification of epoxiconazole for developmental toxicity at RAC-9
RAC/09/2010/03_rev.2	Appointment of RAC (co-) rapporteurs for intended CLH dossiers
RAC/09/2010/11	Status report on submitted proposals for harmonised CLH
RAC/09/2010/04	Recommendation to RAC on the appointment of (co-)rapporteurs for the mercury in measuring devices restriction dossier
RAC/09/2010/05_rev.1	RAC procedure for admission to the work of RAC of regular and sector-specific observers from the stakeholder organisations and their experts
RAC/09/2010/06	ECHA Secretariats responses to RAC comments on proposed admission of new stakeholder organisations as observers of the work of RAC
RAC/09/2010/07	Revision of the Rules of Procedure for RAC
RAC/09/2010/08	RAC manual of conclusions an recommendations
RAC/09/2010/09	Draft working procedure for the appointment of rapporteurs and co-rapporteurs by RAC and SEAC for authorisation applications

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