3rd November 2008

RAC/M/03/2008 final

Minutes of the 3rd meeting of the Committee for Risk Assessment
1-3 July 2008

I. Summary Record of the Proceeding

Item 1 – Welcome & Apologies

The Chair welcomed the participants to the meeting, especially the 5 new members appointed by the Management Board (MB) since the previous meeting. The Chair also introduced participants attending for the first time, including one adviser (NL). One observer (NO) attended for the second time. The RAC was informed that the meeting was recorded for the purpose of writing the minutes and that the recording would be destroyed once the minutes had been endorsed.

For this third meeting, apologies were received from 2 members. Five additional members were absent. The list of attendees is given in Part III of these minutes.

Item 2 – Approval of the Agenda

The Agenda, revision 1, was adopted after the Secretariat added one point on participation of international organisations (the OECD) and under AOB a point on QSARs was added by the RAC. The Chair presented all room documents which were also circulated electronically before the meeting. The documents distributed for the meeting, including room documents, are listed in Annex I.

Changes to the order of agenda points were agreed at the meeting but are not reflected in the minutes. The final agenda is attached to these minutes as Annex II.

Item 3 – Declarations of conflicts of interest to the Agenda

The Chair asked if there were any Conflicts of Interest to be declared specific to the meeting. In relation to agenda point 7 two members declared their membership of national environmental NGOs, BUND and Danish Nature Conservation Organisation, both in the list of non-eligible organisations given in Annex II to Doc. RAC/03/2008/22. The RAC considered that, on being aware of this potential conflict of interest, this would not exclude the members from participating to the discussion on that agenda point.

Item 4 – Adoption of the draft minutes of the RAC-2

a. Adoption of the minutes

The Secretariat introduced the revised minutes, highlighting that the comments received from 2 members and the observer from Norway had been incorporated, where relevant, in the revised version.

The RAC adopted the revised minutes as circulated, and the Secretariat will distribute the final clean version, which will also be made available on the ECHA public website.

b. Action points arising from previous meetings

The Chair reported on the status of progress of the Action points from the second meeting of the RAC and suggested that the points that had not yet been finalised will be transferred to the RAC-3 Action point list if still relevant.

Item 5 – Administrative Issues

a. Change in the RAC composition

The Chair presented Doc RAC/03/2008/19 on changes in the RAC composition. One member (nominated by Poland) had withdrawn his membership since the last meeting and 5 new members, nominated by Bulgaria, Finland, Italy, Poland and Sweden, were appointed by the MB at its previous two meetings (in April and June 2008). The newly-appointed members present introduced themselves.

b. Reimbursement rules – revised reimbursement rules

The Chair informed the RAC that in their meeting in April the Management Board had adopted the revised guide for the reimbursement of travel, hotel and subsistence expenses for Board members, Committee members and any other experts attending meetings of the ECHA. The updated guide had been uploaded in the RAC CIRCA Interest group, and at the meeting the Chair explained the main changes made.

c. Signing declarations by members

In accordance with the RAC Rules of procedure, all members were required to fill and sign the declarations of interests, commitment and confidentiality and return them to the Secretariat either at the meeting or within a 2 week period.

The signed declarations will be published on ECHA's website.

The adviser and observer of the meeting were invited to fill and sign a declaration of confidentiality.

Item 6 – Rules of Procedure (RoPs)

The Secretariat presented to the RAC a feedback from the Management Board meeting (see Document RAC/03/2008/21) with regard to the adoption of the RoPs for the ECHA Committees and Forum and informed members that this document comprising the Rules of Procedure for all 4 bodies has been made available on ECHA's website.

The agreement between the EU and the EEA-EFTA countries means that Norway, Iceland and Liechtenstein can also nominate members to be appointed by the MB, and the RoPs will need to be revised very soon to reflect this change.

The Chair concluded that the RAC RoPs would be revised in the autumn, taking the opportunity at the same time to streamline the article on confidentiality following the example of SEAC RoPs as recommended by the MB.

Item 7 - Stakeholder participation

a. Outcome of the call for participation to ECHA's work

The Secretariat presented the process of identifying stakeholders to participate in ECHA activities, which resulted in a list of 32 eligible stakeholder organisations, including 16 industry sector-specific organisations and 16 organisations with a wider interest that wished to participate in ECHA's work including the activities of the Committees and the Forum. Of these, 14 industry sector-specific and 14 wider interest organisations had expressed interest in RAC. It was clarified as well that the call for

stakeholders remains open and in the future more stakeholder organisations could express an interest to participate in ECHA's work.

The Secretariat then asked the RAC to agree to the proposed procedure and decide which stakeholder organisations to invite from the eligible ones that had expressed an interest to participate in the Committee's work. The Secretariat informed the meeting that the Member State Committee had agreed to invite all 14 eligible non-sector specific stakeholders that had expressed an interest in participating to its work, to be reviewed within 6 months, noting that the Chair had the prerogative of organising closed sessions within the meeting and that a code of conduct is planned for stakeholders. In addition, the MSC had proposed to invite an organisation representing the small and medium-sized enterprises, UEAPME, to bring the total number of invitees to 15.

A debate took place clarifying the role of stakeholder observers at the meetings, the number of the stakeholder observers to be invited, the management of stakeholders' interventions and the application of the duty of confidentiality.

The RAC considered that the role of stakeholder observers was mainly to follow the proceedings to ensure transparency, but also to contribute with specific knowledge to bring the discussion forward.

The RAC was concerned that the balance between the committee members' discussions and the interventions by stakeholders should be appropriately managed, and proposed the RAC Chair to be responsible for this. The RAC proposed that contributions and interventions should be communicated to the chair in advance of a meeting, and that one spokesperson could be nominated to represent a number of interest groups with common interests. The Secretariat agreed to discuss these suggestions with the invited stakeholder organisations to agree on a best practice protocol for the meetings.

The RAC discussed the necessity of involving downstream user organisations in their work and the Secretariat responded that since the call remained open downstream user organisations still had the opportunity to respond to the call. Furthermore, the RAC considered excluding the academic organisations since there were other platforms for the communication of the Committee's work via the scientific societies, but finally it was agreed to keep flexibility on this issue.

Following the discussion, the Chair concluded that the RAC agreed to invite the 14 eligible non-sector specific stakeholder organisations (see conclusions and action points for the list of organisations) to participate in their work as observers and gave a mandate to the Secretariat to invite each of the stakeholder organisations to nominate one regular attendee. In addition, one organisation, UEAPME, representing the small and medium-sized enterprises would be invited. The RAC expressed a wish to review the proposed procedure and the list of invited stakeholder organisations in the light of experience after 6 months.

b. Code of conduct for stakeholder observers

Elements for a code of conduct (Annex III to RAC/03/2008/22) had been discussed at the second MSC meeting 24-25 June 2008, and the suggestions had been reflected in

the ECHA Draft Code of conduct for observers, presented as room document RAC/03/2008/35. It was highlighted that ECHA wished to have a common Code of conduct for observers applicable to all of ECHA's bodies.

The RAC members commenting on the proposed code of conduct all expressed their agreement and only a few questions were raised. The first was in relation to the rules on confidentiality and whether paragraph 13 was meant to cover media briefings. The Secretariat agreed to amend the text of paragraph 13 to include reference to media briefings in relation to the need to maintain the confidential nature of discussions and individual views.

The second issue was related to the distribution of documents prior to and during a meeting by the stakeholders. Some members expressed their concern related to distribution of room documents without restrictions that could force the committee to postpone decision making, and concern that the stakeholder observers would use the opportunity to re-submit information already provided during the public consultation. It was therefore agreed to revise paragraphs 14-16 of the draft Code to address these issues.

The Chair thanked the Committee for their input which would be used to revise the document and present it to the MSC with the aim of finalising and providing to the stakeholder observers before their first attendance to any meeting of the ECHA Committees.

Item 8 – Procedure for appointment of rapporteurs and co-rapporteurs

The Chair introduced the revised version of Document RAC/02/2008/13 and the response-to-comments table prepared by the Secretariat.

A few members highlighted that in additional to the members' personal expertise also expertise at national level could be a relevant factor when appointing rapporteurs.

The RAC agreed with the proposed revised document with minor changes.

Item 9 – Working Procedures- C&L Annex XV dossiers

Opinion Template Example and Opinion Support Document Example

As agreed at the previous meeting, the Secretariat presented an example of a template for an Opinion and a filled-in example of an Opinion and an Opinion Support Document (OSD) to illustrate ECHA's vision of the content of an OSD. ECHA had already made a proposal (Doc. CA/11/2008) to the REACH CA meeting on 27-28 March 2008 regarding the necessity of having such a support document for all its decisions and opinions. The CA meeting had agreed that such a document should be available with the purpose of e.g. providing the Commission with the consolidated scientific and technical justification for the RAC's opinion. The further discussion at the CA meeting had focused on who would be responsible for preparing the OSD.

The main concerns expressed by some of the RAC members were in relation to taking responsibility for a document which may be long and complex and may contain information that might not be completely relevant to the final opinion of the RAC. If the RAC was to take responsibility for the document it might be necessary to check all details for accuracy, even those not directly related to the opinion. This would be an

extra burden on the RAC, increasing the task of the rapporteur significantly. It was recognised though that the final opinion should contain a statement of reason according to the draft Regulation on classification, labelling and packaging of substances and mixtures (CLP Regulation) and that in cases where the opinion was not fully supporting the original proposal, a background document of a similar level of detail as in the original proposal might be required. For reasons of efficiency the best starting point for this background document would be the original Annex XV report. In response to a proposal that the MS CA should make a revised Annex XV proposal on the basis of the RAC's opinion, the Secretariat replied that this was not foreseen in REACH without re-submitting the proposal and restarting the whole process. The RAC recognised the need to support as much as possible the legal process in the Commission and to avoid any misunderstanding or misinterpretations that could result if the relevant information would be scattered among several documents, e.g. the original Annex XV dossier, minutes of meetings, written comments and response-to-comments tables. To a question on the legal status of such documentation, it was clarified by ECHA's legal adviser that any appeals in court would normally be on the basis of the Commission decision (e.g. the adaptation to technical progress of Annex I to Dir 67/548/EEC) resulting from an opinion, as the opinion itself including its supporting documents, could not be regarded as legal text.

After a long and lively discussion the RAC concluded that an OSD, as a background document supporting the opinion, should be developed, possibly renamed as 'background document', since it was felt that the opinion itself containing the statement of reason, i.e. a short summary of the scientific basis of the opinion (in particular where this opinion would differ from the original proposal), would need further support by the more detailed background document containing all the necessary scientific arguments.

The RAC also agreed to the process proposed by ECHA that the submitting MS, possibly supported by ECHA, would provide their response-to-comments for the comments resulting from the public consultation and, if relevant, a first proposal for the OSD. The rapporteur together with the co-rapporteur, if appointed, would then review the Annex XV report and the response-to-comments and provide his/her opinion. The opinion would be presented to the RAC for its comments and agreement and in parallel the rapporteur would develop the OSD, in co-operation with the ECHA Secretariat if wished. The RAC noted that as it would wish to endorse only the parts of the OSD necessary for arriving at the opinion, the OSD could therefore contain a disclaimer stating that RAC had only endorsed the relevant parts of the OSD. Alternatively, parts not directly relevant for the opinion could be removed. The Secretariat added that ideally the OSD should only contain the relevant data. One member provided an example at the meeting of how this could look based on the example OSD provided by the Secretariat. The RAC accepted that the OSD could be endorsed either by written procedure or at a meeting.

The Chair concluded that the members agreed with the ECHA's proposal to adopt not only the RAC opinion but also to endorse the respective parts of the OSD reflecting the work of the committee. As follow-up the Secretariat would edit the content and terminology used in the template of the opinion, the filled-in example of an opinion and OSD to reflect the agreement that the opinion should contain a justification summarising the scientific grounds. The OSD should include a preamble underlining the relevant parts that the RAC had evaluated and indicating where changes had been made and approved by RAC in the OSD to reflect their opinion.

The Chair also concluded that the first C&L Annex XV dossiers would be used as test cases for all members, and that the RAC would evaluate the distribution of the required information between the opinion itself and the OSD when finalising these first cases.

Accordance check

The Secretariat explained the purpose and procedure for the accordance check, as agreed at RAC-2, in more detail as described in document RAC/03/2008/26 and underlined that the check should focus on checking the availability of necessary information, and not enter into an evaluation of the data per se.

The Chair introduced the accordance check principles and the format of the accordance check report specified in Appendix I of document RAC/03/2008/26. It was clarified that ECHA would make a first accordance check of an Annex XV dossier and, on request, should give the outcome of its accordance check to the rapporteur. Some members noted that additional work should be avoided and indicated their support for a co-operative and "friendly " approach for the accordance check.

The RAC agreed that the rapporteur should make the accordance check jointly with ECHA but considered that the final approval of the accordance check report by the RAC would not be necessary and requested the procedure to be modified accordingly. In addition, a few editorial observations to the check list in Appendix I were made. The Secretariat would amend the document based on these observations and with these remarks, the RAC agreed to the document.

Processing a C&L dossier

The Secretariat presented document RAC/03/2008/27, containing a proposal for processing an Annex XV dossier for a harmonised C&L, clarifying the timelines and main procedural steps.

The Chair went through the process step by step and underlined that the submitting MS had agreed to provide responses to comments submitted by other MS CAs and by parties concerned, integrating these, where relevant, into the background document provided by the ECHA Secretariat. The rapporteur would then use these documents as a basis for the development of the opinion on the proposal in the original Annex XV report.

The Commission (DG ENV) clarified that a foreseen timeframe of 18 months was given in Article 39 of the proposed Regulation on harmonised classification and labelling of hazardous substances and mixtures (CLP Regulation). The proposed timelines for the procedure suggested by the Secretariat was around 6 months from public consultation, followed by response to comments from submitting MS and RAC written commenting round on rapporteur's first draft opinion, to first discussion at a RAC meeting on a revised draft opinion, which was shorter than the envisaged legal deadline of 18 months thus allowing extra time for further discussions of difficult substances in more than one RAC meeting..

Many members considered that the timelines were too short, in particular the one for the RAC to provide comments to the draft opinion and emphasized the need of feasible timelines for the RAC and more flexibility for the rapporteur. It was also pointed out that the timelines may need to be dossier dependent to some extent considering the submission date in relation to the fixed dates of the RAC meetings when the dossier could be discussed.

Several members also raised the question about the necessity to use IUCLID 5 to access the documentation when developing an opinion. The Secretariat explained that the Annex XV report was a MS-Word document within the IUCLID 5 dossier which could be extracted from the dossier and provided to the RAC, as well as being posted on the ECHA website for public consultation in pdf format. However, in order to have access to the detailed description of the studies in robust study summary format IUCLID 5 would be required to view the full dossier.

One member pointed out that not all Annex XV dossiers for harmonised classification and labelling would have an IUCLID technical dossier at the moment and may not need one for the purposes of registration under REACH, e.g. the plant protection products. Hence such an annex would only need to be generated for the purpose of C&L. The Secretariat underlined that the default is that the robust study summaries would be provided via IUCLID, but agreed to evaluate if this would be a strict requirement also for active substances used in plant protection products and biocidal products.

The Chair concluded that the RAC agreed to the process and procedures outlined, but wished to comment further on the timelines after the meeting. Comments on the timelines are to be sent by 3rd September 2008.

Item 10 – Working Procedures – Restrictions dossiers (including transitional (Article 136 (3)) dossiers)

Conformity check

The Chair summarised the follow up activities after the RAC-2 meeting and presented the revised version of the document describing the conformity check (RAC/02/2008/15) and the response-to-comments document prepared by the Secretariat responding to the comments received from the RAC.

The RAC endorsed the revised document with minor changes; see part II RAC-3 Conclusions and Action Points.

Proposal for handling 793/93 transitional dossiers

The Secretariat presented a proposal for handling the dossiers resulting from non-finalised work by previous committees under Regulation 793/93, which fall under the transitional measures for existing substances (Article 136(3) of REACH), and explained that transitional dossiers for about 27 substances would be expected by 1 December 2008. The Secretariat had prepared an overview of the dossiers and what kind of risk management measures could be expected for each of them. The MSCA would be consulted in the near future to provide further details.

The Secretariat noted that according to Article 136 of REACH there was no legal obligation for the RAC (or SEAC) to be involved. However, it seemed to be helpful for understanding the processes, e.g. the conformity check process, to use some of the transitional dossiers as test cases for RAC and SEAC for future restriction proposals.

For some of the substances, other legislative measures than restriction will probably be identified as relevant. The RAC concluded that it would be useful for the RAC to discuss also these dossiers in order to understand the interface between REACH and other EU legislation.

Furthermore, learnings from the test cases could be used as feedback to the ECHA guidance teams to refine the format for Annex XV Restriction report and for the envisaged future revision of the guidance on preparing a restriction dossier.

RAC agreed to prioritise the transitional dossiers giving the highest priority to dossiers proposing restrictions followed by those proposing other Community wide measures. The RAC noted that it would appreciate the opportunity to comment on the 3rd category of dossiers in which local or national measures were proposed, however appreciating the short timeframe available this category of transitional dossiers were recognised to be clearly a lower priority.

One member asked whether the rapporteurs appointed for the test cases would become rapporteurs for the formal submission and the Chair agreed that this might be an efficient use of resources.

The Secretariat noted that a very limited number of transitional dossiers (around 3) proposing restrictions of a nature likely to lead to a restriction under REACH would be expected by 1 December 2008. The RAC could use the opportunity to clarify the interface between RAC and SEAC, develop a common understanding on what is a conforming dossier, and provide observations to the submitting MS CA to allow them to complete and improve the dossiers where relevant, before submission of restriction proposals after 1 June 2009.

The Chair concluded that the RAC agreed to use the transitional dossiers as test cases for restriction proposals before formal submissions by Member States next year.

Item 11 – Planning of the work for 2008 and 2009

Registry of Intentions of MSCAs

The Chair presented the current content of the registry of intentions for proposals for harmonised classification and labelling which was based on information provided by MS and clarified that the document had been distributed for information and in order to plan the work of the RAC for 2008/2009.

Item 12 – Appointment of rapporteurs

Annex XV C&L proposals

Diantimony trioxide

Hexabromocyclododecane (HBCD)

Mycophenolic acid, triethylamine salt (MPA – TEA)

The Secretariat made an introduction for the first three Annex XV C&L dossiers submitted to ECHA and clarified that the C&L proposals concerned carcinogenicity, reproductive toxicity and repeated dose toxicity. It was specified that a pre-accordance check had been made by ECHA. The first observations were that the format of the reports was essentially in line with the Guidance, but the IUCLID part of the dossiers was almost empty. For two of the dossiers there were clear indications of the scope but for the third one no justification for Community wide C&L was given for end-points not foreseen as harmonised endpoints in the REACH Regulation. The Annex XV reports contained references to reports from other legal processes that were not (yet)

publicly available. Another substance is used for pharmaceutical production and the Annex XV report is based on incompletely referenced summary information for structurally related pharmaceutical substances. While the sources are highly reliable it is unclear at this stage whether the brief extract is sufficient to allow an evaluation of the reported results.

The Secretariat pointed out that in future Annex XV dossiers would be based on the registration dossiers ensuring that a IUCLID technical dossier would be available. Any proposal for action at Community level had to be justified, either automatically with a reference to the end-points listed in Article 115, or case by case with specific reasons.

In the discussion which followed some members asked for clarifications on what the RAC should form an opinion on; only harmonised endpoints or other endpoints for which data in the dossier would allow a classification. For example it was questioned whether the submitting MS in making a proposal for reproductive toxicity would also provide an evaluation of the data available for the other endpoints under REACH that may potentially be harmonised (i.e. carcinogenicity, mutagenicity and respiratory sensitisation) and if the data were not provided nor assessed, was it the role of the RAC to suggest classification for an endpoint that was not included in the original proposal. The Secretariat underlined that there was not such an obligation in the REACH Regulation, however, if there were also data available indicating that the substance was also carcinogenic it might be advisable for the submitting MS to include an evaluation of these data and present a conclusion on whether a classification was appropriate or not. However, it was not the role of the RAC to suggest classification for an endpoint that was not included in the original proposal.

The Secretariat also pointed out that harmonised C&L for any end-point beyond those listed in Article 115 required a justification on the need for a Community wide harmonised classification. The RAC would be required to judge such justifications. However, to ensure consistency of judgements, the development of examples, with support from ECHA, COM and MS CAs on what would constitute a well-founded justification was supported by the RAC.

The Secretariat reported that the ECHA accordance check should be finalised by 10th July and then the outcome would be provided to the appointed rapporteurs.

The Chair summarized that two of the dossiers were for ESR substances and justifications for the proposals should be based on their Risk Assessment Reports and the third dossier was for a pharmaceutical intermediate.

The Commission (DG JRC) informed the RAC that because a large number of risk assessment reports had been received at the end of May some were still waiting to be formatted and published on the ECB website. However, the reports relevant to a submitted C&L proposal would be prioritised for publication.

(Pre-)Appointment of rapporteurs and co-rapporteurs

The Secretariat had invited volunteers to act as rapporteurs or co-rapporteurs for the first 3 submitted C&L dossiers and for a further 20 substances in the registry of intentions (RoI) for harmonised C&L. In the Room document RAC/03/08/31 Rev.1 the member's responses were collated and where there was more than one name against each position the Secretariat had made a first proposal for selection based only on an even distribution of the dossiers. The Chair noted that the rapporteurs and co-

rapporteurs should be appointed for the first 3 submitted dossiers and a pre-appointment of rapporteurs and co-rapporteurs for the other substances would be desirable. The Chair also announced that Germany had sent a notification withdrawing 4 of their substances from the RoI and asked the volunteers for those substances to reconsider their (co-) rapporteurships for the next substances to be notified by the Member States.

Two members declared their familiarity with some of the substances from previous working activities and asked the RAC and the Secretariat whether this would be considered a conflict of interest or if they could be volunteers for rapporteurship for those substances. RAC agreed that there were no conflict of interests. In the case of formaldehyde, France was the submitting MS for a proposal in relation to carcinogenicity but the substance was also undergoing evaluation by Germany as a biocide, which may require a classification proposal for all other endpoints. The question from one member was whether employment by the German organisation responsible for preparing the biocides dossier would represent a conflict of interest for rapporteurship of the proposal from France. The Secretariat suggested that the member put forward their candidature for the dossier for pre-appointment by the RAC and this potential conflict of interest would be examined in more depth prior to the dossier submission which in any case would not be until 2009.

The Secretariat was asked for more information about the content (i.e. the endpoints for which classification was proposed) and more specific timings of the C&L proposals for the substances in the RoI to better identify what kind of expertise would be relevant and, therefore, who would be the most appropriate rapporteur. The Secretariat informed the RAC that the MSCA had been asked to provide more information in the RoI and when this information became available the pre-appointed rapporteurs and co-rapporteurs could re-evaluate their commitment and availability. Furthermore, at the previous CA meeting a proposal to establish a forum for information exchange between the CAs on planned submissions had been put forward. This forum would also facilitate the provision of better information to the RAC on proposed intentions of Member States.

Following these clarifications other volunteers for rapporteurship/co-rapporteurship for the rest of the substances identified themselves.

Finally, RAC made an appointment of the rapporteurs and co-rapporteurs for the first three dossiers submitted and a pre-appointment of all rapporteurs and co-rapporteurs for the substances for which the intentions from MSCA had been registered in the RoI.

Item 13 – Participation of International organisations

The Secretariat presented the background to the proposal to invite one representative from the Secretariat of the Organisation on Economic Co-operation and Development (OECD) to participate as an observer in the RAC activities.

Considering the increasing recognition of REACH as an international model for regulation of chemicals and in accordance with Article 107 of REACH, the MB had approved at their meeting in April the participation of observers from the OECD in the ECHA activities, underlining the value and advantages of such technical and scientific cooperation that would allow REACH to be represented globally through the OECD. Therefore, the ECHA committees were recommended to agree to invite one observer from the OECD Secretariat to take part in their work.

RAC welcomed the idea for promoting cooperation and joint activities with the OECD and proposed to develop a strategy paper related to common activities with the OECD (e.g. related to QSAR, development of testing methods, etc.).

The RAC agreed to invite a representative of the OECD Secretariat to their meetings as observer and asked the Secretariat to send an invitation, also requesting the designated participant to present the role and main activities of the OECD and possible common activities with the RAC at the first meeting to which (s)he will participate.

Item 14 - Feedback from other ECHA bodies

a. Management Board meeting (23-24 April and 18-19 June)

The Secretariat noted that relevant feedback was already given during the Agenda Items 5a, 5b, 6, 7, 13 and 15c. Next meeting of the MB will be in September.

b. Member State Committee meeting (24-25 June)

The Secretariat presented the main discussions and outcomes of the second MSC meeting (24-25 June) related to working procedures for Substances of Very High Concern (SVHC) including draft template for MSC agreement on identification of SVHC, and for examination of testing proposals and related draft decisions and stakeholder participation. It was underlined that as the MSC process did not envisage a rapporteur, the Secretariat would carry out accordance check on Annex XV dossiers and draft the agreement on the proposals for SVHC that the MSC should agree with or not, within 30 days. It was envisaged, also in view of the strict timelines, to use written procedures to the maximum extent to facilitate the processes.

The Secretariat also informed RAC that four more MSC meetings were planned in 2008 and that 16 proposals for SVHC had been received. They would be discussed at the MSC meeting in October. Regarding testing proposals, it was explained that the first testing proposals were expected in 2009.

c. Committee for Socio- economic Analysis (2-3 April) and SEAC Inter-sessional WG meeting (11-12 June)

The Secretariat introduced the main discussions and outcomes of the first SEAC meeting (02-03 April) which related to SEAC Rules of Procedure (RoPs), discussion on the tasks of the committee and working procedures. In practice, SEAC would start working in 2009 and would deal with data validation issues and SEA issues in 2008. One outcome of the first SEAC meeting was the decision to establish an inter-sessional SEAC working group inviting up to 5 RAC members to take part in that working group.

During the first meeting of the SEAC Inter-sessional WG that was held on 11-12 June the main discussion points were related to good cooperation between committees, further restriction-related procedures, shared access to the CIRCA RAC and SEAC Interest groups, RAC and SEAC rapporteurs good interaction and cooperation, Joint WG to support both rapporteurs. The general conclusions from the group meeting pointed to the need for high-quality Annex XV dossier submissions, a need to match the RAC and SEAC opinions, use of test cases for the purpose of close Committees cooperation, the challenge of producing one common OSD from the RAC and SEAC, when necessary.

RAC was also informed about the planned workshop on 21-22 October that ECHA would organise for the SEAC, with the title 'Workshop on Applying socio-economic analysis as part of restriction proposals under the REACH Regulation'. The Secretariat invited all RAC members who were interested in participation in the workshop to participate to it.

One member suggested in some cases when discussing individual Annex XV dossiers to invite the SEAC rapporteur for that dossier to take part in the RAC meeting(s), in order to avoid problems in drafting the OSD and to facilitate the discussion regarding that substance in both Committees and the coherence and interaction between them.

Item 15 – AOB

a. Next meetings *(September 16-19, 2008 tentative)*

(November 18-21, 2008 tentative)

The Chair informed the RAC that the next meeting was planned for 16 to 19 September 2008 in Helsinki but taking into account the envisaged workload, it seemed unnecessary to have two meetings before the end of the year. Therefore, the proposal was to cancel the meeting in September.

RAC agreed with this proposal and suggested to the Secretariat instead to establish a working group consisting of the rapporteurs and co-rapporteurs for the three substances, and invite all the RAC members to attend to allow the RAC to capture the learnings from the first accordance checks. The RAC agreed that if the attendance would be low the face-to-face meeting could be substituted with a telephone conference.

The meeting planned for 18-21 November will take place with the number of days to be confirmed later.

Proposed meeting dates in 2009

The Chair introduced the Secretariat's proposal for meeting dates in 2009, given in room document RAC/03/2008/33, and clarified that since it was not clear whether 5 or 6 meetings would be needed in 2009, it had been proposed to block in total 7 weeks, whereby the March and May RAC meetings could be combined to one meeting in April if only 5 meetings were needed.

The RAC took note of the meeting dates, and several members asked the Secretariat not to reserve three separate weeks when only 1 or 2 would be used. The Secretariat explained that the reasoning behind the Secretariat's planning was to have the meetings evenly distributed in time for spring 2009.

Members recognised the difficulties in planning meetings when the number required was dependent on the workload of the Committee and this was not yet fully known, Nevertheless the preferred approach was to schedule the maximum number of meetings envisaged and then to cancel meetings that were not needed rather than to move meeting dates.

The Secretariat agreed to consider the RAC comments in finalising the dates for the 2009 meetings.

b. Proposed structure of the RAC CIRCA interest group and instructions on working with CIRCA

The Secretariat introduced document RAC/03/2008/34, in which the use of CIRCA is explained for access and distribution of RAC documents, and made an on-line demonstration of the possibilities of the CIRCA Newsgroups as an important instrument for commenting on documents.

c. Implementing rules for the Fee Regulation

The Secretariat informed RAC members about the current status of development of the implementing rules of the Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.04.2008), the so-called Fee Regulation..

It was explained that the MB had started the discussion of the implementing rules for the Fee Regulation which, inter alia, addresses the remuneration of tasks performed by the members of the committees, but as the remuneration for the work of the committees is for the restrictions and authorisation procedures which only start mid-2009, it was intended that the MB would adopt their implementing rules by the end of 2008.

The Secretariat clarified that the C&L process was not covered in the Fee regulation and no remuneration should be expected.

One member asked for clarification in case of remuneration how the compensation could be organised if the rapporteur's organisation was not a REACH Competent Authority and further asked whether it would be possible to arrange transfer of the remuneration directly to the rapporteur's institution, and not via the Competent Authority.

The Secretariat answered that according to Article 14 (1) of the Fee Regulation, such transfers are to the Competent Authority and the Fee Regulation was very clear in the issue.

d. QSARs

Concerning QSARs, one member raised the issue of capacity building and use of QSAR methods in Member States, which had also been highlighted at the last OECD QSAR workshop. Taking into account the need of having a QSAR subgroup to follow up on the non-finalized work of TC-NES QSAR Subgroup, he proposed to the RAC to prioritise establishment of such a Joint RAC/MSC WG.

Many members supported the proposal and requested the Secretariat to consider feasibility of and need for establishing a joint RAC/MSC WG on QSAR already in an early phase to address the unfinished work of the TC-NES QSAR subgroup and future work on QSAR.

The Secretariat proposed that, along with consideration of the need for a joint RAC/MSC PBT working group, the mandate and work programme of a joint QSAR working group needed to be fully explored. The RAC requested the Secretariat as a first step to raise the proposal of the RAC at the next MSC meeting in September.

Item 16 - Action points and main conclusion from RAC-3

The Secretariat presented in detail a draft table of the decisions and action points agreed at the meeting for each agenda item to be endorsed by the RAC at the meeting.

The RAC commented on the decisions and action points, which the Secretariat amended accordingly, and endorsed the document.

The Secretariat agreed to distribute the table to the members on the day after the meeting and it is also attached as part II of the meeting minutes.

II. Conclusions and action points

RAC-3 ACTION POINTS & MAIN CONCLUSIONS
(as adopted at the RAC-3 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
4. a) Draft minutes b) action points arising from previous meetings	• a) the RAC adopted the Draft final minutes without changes • b) Action points not yet addressed to be listed in AP for RAC-3	• a) adopted minutes of RAC-2 to be uploaded to CIRCA and ECHA website (SECR / after the meeting) • b) Action points to be transferred to list of action points for RAC 3
5 Administrative issues c) signing declarations by members	• RAC members to sign declarations 1, 2 and 3. Observers and stakeholders and invited experts need to sign only the confidentiality declaration.	• SECR will distribute a declaration template in electronic format (SECR / after the meeting) • Members have to return the signed forms within two weeks, i.e. by 17 July.
6. Rules of Procedure (ROPs)	• RoPs approved by MB with one change. • Will require revision relatively soon to take account of the EEA-EFTA agreement on REACH, at which time opportunity to streamline certain aspects in line with SEAC RoPs would be taken.	• Final RoPs to be made available on the ECHA website and CIRCA (SECR/after the meeting) • Secretariat to provide a proposal for revised RoPs in the autumn reflecting the EEA-EFTA observers and the streamlining required by the MB in line with the SEAC RoPs.
7. Stakeholder participation a) outcome of the call for participation to ECHA's work	• The RAC agreed to admit the following organisations expressing an interest in RAC to contribute to its work including participation to its meetings as observers: BEUC - Bureau Européen des Unions de Consommateurs, BusinessEurope - The Confederation of European Business, CEFIC, CONCAWE, Eurometaux (*European Association of the Metals Industry), European Coalition to End Animal Experiments* (ECEAE), European Trade Union Confederation (ETUC), Health and Environmental Alliance, European Environmental Bureau (EEB), Friends of the Earth Europe, Greenpeace International, WWF European Policy Office, ECETOC, EUROTOX (*Federation of European Toxicologists & European Societies of Toxicology)*. In addition the SME organisation UEAPME would be invited to consider participation to RAC work to aim for a balanced representation of Industry organisations, making a total of 15 organisations to be	• Send a general invitation to the selected stakeholder organisations expressing their interest to the RAC work (SECR/by end of July) indicating review of the decision in 6 months time

	invited. • Invitations from RAC to eligible industry sector-specific organisations where relevant to discussions on specific dossiers/issues. • The RAC agreed that to ensure continuity it would be important to have one regular attendee per organisation invited. • Stakeholder observers should inform and send information to the chair in advance of the meetings concerning the contributions/interventions they wished to make. Chair to consult Rapporteur where appropriate. • Interventions should be preferably organised by having a limited number of spokespersons at the meetings, one per interest group. • In any case, Chair should manage the balance and control the interventions made by observers • The list of invitees and procedure should be reviewed within 6 months	
7 b) code of conduct for stakeholder observers	RAC expressed general agreement to the draft code of conduct with the following observations: • Confidentiality concept should be clarified in the text, in particular regarding the rights of representatives of stakeholder organisations to report back to their constituencies, and whether it should be explicitly mentioned what is or is not acceptable to report to the media and that confidentiality of the deliberations and views expressed should be maintained • Distribution of documents by stakeholders should be clarified with respect to room documents and that RAC should have discretion not to take late documents into account. • Case- owners to be separated from the stakeholders • The interventions of stakeholders should be limited to avoid stakeholders dominating the meeting, and if possible, even agreed beforehand. • interventions at the meeting should	• SECR will prepare a new version on code of conduct based on the discussions in the RAC and the MSC with the aim of agreeing on one code of conduct for all ECHA bodies.

	not repeat comments made in the public consultation	
8. Procedure for appointment of rapporteur and co-rapporteur	• The document, RAC/02/2008/13_Rev.2, was endorsed with the following change: reference to 'main manufacturing site' on page 3 will be removed	• SECR to modify the document and upload the final version on CIRCA.
9. Working Procedures - C&L Annex XV dossiers a) Opinion b) Opinion support document c) Accordance Check d) Processing a C&L dossier	• a+b) The RAC agreed that a background document supporting the opinion is needed when the RAC adopts an opinion. • a+b) The RAC agreed that the background document must support the legal process in the Commission. • a+b) RAC agreed to endorse only those parts of the background document related to their opinion • a+b) RAC should justify their opinion in the background document based on all scientific key elements and argumentations for each endpoint or study for which the harmonized C&L was proposed in order to avoid different interpretations • a+b) The terminology and exact content of the opinion and the background document supporting the opinion (opinion support document) needs to be further elaborated; the opinion should contain a justification which is a summary of the science, and the support document should include a pre-amble highlighting the most relevant sections and indicating where the RAC had proposed changes in the background report to reflect their opinion. • a+b) First submitted C&L Annex XV dossiers to be used as testing cases for all RAC members • c) The RAC agreed to Doc 26 on the accordance check, noting that a few editorial changes to the annex with the questions would be made. • d) The RAC agreed to the process description given in document 27 with one change regarding RAC involvement in accordance check. • d) The timeline needs to be considered	• c) SECR will edit document 26 and circulate the final version. • d) The RAC is invited to send comments on the time line proposed in doc 27 within two months, i.e. by 3rd September.
10. Working Procedures -	• a) The RAC endorsed Doc 15_rev1 on criteria for conformity check with	• a) final version of Doc 15_rev1 will be circulated after the

Restrictions dossiers (including transitional (Art 136 (3)) dossiers) a) Conformity check b) Proposal for handling 793/93 transitional dossiers	the following changes: deletion of reference to 'Voluntary measures by IND' in the section on justification that action is required at community-wide level, and addition of 'whether the dossier has already been agreed in other contexts' in the section on information on hazards and risks. • b) The RAC recognised that there is no legal basis for involvement of the RAC on the transitional dossiers. Therefore it was agreed to use them as test cases or pre-discussion for restriction proposals before MSCAs later formal submissions. • The RAC would take the best examples to work on, i.e. the ones likely to provide the greatest learning experience. • The RAC agreed that highest priority were dossiers containing restrictions followed by those proposing other community wide measures, but also requested to be given the opportunity to comment on the 3rd category of dossiers where local or national measures were proposed. • Timely communication of outcome to MSCA agreed to be important to allow taking into account when submitting their formal dossiers • Test rapporteurs could become the rapporteurs for the formal submission. • MSCA to be requested to complete transitional RoI on types of measures likely to be proposed.	meeting (SECR / after the meeting) • b) SECR will request MSCAs to complete transitional RoI on types of measures likely to be proposed.
12. Appointment of rapporteurs Annex XV C&L proposals: a) Diantimony trioxide b) Hexabromocyclododecane (HBCD) c) Mycophenolic acid, triethylamine salt (MPA-TEA)	• Rapporteurs and co-rapporteurs for the first three dossiers were appointed by RAC. • RAC made a pre-appointment of all rapporteurs and co-rapporteurs for the substances for which the intentions from MSCA were registered in the Registry of intentions. • RAC agreed on a working group in Sep. 2008 to capture the learnings from the first accordance checks. • RAC were informed that 4 substances 6 to 9 in Table 2 were withdrawn by DE from RoI	• Some more information to be requested from the MSCA about some of the registered intentions for submission of Annex XV dossiers (Secr/ …) • ECHA accordance check report to be provide for first 3 dossiers to Rapp & co-rapp by 10th July • SECR will distribute a revision of document RAC/03/2008/31 which includes the names of the rapporteurs and co-rapporteurs for all the substances

	• RAC considered ECHA may need to offer assistance to MS CAs on requirements for Annex XV C&L submissions in IUCLID format for biocides and pesticides.	
13. Participation of International organisations	• RAC agreed to invite the OECD Secretariat to take part in the meetings of the committee as observer. • observer from the OECD Secretariat to be requested to present the role and main activities of the OECD and possible common activities with the RAC.	• SECR to send a general invitation to the OECD Secretariat for participation of their representative in the RAC meetings. • SECR to send a request to the invited OECD Secretariat participants to make a presentation for the next RAC meeting.
14. Feedback from other ECHA bodies c) Committee for Socio Economic Analysis (2-3 April), and SEAC Inter-sessional WG meeting (11-12 June, 2008)	• RAC was invited to take part in the SEAC workshop on 22-24 Oct 2008 organized by ECHA. • RAC agreed good cooperative working relations with SEAC to be established. • Joint working group clarifying the respective roles in Annex XV restriction procedure to be considered.	• SECR to send an invitation to RAC members for the SEAC workshop.
14.AOB a) Next meetings b) Proposed structure of the RAC CIRCA interest group and instructions on working with CIRCA c) Implementing rules for the fee regulation	• a) RAC agreed that the planned meeting for Sep. 2008 is not necessary and may be replaced with a working group. • ECHA was requested by RAC to consider feasibility of and need for establishing a joint MSC/RAC WG on QSAR already at an early phase to address the unfinished work of the TC-NES QSAR subgroup and future work on QSAR.	• SECR to present issue of joint WG to MSC at its September meeting
GENERAL		• all presentations and room documents on Circa (SECR /by 04/07/08) • conclusions and action points (i.e. this doc) to be uploaded to Circa (SECR /by 04/07/08) • remaining mini-CV to be published by SECR • Missing mini CVs to be provided by members.
Actions carried over from RAC-2	• ECHA requested by RAC to consider feasibility of and need for establishing a joint MSC/RAC PBT WG already at an early phase to address the unfinished work of the TCNES PBT subgroup and future work on PBTs.	• SECR to present issue of joint WG to MSC at its September meeting

III. List of Attendees

Members		**Representatives of the Commission**
BARANSKI Boguslaw		ASCHBERGER Karin (DG JRC)
DI PROSPERO Paola		BINTEIN Sylvain (DG ENV)
DUNGEY Stephen		GRAJALES Sylvie (DG ENTR)
GREIM Helmut		
GRUIZ Katalin		**ECHA staff**
HALKOVA Zhivka		DANCET Geert
HOYAUX Daphné		DE BRUIJN Jack
KADIKIS Normunds		CALVO TOLEDO Juan Pablo
KREUZER Paul		DEMI Rossella
LE CURIEUX-BELFOND Olivier		ERICSSON Gunilla
LEINONEN Riitta		HAUTAMAKI Anne
LOSERT Annemarie		KARHU Elina
DUNAUSKIENE Lina		MAURER Diana
LUND Bert-Ove		MUNN Sharon
NUNES Céu		RASMUSSEN Kirsten
PICHARD Annick		SCHOENING Gabrielle
POLAKOVICOVA Helena		VAHTERISTO Liisa
POSPISCHIL Erich		VASILEVA Katya
PRONK Marja		YLÄ-MONONEN Leena
RUPPRICH Norbert		
SCHULTE Agnes		
SMERHOVSKY Zdenek		
SMITH Andrew		
STOLZENBERG Hans-Christian		
SULG Helen		
TARAZONA Jose V.		
TOMSONE Margita		
TYLE Henrik		
VAN MALDEREN Karen		
VILANOVA Eugenio		
ZGLOBIU Mariana-Elena		

Advisers to the RAC members

Ms. HAKKERT, Betty (adviser to Marja PRONK)

Observers

Ms VAN DER HAGEN, Marianne (observer from Norway)

IV. List of Annexes

ANNEX I. List of RAC-3 meeting documents submitted to the RAC Members

ANNEX II. Final Agenda

ANNEX I.

Meeting documents submitted to the Members of the Committee for Risk Assessment (RAC-3)

Document Title	**Document number**
Draft Agenda (Agenda Item 2. Rev 1)	RAC/A/03/2008_rev.1_room doc
Final Minutes of RAC 2 (Agenda Item 4)	RAC/M/02/2008 draft final
Action points and main conclusions of the 2nd meeting of the Committee for Risk Assessment (Agenda Item 4)	RAC/03/2008/19
Change in composition of the RAC (Agenda Item 5)	RAC/03/2008/20
Rules of Procedure of the Committee for Risk Assessment. Cover note. (Agenda Item 6)	RAC/03/2008/21
Admission of stakeholder organisations as observers (Agenda Item 7)	RAC/03/2008/22
Appointment of rapporteurs and co-rapporteurs (Agenda Item 8)	RAC/02/2008/13_Rev.2
Response to comments on RAC/02/2008/13_Rev.1 (Agenda Item 8)	RAC/03/2008/23
Example template for RAC opinion on Annex XV Proposal for Harmonised C&L (Agenda Item 9)	RAC/03/2008/24
Draft example of an Opinion Support Document for an Annex XV Proposal for Harmonised Classification and Labelling (Agenda Item 9)	RAC/03/2008/25
Procedure for submitting an Annex XV dossier for C&L: Accordance check (Agenda Item 9)	RAC/03/2008/26
Proposed working procedure for processing an Annex XV proposal for Harmonised Classification and Labelling (Agenda Item 9)	RAC/03/2008/27
Criteria for conformity check (Agenda Item 10)	RAC/02/2008/15 Rev1
ECHA Secretariat responses to RAC comments on RAC/02/2008/15 (Agenda Item 10)	RAC/03/2008/28
Processing of Transitional dossiers under Article 136(3) of REACH (Agenda Item 10)	RAC/03/2008/29

Registry of Intentions of MSCAs (Agenda Item 11)	RAC/03/2008/30
Request for Rapporteurs / co-rapporteurs (Agenda Item 12. Rev.1- a room document)	RAC/03/2008/31 and RAC/03/2008/31 Rev.1
Hand-over existing substances to the European Chemicals Agency - document of 17th Joint meeting of the competent authorities for the implementation of Directive 67/548/EEC (new substances) and Council Regulation 793/93/EEC (existing substances) (Agenda Item 10)	RAC/03/2008/32_room doc
Proposed Meeting dates 2008/2009 (Agenda Item 15)	RAC/03/2008/33_room doc
Using the RAC CIRCA Interest Group (Agenda Item 15)	RAC/03/2008/34_room doc
Draft ECHA Code of conduct for observers	RAC/03/2008/35_room doc
Guidance on conflicts of interest (Agenda Item 5c)	RAC/03/2008/36_room doc

ANNEX II.

01 July, 2008

RAC/A/03/2008 final

Final Agenda

Third meeting of the Committee for Risk Assessment

1 -3 July 2008

Helsinki, Finland

1 July: starts at 9:00
3 July: ends at 12:30

Item 1 – Welcome & Apologies

Item 2 – Approval of the Agenda

RAC/A/03/2008_rev.1
For approval

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of the RAC-2

a) Adoption of the minutes
b) Action points arising from previous meetings **RAC/03/2008/19**

RAC/M/02/2008 draft final
For adoption

Item 5 – Administrative Issues

a) Change in the RAC composition **RAC/03/2008/20**
b) Reimbursement rules - revised reimbursement rules ***For information***
c) Signing declarations by members ***For signature***

RAC/03/2008/36 (Room document)

Item 6 – Rules of Procedure (ROPs)

Adoption of RAC Rules of Procedure by the Management Board

RAC/03/2008/21

For information

Item 7 – Stakeholder participation

a) Outcome of the call for participation to ECHA's work **RAC/03/2008/22**

For decision

b) Code of conduct for stakeholder observers

RAC/03/2008/35 (Room document)

Item 8 – Procedure for appointment of rapporteur and co-rapporteur

Procedure for appointment of rapporteur and co-rapporteur

RAC/02/2008/13 rev.2

RAC/03/2008/23 (Response to comments)

For agreement

Item 9 – Working Procedures - C&L Annex XV dossiers

- Opinion Template Example **RAC/03/2008/24**
- Opinion and Opinion Support Document Example **RAC/03/2008/25**

For discussion

- Accordance Check **RAC/03/2008/26**
- Processing a C&L dossier **RAC/03/2008/27**

For agreement

Item 10 – Working Procedures - Restrictions dossiers (including transitional (Art 136 (3)) dossiers)

- Conformity check **RAC/02/2008/15.rev.1**

RAC/03/2008/28 (Response to comments)

- Proposal for handling 793/93 transitional dossiers **RAC/03/2008/29**

For agreement

RAC/03/2008/32 (Room document)

Item 11 – Planning of the work for 2008 and 2009

Registry of Intentions of MSCAs **RAC/03/2008/30**

For information

Item 12 – Appointment of rapporteurs

Annex XV C&L proposals:

Diantimony trioxide
Hexabromocyclododecane (HBCD)
Mycophenolic acid, triethylamine salt (MPA-TEA)

RAC/03/2008/31_rev.1

For decision

Item 13 – Participation of International Organisations

OECD

For decision

Item 14 – Feedback from other ECHA bodies

a) Management Board meeting (23-24 April and 18-19 June, 2008)

b) Member State Committee meeting (24-25 June 2008)

c) Committee for Socio Economic Analysis (2-3 April), and SEAC Inter-sessional WG meeting (11-12 June, 2008)

For information

Item 15 – AOB

a) Next meetings *(September 16-19, 2008 tentative)*
(November 18-21, 2008 tentative)
Proposed Meeting dates in 2009 **RAC/03/2008/33**
(Room document)

For information

b) Proposed structure of the RAC CIRCA interest group and instructions on working with CIRCA

RAC/03/2008/34
(Room document)

For information

c) Implementing rules for the fee regulation

d) QSARs

Item 16 – Action points and main conclusions of RAC-3

Table with Action points and decisions from RAC 3

For endorsement