RAC/M/02/2008 FINAL

Final

Minutes of the 2nd meeting of the Committee for Risk Assessment
11-13 March 2008

I. Summary Record of the Proceeding

Item 1 – Welcome & Apologies

The Chair welcomed the participants to the meeting. The participants attending for the first time, including the observer from Norway, introduced themselves. 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 second meeting, apologies were received from 3 members. Two members had informed the Secretariat that they could only attend the meeting in part. The list of attendees is given in Part III of these minutes.

Item 2 – Adoption of the Agenda

The Agenda, revision 2, was adopted after the Secretariat added two points under AOB, one on Stakeholder Participation, and another on Action points agreed at the RAC-1 meeting.

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. No such interests were declared.

Item 4 – Adoption of the draft minutes of RAC-1

The Secretariat introduced the minutes, highlighting that the aim was to achieve a balanced level of detail serving both purposes of recording the discussions and decisions at the meeting, as well as informing the general public.

An updated version highlighting the comments received from 5 members had been distributed as a room document. The RAC reviewed the proposed changes one by one, immediately agreeing to all changes except two which were discussed as follows.

The first point discussed was the Secretariat's proposed additional text for agenda point 6 regarding the history and intention behind ECHA's committees, where some members suggested a modified wording to which the meeting agreed.

Note: In the context of this issue, some questions were asked about the future of the existing committees. The Secretariat stated that the Technical Committees (TC) on Classification and Labelling (C&L) and New and Existing Substances (NES), as well as the Risk Reduction Strategy Meetings and the Limitations Working Group, would cease to exist as ECHA would take over their role. Furthermore, the consultation of the Scientific Committee for Health and Environmental Risk (SCHER) as currently carried out under ESR would not continue. The Secretariat also pointed out that the cooperation of the RAC with similar bodies, e.g. the scientific committees of EFSA and EMEA, is to be established in accordance with Art. 110 of the REACH Regulation.

The second discussion point was raised by Olivier Le Curieux Belfond, supported by another member, who stressed that from his point of view the time for the Secretariat to prepare and distribute the first version of the draft minutes should be shortened to 3 or even 2 weeks and the final draft, including comments from the RAC could be then

available within 4 weeks. He had stated this already at the previous meeting and requested it to be reflected in the RAC-1 minutes, under agenda point 5. The RAC agreed to a compromise text to include the arguments raised above that is included in the final meeting minutes.

With these changes the minutes were adopted.

The Chair suggested a discussion on the style, content, including level of detail, and timeline of the minutes of the RAC meetings.

One member expressed his preference for the minutes to be in two parts: one being an exact transcription of the meeting and the other a shorter summary, the latter to be made publicly available on the ECHA website. In addition, another member noted that some other international meetings provided their meeting minutes on the last day, and the minutes were endorsed at those meetings, suggesting that the RAC could do the same.

The majority of members taking the floor agreed that decisions taken should be described in sufficient detail but minutes should be a summary (reflecting only the key elements from the discussions) focusing on the main resulting action points. They asked the Secretariat to keep the style and length of the minutes of RAC-1 for now and evaluate later if shorter minutes with less detail would be preferable, given that the reporting of the scientific discussions on dossiers must reflect the arguments and allow an in-depth understanding of the final outcome.

The Chair reminded the RAC that its final minutes would be published on ECHA's website and that the style follows the one of the Management Board's minutes, including the habit not to allocate positions taken to participants, unless specifically requested. The Chair also made clear that a shorter deadline than 4 weeks for the draft minutes would not be realistic. However, the Chair acknowledged the need to make available the outcome of the meeting very shortly after the meeting and proposed to try to adopt an action-point table as the last agenda point of the meeting. The RAC welcomed the proposal and agreed to the 4 week deadline.

Mr Le Curieux Belfond suggested to prepare in addition to the minutes a full transcription of the meeting and to make them both available on CIRCA in order to guarantee transparency of the process of the compression of the discussions into a summarised document (i.e. the minutes). However, this was not supported by the other members who pointed out that the role of scientific discussions within the RAC was to reach agreement and thus members should be able to change opinion during a meeting as a result of the discussion but without being held responsible for every single word spoken. It was also noted that additional documentation, such as the opinion (including its justification) and the proposed Decision Support Document, would reflect the discussion and its outcome, and thus in deciding on the level of detail required in the minutes, the coverage provided by these other documents should also be taken into account.

The Secretariat also reminded the RAC that any publication of a transcript of the meeting naming individuals would require an explicit consent of each RAC member.

Item 5 – Administrative Issues

a. Change in composition of the RAC

The Chair presented Doc RAC/02/2008/12 on changes in the RAC composition. Three members had withdrawn their membership since the last meeting, two as they had been recruited by ECHA and one because he had become head of a newly created national

centre for chemicals. The Chair informed the RAC about the official nomination by Finland of Mr Paul Kreuzer, awaiting appointment by the Management Board (MB).

b. Reimbursement rules

The Chair informed the RAC that a document containing frequently asked questions with regard to the reimbursement rules was being developed by the Secretariat; it would be sent to the RAC for comments and circulated for the next RAC meeting in July. All members were reminded not to make travel arrangements, before they had received an invitation as this would be in conflict with the financial regulation the Agency has to follow. In this context, some members stressed that, *inter alia* due to national administrative procedures required to arrange their participation to a meeting, they needed the invitations as early as possible.

Some members requested confirmation in writing that ECHA will reimburse unused tickets in case there were unforeseen changes out of members' control. The RAC proposed to give a definition of "flexible ticket" in the announced document, and proposed to suggest to the Management Board of ECHA to reconsider the reimbursement rules, in particular in relation to the use of 'non-flexible tickets' and to allow "flexible economy tickets". Several members stated that this is common practice in other EU committees, e.g. relating to EFSA or DG SANCO.

Some members asked when the reimbursement for the first RAC meeting would be done and if this could be accelerated. In particular, those who paid their participation themselves would strongly prefer to be reimbursed for the previous meeting before they participate to the next one. The Secretariat answered that normally the reimbursement would be made 4 weeks after receiving the last form. As for the first RAC meeting a couple of problems had to be solved, but it is anticipated that the reimbursement of the following meetings should be smoother.

Members requested ECHA to provide each member with a specification of the amounts reimbursed to allow monitoring of the payments.

The Chair concluded that the Secretariat would take the requests back to the financial unit to check what would be feasible and, as far as possible, address these matters in the 'frequently asked question' or the rules themselves and give an update at the next meeting.

c. Mini CVs

So far 27 RAC members had sent their Mini CVs for publication on ECHA's website. It was agreed that the remaining 7 members provide their mini-CVs by 17 March at the latest.

Item 6 – Feedback from other ECHA bodies

a. Management Board meeting

The Secretariat highlighted that the adopted MB minutes as well as the main meeting documents are published on ECHA's website. However, it proposed to keep the RAC up-to-date regularly on relevant decisions taken by the MB since the last RAC meeting. Of current relevance were the following:

- The MB had agreed on some guiding principles on membership to the Committees, especially the eligibility criteria for the RAC and the SEAC and how the members' independence should be guaranteed.
- The appointment of SEAC members had taken place allowing the first SEAC meeting to be held in April 2008.
- In addition, the MB had agreed that appointment of members to the RAC and the SEAC could take place through a written procedure.
- The MB had approved a policy paper on cooperation with stakeholders, resulting also in the preparation of a call for expression of interest inviting stakeholder organisations to indicate their interest to participate to ECHA's work as observers, including participation the Committees. The call is published on ECHA's website.
- Another result was the invitation of EEA-EFTA countries to participate as observers in the ECHA committees, the Forum and networks, until they become members through the EU-EEA-EFTA agreement.
- In addition, the MB had discussed and agreed a communication strategy for ECHA as well as other more general points, such as to documents.
- The MB had also 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.
- The next MB meetings will be on 23-24 April and in June.

b. Member State Committee meeting

The Chair of the MSC introduced the main discussions and outcomes of the first MSC meeting (26-27 February) which related to Rules of Procedure (RoPs) and the tasks of the MSC. As defined in REACH, the first tasks would be related to dossier evaluation (including seeking agreement on testing proposals and need for additional information) and tasks related to identification of Substances of Very High Concern (SVHC). Especially the latter was expected to generate a lot of work already from autumn 2008.

It was underlined that the draft RoPs for the MSC, RAC, SEAC and the Forum had the same main structure deviating where relevant due to differences in the establishing provisions in REACH and due to differences in the tasks and roles of the different bodies. The main discussion points on MSC RoPs had been firstly whether members may have alternates and if not what role an invited expert, replacing the member, would play in the decision making at meetings. This discussion triggered a proposal to allow a member to give a proxy to another member, which for the specific case of the MSC was agreed, given the specific role and tasks of the Committee. Secondly, MSC members' independence was discussed, and thirdly the proposed deadlines.

MSC also decided not to appoint co-opted members or establish working groups at this point of time. MSC decided to invite the EEA-EFSA countries to MSC meetings as observers.

Responding to the question whether there would be one PBT Working Group (WG) serving the three ECHA committees (MSC, RAC, and SEAC) and whether it was foreseen that the RAC would be involved in the scientific work to evaluate PBTs, the Secretariat clarified that the issue of a joint WG serving two or all three committees for

PBTs or on any other issue was not decided yet but agreed that the necessity should be further discussed and considered. It was underlined that the MSC's tasks and role, timelines and working procedures are different from those of the RAC, to be borne in mind when considering how a joint WG would operate.

Item 7 – Rules of Procedure (RoPs)

The Chair recapped the commenting process on the version 2 sent out after RAC-1 on the 18th February. A proposal from a member along with a few editorial changes (to improve clarity) had been introduced into a version 3 that was distributed 29th February. In addition, the text in Art 9(5) and 9(6) had been replaced with text taken from the MB's guiding principles for appointment of members of the RAC and the SEAC, adopted at its February meeting.

Art. 9 and Annex 2 (Independence). A lengthy discussion took place regarding the wording of Art. 9(5) related to consultancy work which may be considered to be incompatible with membership of the RAC. With reference to public institutes carrying out consultancy work, one member pointed out that public institutes may be involved in projects with companies that may be REACH registrants on topics of REACH relevance, as well as those not directly related to REACH, such as risk assessments of pharmaceuticals or investigation of eutrophication of water bodies by detergents. Clarification was requested whether the provisions in Art 9(5) were related to the direct personal involvement of a member with such contracts, or if the public institute had to withdraw or refrain from entering into contracts with any REACH registrant, chemical industry association or other interested party. The Secretariat clarified that the proposed text, as suggested by the MB, concerned the personal involvement of the member in such contracts.

The Secretariat underlined that in addition to the provisions of Art 9(5), involvement in any kind of consultancy activities related to REACH must be declared. To address the concern, a slight amendment was introduced in paragraph 5, as reflected in the final version endorsed by the RAC.

As regards the need to include in the declaration of interests (Annex 2) being employed by an MSCA, the Secretariat confirmed that this should be included as a potential conflict of interest in the annual declaration.

Art. 10 and Annex 3 (Confidentiality). The proposal to replace the words "competent authorities" in Art. 10(1), by the same term as used in the Forum's declaration of interest ("relevant public authorities") was agreed to.

Art. 20 (Written procedure). A reference to Art. 19(5) was added to Art. 20(4), stating that 'In the event of non-consensus, Article 19(5) shall apply'. Moreover, as the majority would be 'simple majority' of **all** members, the word 'all' was added to Art 19(4) and Art. 20(3). For procedural issues the tacit agreement was agreed to be indeed relevant and thus that wording remained unchanged.

Clarification was requested of the relation between the independency and transparency in respect of voting according to Art. 19. The Secretariat explained that the goal was to achieve consensus and in case of a minority opinion of a person(s) this named statement would be included in the opinion, which would be published on the website in accordance with Art. 11(3).

The Secretariat asked for the RAC members' opinion on how to proceed with the commenting in a written procedure, to use either e-mail or the discussion group

functionality of CIRCA. Some discussion took place after which the RAC agreed to try the CIRCA option.

The Chair concluded that with the modifications agreed at the meeting the draft RoPs were unanimously endorsed by the Committee and could be forwarded to the MB for approval. After applying the RoPs for a period of at least a year the RAC could evaluate at that point in time if there would be any need to update the RoPs in light of user experience.

Item 8– Procedure for appointment of rapporteur and co-rapporteurs RAC/02/2008/13

The Secretariat proposed that the RAC would start the process for appointment of rapporteurs immediately after registration of a Member State's intention to submit an Annex XV dossier by identifying a possible (volunteer) rapporteur. As soon as the dossier would then be received by ECHA, the Secretariat would formalize the appointment, including concluding the remuneration contract.

The need was identified to have enough information in the Registry of Intentions to allow an appropriate rapporteur to be appointed. It was agreed that the form developed for the Registry of Intention should therefore include an additional column prompting the provision of more information on the aspects to be addressed in the dossier.

Reacting to a request to better define the tasks of a rapporteur the Secretariat proposed to develop a discussion paper on this for the next meeting, together with a template for a RAC opinion.

If no RAC members volunteered to act as rapporteur for a given dossier, the Secretariat explained that it would then approach individual members, taking due consideration of the proposed selection criteria in the document.

Some members queried the principle that suggested that a rapporteur should not be selected from a Member State with a 'major manufacturer' of a substance since in their opinion it could also be viewed as an advantage if there was a need to consult the manufacturer. The Secretariat answered that this was a recommendation rather than a strict exclusion criterion.

With regard to the need of a co-rapporteur and his/her possible role in the assessment process of an Annex XV dossier, the RAC considered two possible options:

(a) both rapporteur and co-rapporteur to be appointed for every dossier;

(b) only rapporteur to be appointed initially, and then after conformity check the rapporteur could propose a co-rapporteur to be appointed (if considered necessary).

The role of the co-rapporteur was also considered, either as working together with the rapporteur on the same aspects or, for those complex dossiers covering a number of different fields of expertise, the co-rapporteur could be selected to cover an area where the rapporteur had less experience. It was also suggested that in the learning phase the first dossiers received by the RAC might benefit from having a co-rapporteur for each dossier. In conclusion, the RAC decided to maintain flexibility in the procedures for appointment of co-rapporteurs to have different options to best fit each case.

Bearing in mind the range of expertise required for some dossiers (e.g. a complex restrictions proposal), the issue was discussed of how to decide when there was a need

to constitute a working group to provide the additional expertise in drafting the initial opinion. The Secretariat reminded the RAC that both rapporteurs and co-rapporteurs should be supported in their work by the Member State nominating them to the RAC, and that it was expected that this support would include access to additional expertise available to the Member State as required by Art.85 of REACH. This could include participation of these experts to the RAC meetings as advisers (paid by MS) or invited experts (if the RAC agreed to invite them to a meeting and if the budgetary provisions allowed funding of this from ECHA budget). The Secretariat pointed out that in future, ECHA would have good facilities for video-conferencing, making it technically possible for advisers to participate to specific parts of meetings via video link. 'Linked' participation would be subject to the same rules as participation to meetings laid down in the Rules of Procedure. However, in addition, and in particular cases, the RAC could establish *ad hoc* working groups to support a rapporteur (and co-rapporteur), drawing on expertise from within and also potentially outside the RAC. In line with its ROP the RAC would then be responsible for the mandate, membership, timing, and deliverables of such working groups. In the context of this discussion the secretariat was asked to provide a description of the expected workload of the RAC members to plan national resources. The RAC secretariat noted that information had been requested from the Member States regarding future Annex XV dossiers and to that point in time very few answers had been received and consequently the workload could not yet be estimated.

The Secretariat underlined that it was necessary for the rapporteur and co-rapporteur to work closely together to present to the RAC one draft opinion for discussion, rather than separate opinions on different parts. Where there were diverging views, these could be brought to the attention of the RAC for discussion.

Referring to the need for all RAC members to have access to any relevant background information used by the (co)-rapporteur in reaching their opinion, it was explained that all documentation available to the rapporteur, including the Annex XV dossier plus the comments received in the consultation process of interested parties, would be made available to all members.

The Commission (COM) asked for clarification in case there would be a need to substitute a rapporteur. The Secretariat explained that the same procedure should be applied as for the initial appointment.

The Chair concluded that the document RAC/02/2008/13 would be revised by the 7th April and disseminated to RAC for members' comments by end of April. A working procedure for (co-)rapporteur identification and appointment would be developed on the basis of the revised document. In addition the task of rapporteurs and co-rapporteurs and relationship with the ECHA Secretariat and Committees, including the SEAC, would be formulated in more detail in separate documents. Regarding resources, the Chair noted that both rapporteurs and co-rapporteurs should be supported by the Member State nominating them to the RAC, and that it was expected that this support would include access to additional expertise available to the Member State. Experience of the handling of the first dossiers could then be fed back into the further development of the procedures. The Secretariat should also provide the RAC with a template for submission of a draft opinion.

Item 9– Interface with other ECHA bodies

a. Interface with MSC, SEAC and Forum

The Secretariat gave a presentation of the role and tasks of other ECHA committees, the Member State Committee (MSC), the Committee for Socio-economic Analysis (SEAC), and the Forum, including a description of the interface and the expected workflows between the RAC and each of the other committees. The Secretariat highlighted the need for a close cooperation between the RAC and the SEAC on the restrictions and the authorisation processes, particularly between the rapporteurs, since they would be developing opinions on the same dossiers in parallel.

The dossiers submitted to the RAC, as well as their content, may, as a consequence, be influenced by decisions taken under substance evaluation involving consultation of the MSC. For example, agreement on further information needs under substance evaluation may later impact on the content of dossiers that the RAC may receive. As the MSC and the RAC might have different views on the adequacy of information required to perform a soundly-based assessment, a co-operation from the beginning might be desirable. In addition, the identification of SVHC by the MSC would impact the inclusion of substances on Annex XIV and thus the applications for authorisation received by the RAC and the SEAC. The role of the Forum in providing advice on the enforceability of proposed restrictions also indicated a need for co-operation and co-ordination of the RAC and the SEAC with the Forum.

Methods to facilitate cooperation between the Committees and the Forum included reporting by the Secretariat of the activities in one Committee to another, use of common documentation to build a dossier, from CSR to Annex XV dossier and Decision Support Document. Informal contacts between members of the different Committees and Forum were encouraged and it was agreed to consider joint or back-to-back meetings or joint working groups to address shared issues.

Responding to a question the Chair conformed that presentations could be distributed and discussed informally with the members of the other committees.

The Chair concluded that there would be a need to revisit this topic in future meetings, and emphasised that close coordination would be necessary to increase efficiencies and to avoid repetition of discussions or duplication of work as far as possible.

Item 10 – Guidance Documents

The Secretariat presented an overview of the development of Guidance Documents and summarised the guidance documents and their status (published, revised and up-dated, future developed guidance documents) as well as the final draft of the Guidance on Information Requirements for the Chemical Safety Assessment (CSA) (in some detail), explaining the difficulties and challenges in front of the ECHA Guidance Team.

One member pointed out that the volume could be problematic for the easy use of the Guidance and asked whether there would be a public consultation, including consultation of the RAC, on the final version. The Secretariat explained that a navigator of 10-15 pages is available in the beginning of the guidance to facilitate its usage. The aim of the team was that each chapter should be of manageable size. The last version of that guidance was available on the CIRCA for MSCA comments and no further consultation was envisaged at this point in time as the guidance is expected to be approved at the next REACH-CA meeting in March. Furthermore, there would be consultations of stakeholders with regard to its up-dating, including consultation of the RAC. The Guidance document on CSA would be made available on CIRCA to RAC as soon as possible.

Item 11 – Working Procedures

a) Main steps in draft SOP flowchart on related C&L Annex XV dossiers to RAC

The Secretariat gave a presentation of the main content and purpose for having standard working procedures giving as an example a draft procedure concerning the processing of an Annex XV dossier for Harmonised C&L. The main part of the procedure was a flowchart with sub-flowcharts mapping all steps in the procedure. The Secretariat requested input on those areas for which the details on the procedure were currently lacking, such as when and how to request input from the dossier author and concerned parties; how to handle and respond to comments; what procedure to follow in the case the RAC does not follow the opinion of the rapporteur; how many times a dossier could be discussed by the RAC; whether there would be a Decision Support Document (DSD); and if so which actor would be responsible for its preparation. The Secretariat highlighted that even though the procedure focussed on the C&L procedures, ECHA envisaged that all three types of Annex XV dossiers would have similar procedures.

Some members noted that in the past processes for the Existing Substances Regulation (ESR) and for the Biocides Directive so-called response-to-comments tables in which comments received and proposed reactions to the comments were recorded had been very useful for capturing the main points and recording the progress of discussions, and the usefulness of such an approach could be considered in the further development of the Committee's working procedures.

The Secretariat responded to the view expressed that the drafting of a DSD should not be seen as the task of the RAC. It was explained that, as also stated at the last meeting, the MSCAs who are the authors of the Annex XV dossiers, would be invited to participate to the RAC meetings and, for the future, conference facilities with video links would also facilitate their participation. In addition, the rapporteur could take bilateral contacts to the author-MSCA, should any clarifications be needed. The Secretariat was proposing that the author of the dossier would, in most cases, be the owner of a DSD which should capture changes to the originally proposed Annex XV assessment report. The RAC welcomed the Secretariat's offer to prepare a practical example of a DSD to better understand the concept, to be discussed at the next meeting of the RAC.

The Secretariat was asked whether it would be legally possible under REACH, taking into account the data sharing obligations, to submit several Annex XV dossiers on the same substance resulting in several DSDs. In response, it confirmed that under REACH, for a particular process, only one Annex XV dossier should be submitted for one substance at any particular point in time, and data sharing should have been triggered earlier in the process during pre-registration. The case of potential read-across of data from one substance to another, in relation to data ownership, would be more complicated and still needed further considerations. The RAC also noted that the working procedures would probably need a revision once their practical application had been tested. The Secretariat agreed that the working procedures should evolve and be fine-tuned based on experience. A discussion took place on the need for the original data (e.g. scientific journal articles, contract house test reports) to be available to the RAC on request, through support from the ECHA Secretariat, without the need to contact the original data holder. However, the harmonised presentation of information in the Annex XV dossier ensuring an adequate level of detail both for the rapporteur and the RAC to reach an opinion, should avoid, in most cases, the need to consult the original data. The Secretariat stated that ECHA was developing rules on access to

information, considering transparency versus the need to protect confidential business information and took the point that the rapporteur should have easy access to any data if needed, including confidential data, not in the Annex XV dossier.

The Secretariat was asked to explain its plans regarding minimising the testing for the substances, taking into account the different tools envisaged by REACH, e.g. data sharing, read across of data, a category approach, which all would require a procedural frame as well as a consideration of confidentiality issues and testing strategies. The Secretariat explained that ECHA's immediate activities were related to establishment of own resources, e.g. Q(SAR)s, developing a category approach and a testing strategy approach, and building up capacity in this regard. The Secretariat was also exploring the use of the OECD QSAR toolbox for use in evaluation and possibly for industry to use as a tool to establish categories. This exploration includes considering how to further develop the C&L category applied approaches for the Annex I entries under Directive 67/548/EEC that ECHA would expect would continue for harmonised C&L proposals under REACH. ECHA would return at the next RAC meeting with some proposal as to how to develop these approaches together with the RAC and the MSC.

The Chair concluded that the RAC considered the draft outline of a working procedure as presented as a good starting point for the development of a more detailed procedure for the processing of the C&L dossiers. The Secretariat will present such a document for discussion and agreement at RAC-3. This working procedure could be tested with the first C&L dossiers.

b) Procedure for conformity check of a submitted dossier

c) Criteria for conformity check

In continuation of the discussions at the last RAC meeting, the Secretariat presented in more detail the whole restriction process, including the legal basis, the key steps in the process, the role of the Registry of Intention (RoI) and its foreseen implementation and the timelines and steps for submission of information by the different players in the process. The Secretariat underlined that as a final outcome of the process, where the RAC's opinion was that a restrictions proposal was appropriate, the RAC would be required to provide robust documentation to allow COM to prepare a draft amendment of Annex XVII within 3 months.

The initial step after receipt of a restriction proposal is a conformity check with the purpose of ensuring that the dossier conformed to the requirements of Annex XV before the publication of the dossier, which would trigger the deadline for the next step in the process.

The Secretariat presented the main points of Doc. RAC/02/2008/14 outlining a proposed procedure for a conformity check of a submitted dossier including the Secretariat's proposal for a workflow that would reflect the requirements of the legal text. As required in REACH, the RAC would be responsible for the conformity check and it should consider how to reach agreement on whether the dossier was or was not in conformity based on the rapporteur's analysis. The Secretariat would provide scientific support and give its informal view regarding the conformity by providing a 'conformity report' according to agreed procedures, which should include a description of co-operation with the SEAC for the restrictions dossiers as this is required in Art. 69(4) REACH. In case a dossier would be considered not to be in conformity with the

required format, the RAC should follow the procedure of Art 69(4) REACH, including the preparation of a letter, jointly with the SEAC, to the author of the dossier indicating the reasons for non-conformity. The Secretariat highlighted the need for a smooth and efficient workflow to be able to keep to the deadline of 30 days. The letter would trigger a deadline of 60 days to bring the dossier into conformity. Failure to comply with this deadline would result in termination of the restriction procedure. In such case the MS may consider to make a new notification to the RoI and resubmit the dossier.

After the presentation the Chair gave the opportunity to the members to give their views on the document, in particular regarding the questions posed. It was agreed that the overall purpose of the conformity check was to evaluate whether or not there appeared to be sufficient information to allow the RAC to form an opinion on the proposal, however the conformity check should not be understood as a conclusive evaluation of neither quality not adequacy of the information provided. The RAC welcomed the informal support of the Secretariat in providing a conformity report to assist the rapporteur in delivering a view within the short timelines and also recognised the value of such support in contributing towards consistency across the dossiers. It was felt that in the beginning the Secretariat, rapporteur and the RAC would need to invest some effort in defining the criteria for a conforming dossier (a process which is already underway), but eventually there could be a lighter, more automatic process, when the view of what a conformity check should include was more widely shared, although the responsibility for the decision would always lie with the RAC. Since a decision on conformity is required within 30 days, it was expected that the use of the written procedure to make a decision would be necessary in most cases, and the conformity report from the Secretariat should be made available no later than 10 days after submission of the dossier.

The Secretariat also proposed that the procedures for Annex XV dossiers for C&L should follow an analogous procedure, also in view of the future Classification Labelling and Packaging (CLP) legislation that, according to the current proposal, would introduce deadlines to the C&L processes, similar to those in the Restrictions title of REACH.

A brief discussion of the proposal for an ‘accordance check’ for C&L Annex XV dossiers took place. The Secretariat noted that since no formal conformity check for C&L dossiers is foreseen in the legal text, the RAC may prefer that the Secretariat perform the task. For the time being the members expressed a wish to be involved in the process, and supported to follow a similar procedure as for restrictions. In any case, since there were no deadlines set as yet for the C&L dossiers, the accordance check on the first dossiers could be made at the RAC meetings.

The Secretariat will provide a draft working procedure on the details to be considered in the restrictions dossier conformity check and the accordance report to the RAC as a draft to facilitate discussions.

The Chair summarised the discussion that the RAC supported the proposal from ECHA on the procedure described for conformity check of the restriction dossiers, and also to apply a similar procedure for C&L dossiers. The RAC agreed that the overall purpose of the conformity check is to check if there appears to be sufficient information to allow the RAC to form an opinion on the proposal, and that it is the RAC that has the responsibility to decide on conformity. The criteria for deciding whether a dossier was in conformity needed to be further developed in a learning-by-doing approach, and this could be facilitated by the handling of ‘transitional’ dossiers as test cases during 2008.

The criteria listed in document RAC-2/2008/15 could probably be categorised into required versus desirable elements, and need to be further developed as a matter of priority, because there will be insufficient time for extensive discussions once the 30-day conformity period comes into force under Title VIII on 1 June 2009. The RAC took note of the strict legal deadlines and the need to co-ordinate the RAC and the SEAC conformity checks. The RAC members were asked to submit their further comments on document 15 in writing by 7th April.

Item 12 – Planning of the work for 2008

a. Progress of transitional and new dossiers

The Secretariat gave a presentation explaining the key differences between the processes of the ESR (Regulation (EC) No 793/93) and the Limitations Directive (Directive 76/769/EEC), and the processes envisaged under REACH when introducing new or amending existing restrictions. The REACH process implements strict deadlines and has an integrated approach to risk assessment and risk management and assessment of benefits and drawbacks (socio-economic impacts) instead of the former stepwise processes. Furthermore, the process envisaged for the unfinished work on the priority substances from the ESR, as addressed by the transitional measures in Art. 136 of REACH, was described.

In addition to the presentation, a room document RAC/02/2008/16 listing the status of the 141 priority substances from ESR had been distributed, sorting the ESR substances into 5 different categories according to degree of finalisation:

> Cat. I) 23 ESR priority substances that do not have a finalised risk assessment.
>
> Cat. II) 27 substances that had a finalised risk assessment, but the risk reduction strategy was not available or not agreed.
>
> Cat. III) For 8 substances the discussions including the risk management measures were finalised under ESR, but not in time to publish the outcome in the Official Journal of the European Communities. COM has approached the concerned MS to clarify the status.
>
> Cat.s IV and V) 80 substances are finalised and published under the ESR programme, and will not fall under Art. 136 of REACH.

For the ESR priority substances listed in Categories I) and II), the Member State which was rapporteur under ESR has the obligation to prepare an Annex XV dossier and submit it to ECHA by 1 December 2008. The final numbers of dossiers falling into these Categories would not be known until June but the lists could be used as a basis for an informal 'Registry of Intentions' of transitional dossiers forming part of the first work plan for the RAC.

The Secretariat clarified that Annex XV dossiers for transitional substances from the ESR programme should be forwarded as one complete Annex XV dossier including all information, i.e. both the toxicological and environmental part. The non-transitional restrictions dossiers may be targeted to a particular concern. Part of the Annex XV dossier could contain information on alternative substances, and the RAC would be required to look at alternatives from a risk assessment perspective.

Regarding substances in Categories I) and II), several RAC members had questions for clarification of the legal procedures for finalising the substances. Several issues were raised, and among those were if the RAC will continue to discuss the risk assessment

that was not finalised under the ESR programme; whether the RAC would be asked to examine any proposal for risk management or only those likely to lead to a restriction under Annex XVII, and if a testing need had been identified, how this would be addressed when Regulation (EC) No. 793/93 was repealed. Furthermore, a situation could arise in which no risk was identified, however the substance could be e.g. a Water Framework Directive (WFD) priority hazardous substance, and that in itself could be a reason to prepare a proposal for a restriction. The Secretariat answered that it was possible that the RAC may wish to provide a view on all the dossiers (e.g. to finalise a risk assessment or to discuss whether a risk should or should not be best managed via a restriction under Annex XVII). However, more concrete planning can best be done when the final number and status of the dossiers is known. The Secretariat confirmed that for transitional dossiers, even if the MS was not proposing an amendment to Annex XVII of REACH, the measures proposed to address the identified risks should be justified and documented following the relevant parts of an Annex XV format, and should be submitted to ECHA by December 1st 2008. COM clarified that this treatment of transitional dossiers was compatible with REACH since it was foreseen in the guidance document on preparation of an Annex XV dossier for restrictions that a MS or the Agency might conclude during the process that a restriction would not be the best management option. In that case a restrictions proposal would not be submitted, but the outcome of the process should be captured by submitting the results in an Annex XV format to ECHA, to document the process, but that the MS, not ECHA, would be responsible for communicating the proposed other measures to the relevant bodies.

The Secretariat added that for any substance covered by REACH, even if the substance was a priority substance under the WFD, the starting point when preparing an Annex XV dossier under REACH would be identification of risks in accordance with the approach set out in Annex I of REACH, and if no risks were identified then the preparation of an XV restriction dossier would not be justified. However, the WFD would still apply on its own right.

COM clarified that according to Art. 136 of REACH, any information requests under Art. 10(2) or 12(2) of Regulation (EC) No 793/93 would be considered as decisions adopted under REACH. For transitional substances for which testing was ongoing but would not be available by 1 December 2008, the MS could only evaluate the impact of the test on the risk assessment when it became available. In the meantime an Annex XV dossier could be submitted containing the risk assessment and addressing the risks already identified, if any. In the situation where the information requirement was not formalised via Art 10 (2) or 12(2), the proposed testing should be described in the risk assessment and Industry should take the requirement into account when preparing for registration. However, the requirement could only be formalised under substance evaluation after registration of the substance.

The Chair concluded that there are around 50 ESR transitional dossiers, to be submitted to ECHA by 1 December 2008. These dossiers would fall into different categories depending on the stage reached in the ESR process and nature of any identified risks thus it was difficult to forecast the workload to the RAC. Information available on these dossiers could be used as a basis for an informal 'Registry of Intentions' of transitional dossiers forming part of the first work plan for the RAC.

b. Appointment of rapporteurs for the first dossiers

The Chair stated that ECHA had not yet received dossiers conforming to Annex XV, and therefore no discussion would take place under this agenda point.

For the next meeting it is expected that it will be known which transitional dossiers from the ESR programme will come to the RAC as the final meetings under the former legislation will have taken place, and there will be a need to allocate rapporteurs to those dossiers. In addition it will also be known which dossiers from the C&L programme will need to be finished by the RAC. For both types of dossiers, a rapporteur from the RAC should be appointed following the procedure to be developed on the basis of a revised document RAC/02/2008/13.

Item 13 – AOB

a. Next meetings *(**July 1-4, 2008 tentative**)*

(September 16-19, 2008 tentative)

(November 18-21, 2008 tentative)

The Chair informed the RAC that the next meeting is planned for 1 to 4 July 2008 in Helsinki and that the exact dates and the venue would be confirmed later.

The Chair agreed to hold the meeting planned for 16-19 September as late in the week as possible, if the duration would be shorter than planned now.

The attention of the RAC was drawn to the fact that the RAC meeting planned for November overlaps with the dates for the last meeting of the SCHER.

b. Stakeholder participation

For information, the Secretariat presented the policy document approved by the MB on ECHA's stakeholder policy, including criteria for stakeholder participation. The paper had been published on ECHA's website together with a call for expression of interest through which stakeholders could apply to participate in the work of ECHA and its committees. The Secretariat will inform the RAC on the outcome of the call for expression of interest. A proposal for admitting stakeholder organisations as observers to the RAC meetings would be prepared based on the received expressions of interest for discussion at RAC-3.

Upon request, the Secretariat explained that the call was not intended for journalists and that the ECHA Secretariat had a Communications Unit to take care of media relations and that it would be planning separate events to inform the public, including journalists, of ECHA's activities.

c. Action Points agreed at the RAC-2 meeting

The Secretariat presented in detail a draft table of the decisions and action points agreed at the meeting for each agenda point to be endorsed by the RAC at the meeting, highlighting that the table was meant as an 'aide-memoire' only, and that the meeting minutes are the final official record of the meeting's proceedings.

The RAC commented on the decisions and action points, which the Secretariat amended accordingly. The Secretariat committed itself to distribute the table to the members on the following day. The table forms part III of the meeting minutes.

During the discussion, a member also raised the issue of PBT[1] assessment and the continuation of the PBT Working Group (WG), which is currently a sub-group under the Technical Committee for New and Existing Substances suggesting to continue the PBT WG as a joint subgroup under the RAC and the MSC. The aim of this PBT WG would be to finalise the discussion started in the TC NES sub-group, where some of the substances, after initial discussion, had been further tested and the results were yet to be discussed to decide on the substance's PBT status. The WG could also be assigned new tasks in support of the work of either MSC or RAC on Annex XV dossiers. This proposal was supported by several other members, who though noted that they would appreciate an analysis by the Secretariat of the particular urgency and need for a PBT WG, as well as the mechanism for establishing a joint working group serving more then one ECHA Committee. The Chair concluded that the Secretariat would further investigate the proposal and bring the outcome to RAC-3.

[1] PBT substances are substances which are Persistent, Bioaccumulative and Toxic

II. Conclusions and action points

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
4. Draft minutes	• Draft minutes adopted with the changes agreed • The style and level of details of the RAC-1 minutes accepted by the majority; some members asked for shorter minutes with less details • **Olivier Le Curieux Belfond** asked for full verbatim report • RAC agreed that reporting of the scientific discussions on dossiers must reflect the arguments and allow understanding of the final outcome. • RAC proposed to prepare Chair's conclusions and action points and possible minority opinions, which shall be adopted by the RAC **at** the meeting	• adopted minutes of RAC-1 to be uploaded to Circa and ECHA website (SECR / by 19 March) • **Olivier Le Curieux Belfond** minority view to be reflected in the RAC-2 meeting minutes including his name • Drafting (SECR/ immediately) and adoption (RAC /at the meeting)
5.b) administrative issues (reimbursements)	• Non-flexible tickets: members requested confirmation in writing that ECHA will reimburse unused tickets in case there are unforeseen changes out of members' control; RAC proposed rules for reimbursement to be amended to allow flexible economy tickets • Delay for final payment: should not be longer than 4 weeks for those who have submitted a complete file in time • Members requested amounts to be paid to be communicated by ECHA in writing	• to be explicitly recorded (SECR) and followed-up (SECR), report on results to RAC-3 • to be proposed to the ECHA financial unit (SECR) • to be followed up (SECR/RAC-3)
6.b) report MSC		• upload the presentation on MSC-RAC interface given at MSC-1 to RAC Circa site (SECR / by 14/3)
9. Interface with MSC, SEAC and Forum		
7. RoPs	• Endorsed with modifications after discussion	• upload the agreed RoPs to Circa and submit them for approval by the MB at its meeting in April 08 (SECR/ asap)
8. Procedure for appointment of rapporteur / co-rapporteur Doc.13	• Agreed: rapporteurs should be identified as early as possible but enough information was needed in the registry of intentions to decide about the required expertise; formal appointment asap. • Co-rapporteur, 2 possible options discussed: (a) rapporteur to propose a co-rapp after conformity check; (b) RAC to	• revise the document i.a. by including different options for deciding on the co-rapporteur (SECR/ 7 April); send it out for written comments (Members / end of April) • include the elements to a SOP (by RAC-3)

	systematically identify and nominate rapp. & co-rapp for each dossier • Co-rapp should basically be a co-worker, to provide a certain initial reviewing of the proposed opinion, with the same field of expertise to support a complex case, or possibly adding a different field of expertise • Any procedures for appointment of co-rapp needs to maintain flexibility as different options are desirable to fit the case • Access to in-depth expertise is sufficient for a member to act as rapporteur, the member can be supported by advisers at the meetings • Tasks of rapporteur needed to be formulated more in detail; • MS obligation to support the rapporteur to be explicitly captured in a revision of Doc. 13 • SOP for rapporteur (co-rapporteur) identification and appointment to be developed on basis of revised Doc.13 • A format (template) for an opinion to be developed • *Ad hoc* working groups can be established to support a rapporteur (co-rapp) on a case by case basis; Rapp to propose, RAC to decide about mandate and membership of such working groups.	
10. Guidance documents		• Guidance document on CSR to be made available to the RAC (SECR / as soon as possible)
11. Working procedures a) C&L	• No firm conclusions but the Secretariat is requested to illustrate the Decision Support Document through a practical example. • The proposed procedure should be better described (including how to deal with commenting; when to bring the issue for discussion to a meeting; access to data that is not in the Annex XV; who are the concerned parties; etc) and tested with a "real" dossier.	• A proposal for a DSD with examples to be submitted to the members (SECR / before RAC-3) • To prepare a paper on the proposed procedure for processing C&L dossiers (SECR / by RAC-3) • First C&L dossiers to be used as test cases (SECR / by RAC-3) • Upload asap a "real" C&L dossier on CIRCA (SECR,/as soon as a dossier available)
b) Procedure for the conformity check c) Criteria for the conformity	Restrictions: • Agreed: Overall purpose of the conformity check is to check whether there appears to be sufficient information to allow RAC to form an opinion on the proposal;	• Provide ECHA SOPs and WINs on conformity check to RAC (SECR/asap - before RAC-3) • **Written comments on Doc. 15 to be provided by**

check Docs 14 &15	• Agreed: process and level of details as presented; • Underlined: need for flexibility; • At the end, RAC decides about conformity; • Agreed: Secretariat supports the RAC by providing a conformity report (useful to meet short timeline and to ensure consistency between different Rapporteurs) • Timeline for conformity report: 10 days or less from submission, in any case the rapporteur needs to be involved as early as possible • Agreed: As RAC decision on conformity required within 30 days -> use of Written Procedure will be necessary in most cases • Underlined: need for coordination between the SEAC & RAC rapporteurs C&L: • no formal requirement for conformity check by RAC, but a similar procedure as for restrictions dossiers supported by RAC ('accordance check') - over time RAC may have less of a role • No deadline for accordance check (yet), thus the first dossiers can be processed jointly at the meetings (learning by doing), but SECR will include the details to be considered in the accordance report in their SOP, and provide to RAC as a draft to facilitate discussions.	**Members / by 7 April;** particularly comments giving a view or recommendation on:- specific items to be examined during the conformity check (elaborating further on the circulated discussion paper); what constitutes 'non conformity'; and any other related comments.
12. Planning the work for 2008	• Transitional dossiers fall into different categories depending on the stage reached in the ESR process and type of conclusions; thus difficult to forecast yet the actual workload to RAC • It is possible that RAC is asked to look at all transitional Annex XV dossiers, even if no restrictions are proposed • Doc 16, Tables: 1-2 status clear (MS will need to submit Annex XV dossiers) and 4-5 status clear (no Annex XV dossier - ESR process will be finished in time), table 3: COM had approached MSs to clarify the status • No Annex XV dossiers yet attributed to the RAC and thus no need to decide on rapporteurs.	• Tables 1 and 2 to be used as a basis for future (informal) 'registry of intentions' to allocate transitional dossiers to Rapporteurs (COM + SECR / by RAC-3)

13. AOB - stakeholder organisations	•	• a proposal for admitting stakeholder observers to be prepared based on the expressions of interests received by 30/4/08 (SECR / by RAC-3)
AOB PBT assessment	ECHA requested by RAC to consider feasibility of and need for establishing a joint MSC/RAC WG on PBT assessment already at an early phase to address the unfinished work of the TC-NES PBT subgroup and future work on PBTs.	• produce a paper (SECR / by RAC-3)
General		• all presentations on Circa (SECR / 14/3/08) • conclusions and action points (= this doc) to be uploaded to Circa (SECR / 14/3/08) • remaining mini-CVs to be submitted to SECR (Members/ by 17/3/08) • SECR to investigate use of Circa for submitting and sharing written comments (to avoid e-mails)

III. List of Attendees

Members		**Representatives of the Commission**
ANDRIJEWSKI Michal Pawel		GRAJALES Sylvie (DG ENTR)
BORGES Teresa		PUOLAMAA Maila (DG ENTR)
DUNGEY Stephen		VAN DER ZANDT Peter (DG ENV)
GREIM Helmut		
GRUIZ Katalin		**ECHA staff**
HOYAUX Daphné		AHRENS Andreas
KADIKIS Normunds		BARANSKI Maciej
LE CURIEUX-BELFOND Olivier		DANCET Geert
LEINONEN Riitta		DE BRUIJN Jack
LOSERT Annemarie		GRODZSKI Karola
DUNAUSKIENE Lina		HANSEN Bjørn
LUND Bert-Ove		HAUTAMAKI Anne
MEZZANOTTE Roberto		KREYSA Joachim
MULLOOLY Yvonne		LIPKOVA Adriana
NUNES Céu		LUOTAMO Marita
ORPHANOU Maria		MUNN Sharon
PICHARD Annick		POLLARD Kevin
POLAKOVICOVA Helena		KARHU Elina
PRONK Marja		RASMUSSEN Kirsten
RUPPRICH Norbert		SCHOENING Gabrielle
SCHULTE Agnes		SUNDQUIST Anna-Liisa
SMERHOVSKY Zdenek		VAHTERISTO Liisa
SMITH Andrew		VAINO Matti
STOLZENBERG Hans-Christian		VASILEVA Katya
SULG Helen		YLÄ-MONONEN Leena
TARAZONA Jose V.		
TOMSONE Margite		**EEA –EFTA observers**
TYLE Henrik		VAN DER HAGEN Marianne
VAN MALDEREN Karen		
VILANOVA Eugenio		
ZGLOBIU Mariana-Elena		

Advisers to the RAC members

DI PROSPERO Paola (adviser to R. MEZZANOTTE)
KREUZER Paul (adviser to R. LEINONEN)

IV. List of Annexes

ANNEX I. List of documents submitted to the Members of the Committee for Risk Assessment (RAC)

ANNEX II. Final agenda.

ANNEX I.

Documents submitted to the Members of the Committee for Risk Assessment (RAC)

Draft Agenda (Agenda Item 2)	RAC/A/ 02/2008_rev.1
Draft Minutes of RAC 1 (Agenda Item 4)	RAC/M/01/2008_rev.1
Administrative issues (Agenda Item 5):	
(a) change in composition of the RAC	(a) RAC/02/2008/12
(b) mini-CVs for publication	(b) RAC/01/2008/11
Draft Rules of Procedure for the RAC (Agenda Item 7)	RAC/01/2008/03a_rev.3
Procedure for appointment of rapporteur and co-rapporteur (Agenda Item 8)	RAC/02/2008/13
Procedure for conformity check of a submitted dossier (Agenda Item 11b)	RAC/02/2008/14
Criteria for conformity check (Agenda Item 11c)	RAC/02/2008/15
Progress of transitional and new dossiers	RAC/02/2008/16
ECHA Policy on co-operation with stakeholder organizations (Agenda point 13, AOB)	RAC/02/2008/17
Proactive engagements with all ECHA stakeholders	RAC/02/2008/18

ANNEX II.

17 March, 2008
RAC/A/02/2008_rev2

Final Agenda
Second meeting of the Committee for Risk Assessment

11-13 March 2008
Palace Kämp Linna, Helsinki, Finland
(Lönnrotinkatu 29, 00180 Helsinki)

11 March: starts at 9:00
13 March: ends at 13:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/02/2008_rev.1
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of the RAC-1

RAC/M/01/2008
For adoption

Item 5 – Administrative Issues

a) change in the RAC composition **RAC/02/2008/12**
b) reimbursement rules- answers to the questions raised
c) mini-CVs for publication **RAC/01/2008/11**

For information

Item 6 – Feedback from other ECHA bodies

a) Management Board meeting (February 13-14)

b) Member State Committee meeting (February 26-27)

For information

Item 7 – Rules of Procedure (RoPs)

Revised draft proposal for RoPs of the Risk Assessment Committee:

- Articles that are still open:
  - Art. 4 Co-opting members
  - Art. 9 (5) and 9 (6) & Annex 2
  - Art. 10 Confidentiality& Annex 3
  - Art. 20 Written Procedure

RAC/01/2008/03a_rev.3

For discussion and endorsement

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

Procedure for appointment of rapporteur and co-rapporteurs

RAC/02/2008/13

For discussion

Item 9– Interface with other ECHA bodies

Interface with MSC, SEAC and Forum

For information

Item 10 – Guidance Documents

a) Guidance for the preparation of an Annex XV dossier (Restrictions, C&L, SVHC)

http://reach.jrc.it/docs/guidance_document/harmonised_classification_en.htm

http://reach.jrc.it/docs/guidance_document/restriction_en.htm

http://reach.jrc.it/docs/guidance_document/svhc_en.htm

For information

b) Other Guidances:

Guidance on preparing the Chemical Safety Report (CSR) (RIP 3.2)

Guidance on information requirements under REACH (RIP 3.3)

Guidance on how to comply with the provisions of the new Regulation on

Classification, Packaging and Labelling of substances and mixtures (RIP 3.6)
Guidance on the preparation of an application for authorisation (RIP 3.7)
Guidance on Dossier and Substance Evaluation (RIP 4.1/ 4.2)

For discussion

Item 11 – Working Procedures

a) Main steps in draft SOP flowchart related to RAC

- Annex XV dossiers – Classification and Labelling

b) Procedure for conformity check of a submitted dossier **RAC/02/2008/14**

c) Criteria for conformity check **RAC/02/2008/15**

For discussion

Item 12 – Planning of the work for 2008

a. Progress of transitional and new dossiers **RAC/02/2008/16**

For information

b. Appointment of rapporteurs for the first dossiers

For discussion

Item 13 – AOB

a. Next meetings (***July 1-4, 2008 tentative****)*
(September 16-19, 2008 tentative)
(November 18-21, 2008 tentative)

b. Stakeholder participation **RAC/02/2008/17**
RAC/02/2008/18

For information

c. Action Points agreed at the RAC 2 meeting

For endorsement