



RAC/M/01/2008 Final

**FINAL**

**Minutes of the 1<sup>st</sup> Meeting of Committee for Risk Assessment (RAC-1)  
29-31 January 2008**

## **I. Summary Record of the Proceedings**

### **1. Welcome and Introduction**

The Chair of the Committee, Ms Sharon Munn, (on secondment from the Commission) welcomed the participants to the first meeting of the Committee for Risk Assessment (RAC), and introduced the Executive Director (ED) of the European Chemicals Agency (ECHA).

For this first meeting, apologies were received from seven members of which three had sent non-voting replacements. One Member did not attend, without apologies, and a further had informed the Secretariat that he would arrive only on the 2<sup>nd</sup> meeting day. The list of attendees is given in Part III of the minutes.

#### **a) Welcome by the Executive Director of ECHA**

The ED of ECHA, Mr Geert Dancet congratulated the members on their appointment following nomination by their MS CAs, and stressed the importance of the work of the RAC as one of the cornerstones of REACH and hence one of ECHA's priorities, underlining that the Committee is a part of ECHA. He emphasised that the RAC is a new type of an independent scientific expert panel which supports the decision making processes under REACH and should thus find its own ways of working, building on and blending past experience and promoting transparency. The first tasks of the RAC were therefore to agree in time on the Rules of Procedure (ROPs) and to develop efficient working practices and procedures. He also pointed out that the members according to Article 85(6) shall be supported by the technical and scientific resources available to the Member States, but that members should not accept any instructions from the Competent Authorities, nor any other party.

#### **b) Tour de Table – auto-presentation of the members of the Risk Assessment Committee**

A *tour de table* in which the participants to the meeting briefly presented themselves took place and it was agreed to use first names when addressing each other.

### **2. Adoption of the Agenda**

The Agenda, revision 1, was adopted after ECHA added a point 3c) Proposal for harmonised templates for mini CVs for the members.

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.

### **3. Administrative Issues**

All attendees were asked to sign the attendance form for every morning and afternoon session they attend. Their attention was drawn to the time table for the meeting included in the additional information tabled for the meeting.

Regarding documentation, the Chair informed the meeting that in addition to the documents already circulated well before the meeting, all presentations would be

uploaded to CIRCA after the meeting, including the room documents made available for agenda items 3c, 6c and 6d.

**a) Reimbursement rules**

The forms for financial identity had been circulated in advance of the meeting and members were reminded to complete it, once only. The Management Board (MB) of ECHA has agreed general rules on reimbursement of travel expenses that will also apply to the RAC. These rules had been made available before the meeting. The Secretariat explained that the procedures to transfer the reimbursement could start only after all forms had been returned to the secretariat, and that the aim was that reimbursement should be made four weeks after the last form has been returned.

Members had several questions concerning the details of the reimbursement rules. The Secretariat provided responses to the extent possible and proposed to confirm and clarify the responses at the next meeting.

**b) Declarations of conflict of interest**

Under this agenda point the Secretariat presented all three types of declarations annexed to the draft rules of procedure:

- Annual Declaration of Commitment
- Annual Declaration of Interests
- Declaration of Confidentiality

After the adoption of the ROPs these declarations have to be completed and signed by the various participants to the RAC meetings in accordance with the provisions of the draft Rules of Procedure (ROPs). However, it was clarified that the duties of commitment, declaring conflicts of interests and confidentiality apply from the first day of their appointment. The oral declaration of interests at the meetings would apply already at the first meeting.

Publication of the declarations of interests would be in line with ECHA's commitment to transparency and it would also be in line with the practice of some other European agencies like the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA). A revised version of document ECHA/RAC-1/2008/03b providing guidance on conflicts of interest would be sent out after the meeting. The topic was further discussed under agenda point five (ROPs).

The RAC members asked for more guidance on the type of interests that would prevent participation to the RAC and which interests to declare in relation to e.g. family and friends, or to membership of certain non-governmental organisations (NGOs). The Secretariat noted that the credibility and the perception of the RAC by the outside world are most important and should determine the member's individual decision to declare any interest. It was also agreed that it could be possible for a member that has declared an interest to provide her/his expertise internally to the RAC and then abstain from the decision phase. The sensitivity of the RAC members to this was therefore important. With this in mind, it was agreed that the RAC members should apply careful judgement for each case and ECHA would then evaluate the relevance of any declaration. For example, close connections with an

applicant for authorisation through family and friends should be declared, as should any active membership of REACH-relevant NGOs.

In this context, some RAC members asked what to declare if they are employed by a university which could have co-operation or joint contracts with industry (including a REACH-relevant industry) on an institutional level. The Secretariat responded that such issues should be declared, but most likely they would not actually pose a conflict of interest if there was no personal involvement with REACH-relevant issues.

One member requested whether it would be necessary to declare an interest for an agenda point when the member is working for the Member State Competent Authority (MSCA) that has submitted the Annex XV dossier. The Secretariat considered such declaration relevant.

In addition, the Secretariat reminded the meeting that relevant companies and relevant industry is wider than just the chemical industry.

Concerning the declarations of confidentiality, one RAC member asked how long the duty of confidentiality was valid after serving his/her final term as a member of the Committee. The Secretariat referred to Art. 105 of the REACH Regulation which does not indicate any time period and therefore the duration of the duty of confidentiality can be considered to be indefinite.

Another RAC member asked how their co-operation with the MSCA would be governed by the duty of confidentiality. The Secretariat noted that the MSCA have access to most of the information in any case, and they furthermore have the duty to support the RAC members they have nominated. It is therefore unlikely that there will be documents available to the RAC which are not accessible to the MSCA.

One member enquired if it would be easily possible to recognise which documents are confidential. The Secretariat responded that it would flag information/documents considered to be confidential and for example Confidential Business Information (CBI) would always be flagged.

One member enquired if members could have advisers who do not come to the meetings of the RAC but would support the members otherwise. The Secretariat responded positively but noted that all advisers should sign the relevant declarations and then they could obtain access to the information if so requested by their RAC member. It is the responsibility of the RAC member to ensure that the advisers respect the same confidentiality requirements as the members.

The design of the Declaration of Interests was also discussed, and it was suggested by some members to modify Part I to also reflect the nature of the declared conflict of interest, e.g. highlighting whether this is a personal or an institutional conflict. The Secretariat agreed to look into this when revising the ROPs.

The Chair then concluded the discussion by stating that some further considerations would be needed. However, she encouraged members to declare all activities and interests that could be seen as causing potential conflicts in the spirit of ECHA's policy on transparency, considering that in the majority of cases the conflict would remain potential and not actually interfere with the participation to the work.

The Chair then asked if there were any Conflict of Interests to be declared specific to this meeting. No such interests were declared.

### **c) Harmonised CVs**

The Secretariat had proposed a format for harmonised short Curriculum Vitae (CV) and had distributed a room document with an example. It might still be relevant to streamline the final format with the other Committees, the Forum, and, possibly, the MB. A final proposal would be sent out after the meeting and the members would be requested to fill it and return it to the Secretariat. The CVs would then be made publicly available on ECHA's website, in line with Article 88(1) of the REACH Regulation.

## **4. Background of the RAC**

The Secretariat presented the legal basis for the RAC and vision on the RAC's modus operandi, to be further discussed under item 6 of the agenda.

It is planned, based on the deadlines in REACH and input from the Member States (MS), to generate an annual or a rolling multi-annual overview of the substances that will be subject to submission of an Annex XV dossier to ECHA. To facilitate the discussions RAC working groups composed of RAC members and other experts, selected from ECHA's expert roster or proposed by the RAC members, could be established for execution of certain tasks. The interface with the Committee for Socio-economic Analysis (SEAC) would need to be established, as well as a working relationship with the Member State Committee (MSC).

The work of the RAC will be co-ordinated by the Chair supported by a scientific secretariat. It will facilitate communication between the RAC members, plan, prepare, organise and follow-up the activities of the RAC, and co-ordinate input from the Secretariat, establish and maintain working relationships with other bodies. ECHA will also support the RAC financially by reimbursing the costs for members and invited experts related to participation in the RAC plenary meetings. Subject to availability of funds, ECHA will support the meetings of the working groups.

RAC members asked how and who initiated working groups, to which the Secretariat responded that there are several possibilities, e.g. the RAC can propose, the rapporteur can suggest or the Secretariat can recommend, but it is always the RAC that establishes a working group.

## **5. Rules of Procedure (ROPs)**

Before opening the discussion of the proposed Rules of Procedure (ROPs), the Chair gave an overview of the timeline: the RAC was appointed by the MB on 17 December 2007, and, as Article 85 of REACH gives 6 months for the RAC to propose draft ROPs to the MB, the formal deadline is 17 June 2008. However, in order to be operational by June 1<sup>st</sup>, it is hoped that the RAC would be able to agree on draft ROPs at its next meeting in March, which would allow presentation of the agreed draft ROPs to the MB at its meeting of 23-24 April 2008.

It was explained that the ROPs were drafted taking due account of, ROPs from similar committees, e.g. those run by EMEA, or EFSA, or the Scientific Committee on Health and Environmental Risks (SCHER), as well as the ones proposed to and discussed by the Forum in December 2007. The Chair suggested that the ROPs should be kept general, following the same pattern for the other ECHA Committees, while Standard

Operating Procedures (SOPs) could be elaborated for specific aspects, should the RAC consider it necessary.

The ROPs were then discussed article by article with the aim to agree on the wording, as far as possible. A revised version recording the proposed and agreed changes of the ROPs was presented in the evening of 30 January for discussion the following morning. The main conclusions and points made in the discussions are summarised below. It was agreed that the secretariat would prepare a revised version reflecting the discussion and would make it available to the RAC members within two weeks.

**Art. 1.** After some discussion, Art. 1 was agreed to contain a direct citation of Art. 76(1)(c) of REACH. This wording includes the mention of evaluations although under Title VI (Evaluation), no tasks are allotted to the RAC.

**Art. 2.** The Chair clarified that this article cites the text from REACH and thus it would not be appropriate to modify the text, e.g. by adding tasks. Details on the tasks should be reflected in the work programme, where priorities could be stated, and which would also be the background document for highlighting the resource need to the MS. The RAC agreed to reword the footnote to Article 2 of the RoPs.

**Arts 3 and 4 were not modified**, although some discussion took place, and for Art. 3 the RAC carefully considered proposals for alternates and for transfer of voting rights in the form of proxies. Finally, the RAC accepted that, as the members were appointed on the basis of their personal specific expertise and as the meetings served as a forum for exchange of views between the experts that should allow for shifting of views in a consensus-building process, it would not be appropriate to advocate either alternates or the transfer of voting rights.

Concerning Art. 3, the Secretariat pointed out that an additional category of members will need to be added when the decision on inclusion of the REACH Regulation in the European Economic Area (EEA) agreement is finalised. It is likely that the agreement will give the EEA countries the right of membership without voting rights.

For Art. 4, the Chair clarified that the procedure for selecting co-opted members will be described in more detail in a future document that the RAC should develop.

**Art. 5.** For Art. 5(2) it was clarified that the resignation shall be in writing. For Art. 5(4) the wording was changed to clarify that the procedure to follow when inviting experts replacing a member is not the one in Art. 6 but the Chair can invite these experts without consulting the RAC. Whilst many members wanted to create an obligation for ECHA to invite the expert replacing a member, the Secretariat explained that for financial governance reasons invitation of such experts needs always to be subject to discretion by the Secretariat but promised to verify the issue.

**Art. 6.** The Chair clarified that a new version of this article had been drafted by the Secretariat in which a new category of observers, the case holders, had been introduced. Furthermore, the article had been rearranged to some extent. At the meeting it was agreed to further rearrange the article and to introduce a catch-all category of other observers.

**Art. 7** A member proposed that the RAC should endorse the Chair assigned by ECHA. After discussion, the RAC agreed that the REACH text was clear in specifying that the Chair of the Committee is an ECHA employee nominated by the ED and no endorsement is thus needed. In case the RAC was not satisfied with the Chair, they could always raise their concerns to the attention of the ED or the MB.

**Art. 8.** The RAC agreed that it is up to the Chair to propose measures in case of breach of the ROPs and that the measures taken would depend on the nature of the breach.

Art. 8(i) was expanded with an example of powers that might be entrusted to the Chair by the Committee to make the text clearer.

**Art. 9.** Art. 9(1) to 9(4) were accepted as proposed. The Chair clarified that Art. 9 (5) and 9(6) are additional to the declaration of interests. Art. 9(5) was intensively discussed and reworded to (1) reflect that the members of the RAC themselves must consider whether their activities and their personal involvement in it, are of a nature which is not compatible with being a member of the RAC and (2) to better define the activities that would be within the scope of this article as well as those specifically outside the scope, such as general training and educational seminars. The Chair proposed to place a reservation on the wording of these paragraphs pending the discussion scheduled for the February meeting of the MB on this issue.

In Art. 9(6) the word ‘private’ was added to the first line for clarification. Concerning Art. 9(7), it was agreed that the RAC would give a mandate to individuals representing the RAC, and the paragraph was reworded accordingly.

In the context of Art. 9, Annexes 1 and 2 were also discussed. For Annex 1, the line ‘position’ was removed, as it was considered to be superfluous. For Annex 2 it was proposed to include in part I a short summary of the nature of the activities which could be considered posing a conflict of interest, with more details provided in part II. The Secretariat agreed to consider the suggestion and would make a proposal after the meeting via a written procedure. The importance of transparency in the declarations of interests was reiterated by the Chair.

**Art. 10.** The basis for the article is REACH articles 118, 119 and 105. A number of members expressed concern that the wording of Art. 10(1) as well as the declaration of confidentiality (Annex 3) would propose treating everything as confidential unless publicly available, and this seemed to contradict both national and Community legislation on access to information. A clause was added to indicate that this article was without prejudice to such obligations under other legislation. Nevertheless a reservation was placed on the paragraph to allow RAC members to seek legal advice on whether signing such a declaration would put them in conflict with their own national legislation.

**Art. 11.** On the publication of information on the Agency’s website, some members requested a rewording under Art. 11(3) with respect to the content of the minutes and the declaration of specific interests to a particular agenda point.

**Art. 12.** The deadlines were modified as follows: invitations must be circulated at least 21 days before the meeting for normal meetings and at least 7 days before urgent meetings.

The Secretariat expects that from 2009, when ECHA has its own conference facilities, it can plan the meetings well in advance and adhere to the planning. Furthermore, the number of days in the text of the ROPs is given as calendar days as national holidays vary across the EU thus making working days a non-harmonised concept. In addition, the Secretariat would wish to develop SOPs, including more detailed procedures for organising meetings to facilitate the preparation for all parties concerned.

One member suggested to use video links as an alternative to participating in the meeting, which could be especially useful for urgent meetings. The Secretariat agreed to check if presence at a meeting via a video link would be sufficient in legal terms for decision points. Other issues in relation to assuring confidentiality, particularly if considering observer participation via video link, would also need to be investigated.

**Art. 13.** The deadline for sending comments on the provisional agenda in Art. 13(2) was increased to five days.

**Art. 14.** For making documents available it was concluded that 10 days was a reasonable general deadline and a reference to the volume of the documents was added to allow an adaptation of the deadline in case of particularly complex, large or short documents. The Chair explained that the future SOPs should aim to differentiate types of documents and the time before the meeting that it would be reasonable to have them available; the SOP development is planned to start in 2008. A member noted that an analysis was needed on how and with which deadlines the output from a working group would be taken to a plenum meeting.

**Art. 15.** The deadline in Art. 15 was changed from five to seven days.

**Art. 16.** Some members proposed to shorten the deadline for the minutes from four to two weeks. One member proposed a deadline of four weeks to have a final version, meaning 2 weeks for the first version, one week for comments and one more week for the last draft version. The member added that minutes should not only be archives but also a real working tool for RAC members; to wait for one month to have a first version may sometimes be too long a period to remember some details in the discussion, in particular when the discussions were numerous and dense. This proposal, however, was seen by the Secretariat as a difficult deadline to achieve in periods with a high workload or around holiday periods.

The point relating to the agenda point on declarations (Art. 16(1) (a)) was reworded in accordance with the comments made on Art. 11(3).

The wording of Art. 16(2) on distribution of documents was reworded to include a reference to Art. 6(12) on participants' access to documents.

**Art. 17** on Rapporteurs was not modified. The Secretariat stated that, in view of the forthcoming implementing rules for the financial procedures, the need to modify Art. 17(3) could arise, including its deletion. Several members stressed the need to develop a procedure for speedy appointment of rapporteurs as already envisaged in Art. 17(2).

**Art. 18** (Working Groups). Some members noted that Art. 87(3) of the REACH Regulation referred to remuneration of working group members, and Art. 18(4), adapting 17(3) for rapporteurs, was added to the ROPs addressing this. Art. 18(4) may also be reviewed once the implementation rules from the MB are available. In



Art.18(5) the draft agenda and meeting dates were added to the list of information to be made available to the RAC.

Regarding Art. 18(1), the possibility to have subgroups of working groups was added to the text. For Art. 18(3) the Secretariat clarified that invited experts can be invited to participate in the working groups and following Art. 6(9) also observers may be admitted to the working groups.

**Art. 19** (quorum and adoption of opinions). The deadline in Art. 19(2) was changed from five to seven days. The Chair clarified that at meetings the RAC could adopt opinions and take decisions only when the quorum was achieved and only the opinions of members present would count in the formal adoption, when considering achievement of consensus, or majority versus minority opinions. Disagreements e.g. by participants to the meeting invited according to Art. 5(4) would not need to be recorded as a minority opinion.

**Art 20.** For the written procedure, the application of tacit agreement for the adoption of scientific opinions was opposed by several members. Consequently, the Secretariat proposed to distinguish between the adoption of an opinion and taking procedural decisions. For urgent questions a deadline of 5 calendar days in the first case and 2 calendar days for the latter case was proposed. It was recognised that the deadlines for urgent decisions as proposed were short, however the expectations were that they would not be used frequently. Art. 20(3) was added by request of members to require a response rate of 60% in adoption of opinions by written procedure. However, this would not be applied to procedural decisions where tacit agreement was retained. In addition, if consensus cannot be reached the minority position(s) shall be reflected in the written procedure report.

**Art. 21.** The reference to the implementing rules on financial issues from the MB was updated.

**Art. 22.** The reference to the required majority was changed by adding the clarification that the two thirds majority referred to members present.

## **6. Planning of the work for 2008 and beyond**

Introducing this agenda item the ECHA secretariat gave a brief overview over the history and intention behind the structure of the ECHA committees.

The RAC will be instrumental in three key REACH processes that will start in the following chronological order: Classification & Labelling (C&L), Restrictions, and later Authorisation (not specifically covered in this meeting).

The secretariat explained that the committee structure as implemented in REACH is based on experience from the past committees dealing with similar issues, especially the Technical Committees (TC) on Classification and Labelling (C&L) and New and Existing Substances (NES) (and its predecessors), the SCHER as well as the Risk Reduction Strategy Meetings, and the Limitations Working Group, underlining that it is meant to take over the strength and to avoid the weaknesses of the previous system.

The new processes introduced by REACH will ensure the (peer) review of the dossiers by appointing rapporteurs. Having one committee, the Committee for Risk Assessment, as the focal point for discussion of all issues within one dossier will ensure a more integrated approach than in the past. Further streamlining is foreseen as described in whereas clause no. 102 of REACH. The members of the RAC are independent, and member states must support them with resources and the legal text lays regulatory deadlines for many of the processes.

The Secretariat recognised that it will be a challenge for the RAC in its start-up phase to address all the different tasks that were previously distributed over several committees.

#### **a) Introduction to the dossier driven tasks of the RAC**

In all three processes the work of the RAC will consist of developing an opinion on a proposal prepared by another party (MS, Industry, ECHA-secretariat upon request of the Commission). These dossiers have to be prepared in the format defined in Annex XV to the REACH Regulation and are therefore called Annex XV – dossiers. It is envisaged that the processing of these dossiers will follow a similar pattern under all three processes, and thus the three procedures should be aligned with regard to deadlines.

In order to allow for a good scheduling of the workload it is foreseen to start with a registry of intentions to prepare a certain type of Annex-XV-dossier based proposals. ECHA has therefore asked Member States to communicate their intentions to prepare C&L and restriction proposals but has not yet received much information.

The Secretariat is in the process of developing standard operating procedures (SOPs) for the processing of the different Annex XV dossiers. For the RAC the first step is always the conformity check, followed by the consultation of parties concerned, before it can prepare its opinion. The ECHA secretariat also expressed its view that there is a need to prepare and approve a decision support document (see below) that would integrate the entire information on which the RAC-opinion is based.

##### **• Annex XV dossiers - Classification and Labelling**

The ECHA Secretariat presented the way it envisages the RAC and the ECHA Secretariat to process C&L proposals that should be provided in the Annex XV dossier format.

This view is based on an analysis of the requirements stated in the legal text, experience with the process for C&L proposals before REACH, and the process planned for C&L under the Classification, Labelling and Packaging (CLP) legislation once it is aligned to the globally harmonised system (GHS).

The revision of the legislation on CLP is ongoing with a target date for adoption by co-decision in 2009. The aim of the new legislation is to align the criteria for C&L of substances and mixtures (preparations) as well as the hazard and precautionary statements with the UN Globally Harmonised System for classification and labelling (GHS), which is a global initiative to ensure that the same substance would have the same C&L worldwide. The GHS is similar to the current EU-system – but not the same, some of the criteria and the approach for mixtures (preparations) is different,

and it aligns C&L for transport with C&L for supply and use of substances. Once agreed the new CLP legislation will be the basis for the classification and labelling work under REACH.

The Commission's proposal for the revised CLP Regulation is now being negotiated in the Council and the European Parliament. The main issues remaining concern the suggestion to extend the scope to also label PBT substances and to introduce a tonnage trigger (1 t/year) in the obligation to notify the C&L. Other issues also still discussed are the obligations of distributors, the validity of testing on humans and non-human primates, the impact on down-stream legislation, and the labelling of consumer products.

If the expected timing is adhered to, the requirements to classify substances in accordance with the new legislation should then apply from 1 December 2010 (note: this is the same date as the deadline for registration of the first phase-in substances under REACH and for notification for the C&L inventory under REACH).

#### • **Annex XV dossiers - Restrictions**

The Secretariat presented a proposal on how the RAC and the ECHA secretariat could process Annex XV dossiers for Restrictions, including a description of the critical processes, deadlines and responsibilities. The key steps in the process are

- notification to the registry of intentions
- submission of an Annex XV dossier in up-to-date IUCLID format
- appointment of rapporteur
- conformity check by the RAC as required in Art. 69(4) of REACH (and in parallel the SEAC)
- public consultation of the original dossier,
- preparation of draft opinions of the RAC and the SEAC
- Public consultation of the draft opinions
- Finalisation, publication and transfer of the opinions to the Commission
- Commission takes the final decision in comitology procedure.

It was proposed that the ECHA Secretariat will brief the Chair of the RAC on conformity of the dossier and it was offered to make this briefing available also to the rapporteur of the RAC/SEAC with a view to assist the RAC/SEAC in their conformity check, for instance by highlighting any obvious deficiencies or inconsistencies with the format and content specified in the legal text.

The need for a good co-operation of the RAC and SEAC was underlined and an approach for this proposed.

In addition, the Secretariat proposed that the author of the Annex XV dossier would be charged with integrating the comments and final opinion and its justification into one consistent Decision Support Document.

### Discussion:

Asked for further details regarding its support to the conformity check, the Secretariat emphasised that the decision about conformity of a provided dossier is ultimately the responsibility of the RAC. However, the Secretariat will develop more detailed proposals and submit these for discussion at the next RAC meeting. The Secretariat added that for Annex XV dossiers for C&L there is no legal requirement for a conformity check. However, it would seem logical to treat Annex XV dossiers consistently and always to ensure before analysing them in detail that they contain sufficient information and are in conformity with the requirements. The ECHA Secretariat will further develop the Annex XV dossier process description for the next RAC meeting.

Asked what the consequences would be if the dossier would not be in conformity, and if the Secretariat could offer a pre-check of conformity, the Secretariat answered that the timelines for conformity checking in Art. 69(4) of REACH have to be followed and that the RAC has the responsibility for the conformity check and thus also to inform the author that the dossier is or is not in conformance. The Secretariat can offer to interested MSCAs an informal check of the dossier before submission, also in view of the tight deadlines, but formally the process begins with the submission of the dossier to the RAC/SEAC, giving them 30 days to conclude on the conformity of the submitted dossier.

It was highlighted and agreed that as a consequence rapporteurs for the conformity check need to be identified as early as possible, e.g. as soon as the substance is in the registry of intentions. The Secretariat clarified that indeed an early identification of rapporteurs is needed but that the formal appointment, possibly requiring a written contract, can only take place after the dossier is officially received by the RAC. The formal nomination of pre-identified rapporteurs could then happen, for example, through a quick written procedure.

Several members of the RAC noted that the rules for conformity check should be established quickly and discussions should start already at the next meeting.

It was discussed whether it would present a conflict of interest if a RAC member has taken part in drafting an Annex XV dossier that is then presented to the RAC. The Secretariat observed that a conflict of interest could be declared; that the rapporteur assigned to the dossier should not come from the authorities drafting the Annex XV dossier, and that representatives for the author MS could be present at the RAC meeting as observers. The meeting agreed to these observations.

### **b) Decision Support Document**

The Secretariat introduced a proposal for generating a decision support document (DSD) explaining that the proposal had originally been submitted to the CA meeting in December 2007.

The objective of such a DSD is to record in a transparent and easily accessible way the scientific and technical reasoning behind opinions and decisions from ECHA, in this case the opinions of the RAC. This would make the entire information easily available to ECHA and its associated experts, to the Commission for its legal process, and also for any future discussions. It would also be made publicly available and

would serve as a basis for registrants (and possible future applicants for authorisation) to update their Chemical Safety reports

The proposal also analysed who would generate the DSD, and suggested that the original authors would have the best knowledge and should therefore draft the document.

### Discussion

The Commission noted that the detailed mechanisms still need to be developed but expressed the belief that it is a very good proposal, evidently based on the learnings from the Existing Substances Regulation (ESR) programme, where the risk assessment reports published by the European Chemicals Bureau served a similar purpose.

Several members raised questions on the procedure for creation and status of the DSD, on MSCA involvement in the process and on the responsibility for producing and approving a DSD, and on the actual content, format and length of it. Some members also raised questions about the usefulness of a DSD, noting that there would be other sources of information on the discussion of the content of a dossier, e.g. the minutes (documenting the steps of the decisions) and the response-to-comments table. The Secretariat, stressing that the intention is not to duplicate work, explained that the minutes of the meeting, for example, reflected only the discussions and conclusions taking place at a meeting, whereas the DSD would integrate these discussions and their impact into a type of updated Annex XV dossier making all information available in one document.

Finally the Chair concluded that the RAC finds the DSD in general to be a potentially very useful 'all-in-one' document to support the further decision-making process by the Commission and for future consultation but that further details needed to be presented before the final position could be taken.

The ECHA Secretariat was requested to provide further details and practical examples (which also include examples of the minutes and the format for the actual opinion) at the next meeting. The discussion on the DSD will continue at the March 2008 Competent Authorities meeting and the outcome of the discussion of the 1<sup>st</sup> RAC meeting would feed into that process.

### **c) Pending/forthcoming classification and labelling dossiers**

For this agenda point two room documents were distributed indicating substances that most likely will be discussed in the forthcoming future by the RAC in a C&L context. The Commission introduced the document ECHA/RAC-1/2008/10 that described the substances for which the C&L under the previous legislation had not yet been agreed. Although it was hoped that an agreement could still be reached on some of the substances in a written procedure before the hand-over date of 01/06/08, most of the substances on the list were expected to be submitted to ECHA/RAC for discussion and opinion.

The Secretariat introduced the document ECHA/RAC-1/2008/09 giving an overview of the replies received to a letter from ECHA of September 2007 to the MSCAs requesting information on pending / forthcoming Annex XV dossiers. Only five MS had replied and the amount of information was insufficient for producing a work plan.

The Secretariat had reiterated the request to the MSCAs at the December 2007 REACH CA meeting. Some of the members offered to contact their MSCA and ask them to forward this information.

However, one MSCA had already submitted two Annex XV dossiers for C&L to ECHA, so the Secretariat and the RAC could in principle start working with these dossiers as test cases. As the dossiers were not submitted in IUCLID format the Secretariat was studying how best to process these two test dossiers.

#### **d) Transitional Annex XV dossiers for existing substances (Art. 136)**

The Commission presented the document (ECHA/RAC-1/2008/7c) that was also presented at the December 2007 Joint CA meeting, indicating which substances are expected to be finalised under the Existing Substances Regulation (ESR) and published in the Official Journal before 01/06/08. For these substances there is no need to submit an Annex XV dossier.

The Commission clarified that in order to publish decisions in the Official Journal before 1<sup>st</sup> June 2008 the discussions would have to be concluded by 15 February 2008. Recommendations directed to the Integrated Pollution Prevention Control (IPPC) Directive, the Water Framework Directive (WFD) or for an Occupational Exposure Level (OEL), that were agreed but for which the decision could not be prepared and published in time, would be taken up by the relevant Commission services without the need to submit an Annex XV dossier to the RAC.

For other substances, although finalised with regard to the risk assessment, there would be no time to submit or finalise a Risk Reduction Strategy (RRS), and thus Annex XV dossiers would need to be submitted by the responsible MSCA according to Article 136 of REACH. These dossiers would therefore need to be processed in the RAC. In response to a question the Secretariat confirmed that a socio-economic analysis was not an obligation for these substances though it would be beneficial when there was a proposal to amend Annex XVII.

Using document ECHA/RAC-1/2008/7c as a basis, the Secretariat proposed to develop a type of provisional working list of anticipated dossiers, which could form the basis for the process of an informal identification of rapporteurs. This was agreed to by the committee.

In response to a query from a member on the process of consultation of the SCHER on these remaining risk assessments, the Commission replied that it would probably not be meaningful to submit these to the SCHER after March 2008.

#### **e) Other tasks**

The Secretariat presented the structure of the foreseen stakeholder consultation process to be used by ECHA for updating, revision, or drafting of guidance documents. This process would include consultation of the relevant Committees, whenever necessary, in order to ensure that the committees subscribe to the guidance that determines the actions of Industry or MSCAs as dossiers prepared using the guidance may be processed by the RAC. The committees are also seen as a source of top-level expertise being available to the ECHA that should be used to the fullest extent at the Executive Director's request.

## 7. Working Procedures

### 7a. Establishment of working group(s)

The legal text and the draft ROPs allows the Committees to establish working groups where appropriate. The Secretariat presented a thought starter, analysing when support from a co-rapporteur or a working group would be needed, and if the number, mandate and composition of working group(s) could be defined at this point in time. The main points of this were:

- before establishing working groups, the dossier types to be dealt with, the (fixed) timelines, and the past experience should be taken into account.
  - Different dossiers would require different expertise that could be best found through appointing one or two co-rapporteurs, but in some more complex cases a working group might be proposed.
  - The fixed timelines would require a smooth operation which also a working group has to adhere to and the past experience is that by having working groups the coordination with the main committee may sometimes be complicated.
- dossier related working groups may be needed
  - They could consist of the rapporteur, co-rapporteur, interested RAC members and their advisers and invited experts.
- Also issue-related working groups (e.g. on human health effects assessment, environmental effects and PBT assessment, exposure and risk management, method development) could be considered, possibly serving the RAC, SEAC and the MSC, thus contributing to the coordination of these committees and the harmonisation of their work.

Upon proposal by the chair, the RAC agreed to start working without a pre-fixed working group structure, noting though that this could potentially place a substantial burden on the rapporteurs.

For the assessment of Substances of Very High Concern (SVHC), a member noted that there could be a need to review the guidelines together with the MSC in a small working group to avoid different interpretation of the same data. The Secretariat observed that there is a need to differentiate between the identification of SVHC (>MSC), and the assessment of restriction or authorisation proposal for such substances (>RAC), and that the work is done in two different Committees.

With respect to the work on harmonised C&L proposals, two members observed that the workload could be substantial as substances from the Biocides and Plant Protection Products programmes are coming in and those substances require a C&L for all end-points. Once an overview is available the workload should be evaluated and the need for installing working group(s) should be considered. The Secretariat suggested considering to assign a rapporteur and co-rapporteur respectively for toxicological and environmental aspects.

One RAC member proposed to actually have a group dealing with C&L for CMR properties, but some others pointed out that experts in C, M or R are normally not experts in the other areas, making such a sub-group difficult to establish.

The issue of the future of PBT assessment was also brought forward, as, in the past, the PBT subgroup had also dealt with Biocides that are potential PBTs. The Chair noted that the mechanism in terms of processes and procedures (and the relevant actors) for the identification of potential PBTs from Plant Protection Products and Biocides would need to be clarified. In any case the task of identification of PBTs/vPvBs rested with the Member State Committee, and thus the RAC's involvement with this task in general would be relevant to the foreseen discussions on the interface and coordination with the MSC. The secretariat noted that one way of ensuring co-ordination could be (a) joint subgroup(s) between ECHA's committees.

The Chair concluded that there was an agreement to start working as one Committee and that at a later stage, taking into account the working experience and the potential workload, dossier-related subgroups or subject related working groups may need to be established.

### **7b. Interface with MSC, SEAC and Forum**

This point was deferred to the next meeting owing to time restraints.

### **7c. Cooperation with other community bodies**

The Secretariat presented an overview of other Community bodies with which ECHA may need to establish ROPs for cooperation, as laid down in Arts. 95 and 110 of REACH. The relevant bodies are EMEA, EFSA, and the Advisory Committee on Safety Hygiene and Health Protection at Work, specifically cited in REACH, as well as the DG SANCO non-food committees, SCHER, the Scientific Committee on Consumer Products (SCCP), and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The Secretariat outlined a number of foreseen activities for this future cooperation, including setting up networks; establishing contacts between the secretariats; assessing possible overlaps, start discussions on data sharing and confidentiality issues; developing memoranda of understanding; and assessing possibilities of joint activities of different committees.

The Chair informed the RAC that ECHA had received an invitation from DG SANCO to participate in the development of a SCCP, SCHER and SCENIHR joint opinion on 1) the use of the Threshold of Toxicological Concern (TTC) in human health risk assessment and 2) approaches to the risk assessment of mutagenic and carcinogenic substances.

The Chair pointed out that since two RAC members were also members of the SCHER, this provided already good possibilities for input to the respective activities. Other RAC members with a specific interest in either of the topics were invited to take contact with DG SANCO, following distribution of the draft mandates after the meeting by the ECHA secretariat.

## **8. Co-opted Members**

### **a) Competence coverage**

According to REACH, the only criterion for co-opting additional members to the RAC would be gaps in the overall expertise. The Secretariat therefore presented an overview and statistical background data of the competence of the RAC members



based on the information in their CVs and competence grids submitted to ECHA, highlighting that all areas of required expertise seemed to be covered by the appointed members.

## **b) Proposals for Co-opted Members**

The ECHA secretariat presented the agenda point clarifying that the co-opted members would be full members of the RAC with equal duties and rights as members nominated by MS. The only difference would be in the way co-opted members are appointed. In addition to co-opted members an expert roster is envisaged from which experts could be invited as the need arises to provide expertise of a specific nature on a particular topic.

After discussion the Chair concluded that

- in view of the analysis of the expertise currently within the RAC it would be unnecessary to decide already now on co-opting additional members.
- the estimated work(over)load is not sufficient reason to co-opt additional member(s), such an issue should be addressed to the MSCAs who are legally obliged to support the members of the RAC
- the procedure for co-opting members should be elaborated on the basis of the ROPs in a specific procedure when the need arises,
- co-opting additional members could be done at any time and thus would remain as an open issue that could be addressed at any RAC-meeting.

## **9. Invitation of observers**

In the past, different practices to stakeholder participation have been applied in different fora (for example TCNES, SCHER, EFSA and EMEA) and therefore an ECHA stakeholder policy had been regarded as necessary.

A discussion document on the topic had been presented to the MB in December 2007 and a concise policy document on this should be presented to the MB for endorsement at its meeting in February. The document identified only two groups of “privileged” observers (ECHA and the Commission), and for other observers, an invitation from the Committee itself would be needed.

The document also underlines the intention of ECHA to ensure the maximum level of transparency possible, while ensuring an equal and fair treatment of all concerned stakeholder groups. Therefore, an open call is planned to invite EU-wide stakeholder organisations to express their interest in participation (as observers) in the work of the Agency, including their participation (as observer) to the meetings. The RAC could then invite observers from those organisations that have expressed interest in participating in the work of the Committee and fulfilled the eligibility criteria put forward by the ECHA Management Board.

In addition, international organisations and 3<sup>rd</sup> countries might be invited by the MB to participate in the work of ECHA. Also in these cases the agreement of the RAC would be necessary before observers could be admitted. As another technical option it was indicated that once the ECHA conference centre is operational, also web

streaming of Committee meetings could be possible, offering more possibilities for interested parties to observe the work of the committees.

The Chair concluded that a more detailed discussion will take place at the next RAC meeting, after the MB decision on the issue.

## **10. Guidance documents**

The presentation and discussions for this agenda item was postponed until the next meeting.

## **11. Document Management**

### **a) Platform for distribution of documents to the RAC – CIRCA**

The Secretariat presented the CIRCA interest group for the RAC, explaining the procedure for getting access. It was specified that CIRCA can be used to store and exchange documents, and to facilitate discussions through newsgroups. Members were informed that the basic administration of their accounts, such as changing email addresses and activating the functionality of automatic alerts, can be managed directly by the users.

The Secretariat asked the RAC member who had not yet signed up to CIRCA to do so as soon as possible. The members can also ask access to CIRCA for their assistants or advisers, but for security reasons access can only be granted for natural persons, not for functional mailboxes. All requests for adding and removing users – including the advisers should be sent to the Secretariat.

### **b) REACH IT – current state of development and plans for accessibility**

The system will be composed of different applications addressed to the principal groups of users: industry, ECHA and the MSCAs, as well as the general public. REACH-IT will be a web based application hosted at ECHA and accessible to the users via internet. The first version is expected to be delivered in March 2008, and available for use in mid-May. The planning foresees 1000 users from ECHA and MSCAs, including members of committees, who would have full access to data stored in REACH-IT, depending on their respective user-profile.

There are several security layers protecting the data in REACH-IT. ECHA and MSCAs are connected by a secure Virtual Private Network (VPN) connection, every ECHA and MSCA REACH-IT user has a personal client certificate and a login/password. The body responsible for discussing the IT security issues related to REACH-IT affecting MS is the Security Officers Network (SON), which aims to coordinate the security implementation of REACH-IT in MS and harmonise security procedures in the MSCAs. The MSCAs will nominate MSCA user administrators responsible for maintaining the user base in each MSCA, as well as Security Officers who can officially represent their MS in SON meetings. These MSCA user administrators can grant (restricted) access to REACH IT (e.g. to consult dossiers from one legal person only). ECHA provides a limited number of crypto-boxes for free, but MSCAs can themselves invest in more boxes. The non-confidential data will be available via ECHA's dissemination site. Confidential data is protected via limited access.

For the RAC members who are working in the MSCAs access is granted via the workplace. RAC members who are not working as part of the MSCA are regarded as external users and need to obtain access through their MSCA.

The individual members of the RAC had several questions after the presentations and asked how REACH-IT supports the RAC's work. The Secretariat explained that the first release(s) of REACH IT are targeted towards the workflow needed by 1<sup>st</sup> June 2008, and this did not include the RAC, for which a Document Management System (DMS) was proposed. The next questions concerned the DMS and how it would be available. The Secretariat replied that the ECHA would be involved in defining the process, in consultation with MSCAs.

This was followed by a question if REACH-IT is a tool to access IUCLID 5 and what the MSCA should do to submit an Annex XV dossier. The Secretariat explained that REACH-IT is accessible to the MSCAs, and Annex XV dossiers will be submitted through it after entering the relevant data in IUCLID. The MSCAs can connect to ECHA and thereby enter REACH-IT. From June 2008 MSCAs should be able to submit Annex XV dossiers via REACH-IT. Some information would in any case be outside REACH-IT and go into a DMS.

It was clarified that a tool has been developed to transfer IUCLID 4 files into IUCLID 5 format using also attached files. There should therefore not be any need to rewrite the information. So the MS would use REACH-IT and industry data would be available via REACH-IT as well.

The Secretariat added that meeting documents will be circulated via CIRCA in 2008, and in the future a combination of a DMS, REACH-IT and possibly CIRCA would be used.

## **12. Any Other Business**

### **a) Next meeting**

The Chair confirmed that the next meeting will take place in the period 11-14 March 2008 (ending at 14:00 on the last day) in Helsinki at a different venue.

The members noted that in planning the meetings of the RAC the dates should be coordinated with the dates for the Biocides technical meeting, SCOEL and SCHER, REHCORN, and REACH CA-meetings, negotiations for the CLP regulation and possibly others as well. The Chair promised to try to avoid overlapping meeting dates for 2009 and beyond, especially through forward planning that would become easier once ECHA had its own meeting facilities.

## II. Summary of the decisions and conclusions reached by the RAC

### III. List of Attendees

<u>Members</u>	<u>Representatives of the Commission</u>
ANDRIJEWSKI Michal Pawel	VAN DER ZANDT Peter (DG ENV)
BINETTI Roberto	GRAJALES Sylvie (DG ENTR)
BORGES Teresa	ASCHBERGER Karin (DG JRC)
DUNGEY Stephen	
GREIM Helmut	<u>ECHA staff</u>
GRUIZ Katalin	BARANSKI Maciej
HOYAUX Daphné	DANCET Geert
KADIKIS Normunds	DE BRUIJN Jack
KORJUS Pia Hannele	ENDEN Petri
LE CURIEUX-BELFOND Olivier	GRODZSKI Karola
LEINONEN Riitta	HANSEN Bjørn
LOSERT Annemarie	HAUTAMAKI Anne
LUKINSKIENE Lina	HEIKKILÄ Minna
LUND Bert-Ove	KREYSA Joachim
MULLOOLY Yvonne	MUNN Sharon
NUNES Céu	MUSSET Christel
ORPHANOU Maria	PEDERSEN Finn
PICHARD Annick	POLLARD Kevin
POLAKOVICOVA Helena	POPESCU Raluca
PRONK Marja	RASMUSSEN Kirsten
RUPPRICH Norbert	VAHTERISTO Liisa
SCHULTE Agnes	VAN DER MADE Sophia
SMERHOVSKY Zdenek	VASILEVA Katya
SMITH Andrew	YLÄ-MONONEN Leena
STOLZENBERG Hans-Christian	
SULG Helen	
TARAZONA Jose V.	
TOMSONE Margite	
VILANOVA Eugenio	

#### Invited experts attending on behalf of a Member

LARSEN Henrik Søren attending on behalf of TYLE Henrik
VAN ELSACKER Paul attending on behalf of VAN MALDEREN Karen
ZAGHI Carlo attending on behalf of MEZZANOTTE Roberto

#### Advisers of the RAC members

JUVIN Philippe (adviser to O. LE CURIEUX-BELFOND)  
KREUZER Paul (adviser to P. KORJUS)

#### **IV. List of Annexes**

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

ANNEX II. Final agenda for the meeting.

#### **ANNEX I. Documents submitted to the Members of the Committee for Risk Assessment (RAC)**

Draft Agenda (Agenda Item 2)	ECHA/RAC-1/2008/01
Background Paper of the RAC (Agenda Item 4)	ECHA/RAC-1/2008/02
Draft Rules of Procedure for the RAC (Agenda Item 5)	ECHA/RAC-1/2008/03a
Guidance on Conflicts of Interest (Agenda Item 5)	ECHA/RAC-1/2008/03b
Decision support document (Agenda Item 6b)	ECHA/RAC-1/2008/06
Transitional Annex XV dossiers for ESR (Agenda Item 6d)	ECHA/RAC-1/2008/07a&b
Status Report - Progress with Existing Substances under Regulation 793/93 based on JM/18/2007 Annex I (Room)	ECHA/RAC-1/2008/07c
Competence Grid for RAC (Agenda Item 8)	ECHA/RAC-1/2008/04
Proposal for co-opted Members (Agenda Item 8)	ECHA/RAC-1/2008/05
Invitation of Observers (Agenda Item 9)	ECHA/RAC-1/2008/08
Pending/forthcoming classification and labelling dossiers (Agenda Item 6c and 6d) (Room)	ECHA/RAC-1/2008/09
Annex XV dossiers for Harmonised C&L – ECB Handover file (Agenda Item 6c) (Room)	ECHA/RAC-1/2008/10
Mini CV example (Agenda Item 3) (Room)	ECHA/RAC-1/2008/11

**ANNEX II. FINAL AGENDA**

18 January, 2008  
ECHA/RAC-1/2008/01 Agenda Rev.2

**Draft Agenda**  
**First meeting of the Committee for Risk Assessment**

29-31 January 2008  
Palace Hotel, Helsinki, Finland  
**29 January: starts at 9:00**  
**31 January: ends at 14:00**

**Item 1 – Welcome and Introduction**

- a) Welcome by the Executive Director of ECHA (Geert Dancet)
- b) Tour de table – auto-presentation of members of the Risk Assessment Committee

**Item 2 – Adoption of the Agenda**

*For adoption* ECHA/RAC-1/2008/01

**Item 3 – Administrative Issues**

- a) reimbursement rules
- b) declarations of conflict of interest
- c) harmonised template for mini CVs

*For information* ECHA/RAC-1/2008/11

**Item 4 – Background of the RAC**

Background of the Risk Assessment Committee –  
(Legal basis, scope, proposed modus operandi)

*For information* ECHA/RAC-1/2008/02

## **Item 5 – Rules of Procedure (ROPs)**

Introduction to the draft proposal for ROP of the Risk Assessment Committee

*For discussion and endorsement*  
ECHA/RAC-1/2008/03a&3b

## **Item 6 – Planning of the work for 2008 and beyond**

- a) Introduction to the dossier driven tasks of the RAC
  - Annex XV dossiers – Classification and Labelling
  - Annex XV dossiers - Restrictions
  - Annex XV dossiers – Application for authorisation
- b) Decision Support Document ECHA/RAC-1/2008/06
- c) Pending/forthcoming classification and labelling dossiers  
ECHA/RAC-1/2008/09 and ECHA/RAC-1/2008/010
- d) Transitional Annex XV dossiers for existing substances (Art 136)  
ECHA/RAC-1/2008/07a&7b&7c and ECHA/RAC-1/2008/09
- e) Other tasks

*For discussion*

## **Item 7 – Working Procedures**

- a) Establishment of working group(s)
- b) Interface with MSC, SEAC and Forum
- d) Rules of procedure for co-operation with other Community bodies (Art. 95 and 110) (EFSA, Advisory Committee on Safety Hygiene and Health Protection at Work, EMEA)

*For discussion*

## **Item 8– Co-opted Members**

- a) Competence coverage - RAC Overall Competence Grid

- b) Proposals for Co-opted members

*For discussion* ECHA/RAC-1/2008/04 and ECHA/RAC-1/2008/05

#### **Item 9 – Invitation of Observers**

- a) Member State observers
- b) Industry, other NGOs
- c) Third Countries
- d) International Governmental Organisations
- e) Other Community bodies

ECHA/RAC-1/2008/08

*For discussion*

#### **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/harmonised_classification_en.htm)

[http://reach.jrc.it/docs/guidance\\_document/restriction\\_en.htm](http://reach.jrc.it/docs/guidance_document/restriction_en.htm)

[http://reach.jrc.it/docs/guidance\\_document/svhc\\_en.htm](http://reach.jrc.it/docs/guidance_document/svhc_en.htm)

- b) Other Guidance

*For discussion*

#### **Item 11 - Document Management**

- a) Platform for distribution of documents to the RAC – CIRCA

- b) REACH IT – current state of development and plans for accessibility

*For information*

#### **Item 12 – AOB**

- a) Next meetings (March 11-14, 2008)

*(July 1-3, 2008 tentative)*

*(September 16-19, 2008 tentative)*

*(November 18-21, 2008 tentative)*