10/02/2009

RAC/M/04/2008 Final

Minutes of the 4th meeting of the Committee for Risk Assessment
18-19 November 2008

Part I Summary Record of the Proceedings

Item 1 Welcome & Apologies

The Chair welcomed participants to the meeting, including the 3 new members appointed by the Management Board (MB) since the previous meeting (see item 5a). The Chair also introduced participants attending for the first time, including 3 advisers (from NL, IT and PL) and 8 observers (1 candidate-member nominated by Czech Republic, 1 OECD representative and 6 stakeholder representatives from EEB, ECEAE, ETUC, CEFIC, ECETOC and HEAL). Participants were informed that the meeting was to be recorded for the purpose of writing the minutes and that this recording would be destroyed once the minutes had been adopted.

Apologies were received from 5 members. An invited expert took part in the meeting as a replacement of Roberto Mezzanotte and an additional member was absent. The list of attendees is given in Part III of these minutes.

The Chair noted that at ECHA new Directors were now in post: Andreas Herdina, Directorate A; Jukka Malm, Directorate B and Christel Musset, Directorate C. Two new members of the RAC Secretariat were also welcomed by the Chair: Steve Hollins, Scientific Secretary and Anna Fuhrmann, Scientific Assistant.

Item 2 Adoption of the agenda

Revision 2 of the agenda was adopted as proposed by the Secretariat. The Chair introduced the documents that were provided at the meeting and all of the meeting documents are listed in Annex I. At the meeting changes were agreed to the order in which agenda points would be taken. The final agenda is attached to these minutes as Annex II.

Item 3 Declarations of conflicts of interest to the Agenda

The Chair asked whether there were any conflicts of interest to be declared specific to the meeting. None were declared.

Item 4 Adoption of the draft minutes of RAC-3

The Chair introduced the revised minutes, incorporating the comments received from 2 members. RAC adopted the revised minutes and the Secretariat was asked to distribute the final version and to make it available on the ECHA website. The Chair reported that all actions from RAC-3 had been carried out.

Item 5 Administrative issues

5a. Change in the composition of RAC

The Chair presented document RAC/04/2008/37 on changes in the composition of RAC. Two members (Zdenek Smerhovsky nominated by Czech Republic and Henrik Tyle nominated by Denmark) had resigned since the last meeting and 3 new members, nominated by Denmark and Norway, had been appointed by the Management Board (MB) at its last meeting (24-25 September 2008). The two participating newly-appointed members introduced themselves.

5b. ECHA Code of Conduct for Stakeholder Observers

The Chair informed participants that an ECHA Code of Conduct for Stakeholder Observers participating in the meetings of all ECHA bodies and Networks had been agreed as an Executive Director Decision on 9 October 2008.
The Code is available on the ECHA website (http://echa.europa.eu/doc/ECHADocuments/conduct_code_stakeholder_observers.pdf) and it had also been uploaded prior to the meeting to RAC CIRCA Interest Group (IG).

The Chair reported on the state of play with regard to stakeholder participation in the work of RAC. All 15 stakeholder organisations interested in RAC had been invited to nominate representatives. Nominations had been received from EEB, ECEAE, ETUC, CEFIC, ECETOC, HEAL and Eurometaux and representatives from all except Eurometaux, attended the meeting as observers from item 7 onwards.

Item 6 Revision of the RAC Rules of Procedure (RoPs)

The Secretariat presented a first revision of the RAC RoPs and the rationale for the revision (see Document RAC/04/2008/38). The revision was to ensure, where possible, the harmonisation of the RoPs with those of the other ECHA Committees and Forum (following the example of the SEAC RoPs); to take account of the special status as members without voting rights for those nominated by EEA-EFTA countries (Norway, Iceland and Liechtenstein), following the EEA Joint Committee Decision 25/2008 concerning the REACH Regulation (EC) No 1907/2006; the Code of Conduct for Stakeholder Observers; the effect on the quorum of members with a conflict of interest; and a proposal for shortening the written procedure in certain cases.

During the discussion on the document, members proposed a 'case-owner' in **Article 6** should be more clearly defined, since this may be ambiguous. The Secretariat explained that in the future a definition of 'case-owner' will be drawn up, but for the current purpose, a MS author is not considered as the case-owner, but rather falls under Article 6 (3) as another participant to the meeting.

When discussing the proposed change to Article 19 related to members with a conflict of interest not affecting the quorum of the meeting, several members expressed concern that Article 9 on independence is too restrictive. For example where there is a potential conflict of interest, such as a member who is from the same Competent Authority that has submitted a dossier for discussion, they would like RAC to take a decision whether there is a conflict of interest and, if agreed, the member should be excluded from voting and also from the quorum. Other members proposed there is a distinction between a member who is from the Member State that submitted a dossier and a member that has actually assisted in the preparation of that dossier. The Secretariat referred to previous discussions on this subject where it was suggested that the perception of a conflict of interest as well as an actual conflict of interest, should be in the minds of the member when making his/her declarations. The Secretariat further explained that the Guidance on Conflicts of Interest clarifies when an interest should be declared and should be consulted by all members. It was agreed to consider adding a further reference to this guidance in the main body text of the RoPs. It was also agreed by RAC that the member had to decide if he/she had a potential conflict of interest or not and declare this to RAC. RAC should not be charged with making this decision on behalf of the member. Once a conflict of interest had been declared for a particular point in the agenda that member should not

participate to any voting on that point (as clearly indicated in REACH) and it was also agreed that this member would not affect the quorum of the meeting,

Following the discussion, RAC agreed the proposed amendments to the RAC RoPs, with the following additions: in Article 3 (2) - "the EEA-EFTA countries that are" and in Article 9 (5) – the word "aforementioned" before "legal entities". On this basis, and after considering any potential further changes following the Forum consultation, the Secretariat would put the document forward to the meeting of the Management Board (MB) scheduled for 26 February 2009.

Item 7 Feedback from other ECHA bodies/activities and other Agencies & Community bodies

7a. Member State Committee (MSC) meetings and outcome of the MSC discussion on establishment of a joint MSC/RAC PBT working group

The Chair of the MSC introduced the main decisions of the MSC taken in relation to the authorisation process. She outlined the state of play with all 16 Annex XV dossiers that had been submitted for identification of substances of very high concern (SVHC), the status of draft recommendations and the role of rapporteurs. Other key issues included the initiation of the discussion on the evaluation process, the involvement of stakeholders and discussion on the revised MSC RoPs.

In relation to possible joint RAC/MSC working groups on PBT and QSAR, the Chair of the MSC explained that although some members had supported the idea, they had suggested that such working groups should only be established when this is justified by the tasks assigned to the Committees. RAC was also informed of a Commission request to ECHA to provide advice and support to the Commission in relation to the UN activities on persistent organic pollutants. MSC had agreed that the Secretariat will explore the options to carry out tasks related to PBTs and QSARS, including the proposal of joint RAC/MSC working groups, in order to identify the most efficient structure.

7b. Feedback from the Management Board (MB) and SEAC-2 meetings

The Secretariat reported on the meeting of the MB that had taken place on 24-25 September. A new Chair, Dr Thomas Jakl from Austria had been elected following the resignation of the previous Chair, Mr Jukka Malm in August.

A discussion had taken place on the 2009 Work Programme and the 2009-2012 Multi Annual Work Programme which is posted on the ECHA website for public consultation. The MB has also invited the Committees and Forum to report back on their work on a regular basis. The MB also decided in accordance with its rules of procedure to admit observers from EEA EFTA States to the MB meetings.

One member asked the Secretariat to pass a request to the MB to consider the possibility for a contractual framework directly between the ECHA and the member's institution, rather than the MSCA. The Secretariat confirmed that this aspect was under consideration by the MB Subgroup on remuneration established to examine the most effective means of administering the transfer of funds to the Member States (see item 9b).

The Secretariat also presented the main outcomes and discussion points from the second meeting of the Committee for Socio Economic Analysis (SEAC) held on 22-23 October, which included a number of issues common to RAC such as working procedures for the conformity check of a restrictions proposal, procedures for the appointment of rapporteurs and their terms of reference, and handling of transitional dossiers. The SEAC had agreed to invite 16 stakeholder organisations to participate to its meetings, most of which were the same as those invited to participate to the RAC. There was also a provisional agreement of the SEAC on the proposed changes to its RoPs, as well as a discussion on a possible joint RAC/SEAC working group and its mandate (see item 7d).

7c. Socio Economic Analysis (SEA) Workshop

The Secretariat summarised the SEA Workshop held on 21 October, to which 11 RAC members had participated, and noted that the main objective had been achieved, namely, to take the first steps in building a common understanding between risk assessors, risk managers and economists. The discussion had focused on the need for RAC & SEAC to work closely together, the challenge of putting the SEA methodology into practice and the preparation by MSCAs of Annex XV dossiers with the possibility of establishing informal networks to assist them that could include stakeholders. Challenges to the application of SEA raised at the workshop were considered to include the scarcity of resources in Member States, along with the need for applied research and development of expertise of all parties (the ECHA Secretariat, members of RAC, SEAC and stakeholders).

One specific output of the Workshop was a proposal to organise a 1.5 day 'crash course in socio-economic analysis for RAC' (see item 14c). RAC members welcomed this proposal and the Secretariat was to send an invitation to RAC participants to this session which was scheduled for February 2009, back-to-back to RAC-5.

7d Joint RAC/SEAC activity - terms of reference

The Secretariat introduced the rationale for establishing a joint RAC/SEAC interaction (see Doc RAC/04/2008/40), namely for identifying good working practices in the development of RAC and SEAC opinions by developing common procedures, where appropriate, and good parallel working arrangements and relations between rapporteurs of the respective Committees, as well as developing a common language between the Committees, whilst accommodating their different disciplines. A first meeting was scheduled for Jan 2009.

After a brief discussion, RAC agreed with the Secretariat's proposal for establishing a joint RAC/SEAC interaction and three RAC members offered to participate. Members agreeing to participate as test rapporteurs in testing the restriction procedures using transitional dossiers were also invited to contribute to the work of the RAC/SEAC interaction (see item 9b). One stakeholder observer expressed an interest to be involved in this activity. The Secretariat was to send an invitation to the first meeting of this interaction and upload a final version of the terms of reference document in RAC CIRCA IG.

7e. 4th Meeting of Chairs and Secretariats of Commission and Agency Scientific Committees/Panels involved in Risk Assessment (RA) held in Parma, 4-5 Nov 2008

The Chair presented the aim and main objectives of the 4th meeting of Chairs and Secretariats involved in RA, the main discussion topics and follow up actions. The

meeting brings together the key players in risk assessment from the Commission bodies and EU Agencies. It is part of a collaborative process to help improve both the quality of EU risk assessments and share best practices. The Chair and the two scientific secretaries of the ECHA Risk Assessment Committee (RAC) attended the meeting. The Chair offered to provide all relevant documents from this meeting to RAC via CIRCA when they become available, and to involve RAC members in follow-up activities. One member asked if it was possible that RAC members would be invited to participate in future meetings of this group. The Chair agreed to consider this request further.

7f. 1st International Risk Assessment Conference (Brussels, 13-14 Nov 2008)

The Secretariat summarised the First International Risk Assessment Conference that had taken place in Brussels (see RAC/04/2008/46). The conference had been organised by the Commission and had included participants from the EU, US and Canada. The objective had been to initiate a global dialogue and exchange of information in relation to risk assessment in order to develop a common understanding of the principles and terminology involved. Future dialogue was planned that was intended to broaden participation to include Japan, Australia and China. It was emphasised that there would be full co-operation with OECD activities, to avoid duplication of effort.

Item 8 Cooperation with OECD

8a. Presentation of the main activities of the OECD relevant to RAC

The OECD participant outlined the OECD programmes related to hazard and exposure assessment and the tools to support this work. The tools that had been developed included an 'eChem' portal, filled with databases on physicochemical properties, environmental fate and behaviour, ecotoxicity and toxicity, contributed by OECD member countries; a QSAR toolbox allowing building of chemical categories and read-across to fill data gaps; databases and guidance documents related to emission scenarios; exposure models; and other hazard assessment activities. A significant focus of the work of the OECD had been in relation to the high production volume (HPV) programme in which 887 substances had been assessed since 1990. The presenter emphasised the synergies between the work of the OECD on hazard assessment and requirements under REACH and expressed the need for future close cooperation.

8b. OECD terrestrial classification system under the Global Harmonised System (GHS) in relation to REACH

One of the members presented a proposal for the involvement of RAC in an OECD working group which had been looking at classification for the terrestrial environment in the context of the GHS, explaining that the data expected to be provided under REACH would be very useful to assist in the further development of such a classification.

Some members noted the importance of this activity, but considered that participation by RAC in such work was not within the mandate of the Committee. It was agreed the Committee does not have a mandate to deal with this issue at present, but noted that ECHA participation in such activities should be further discussed with the Commission.

Item 9 Working procedures - restriction dossiers (including transitional (Article 136 (3)) dossiers)

9a. Conformity check – working procedure

The Secretariat presented the proposed working procedure on conformity check of a restriction dossier (see Doc RAC/04/2008/44). It was recalled that both RAC and SEAC should share responsibility for conformity check, based upon Article 69 (4) of REACH. The proposition was for an 8-step parallel procedure within the framework of the strict timelines laid down in REACH.

Some members expressed concern regarding the short timelines for the conformity check, especially in those cases when ECHA is requested to prepare and submit an Annex XV dossier and where therefore the Secretariat would not prepare a draft conformity check report. Clarification was requested about the consequences of not complying with the 30-day deadline. The Secretariat recalled that rapporteurs should be aware of the timeframe for the conformity check procedure and generally should respect them. However, according to the RAC RoPs, a rapporteur may be replaced during the procedure. In extraordinary situations where the deadline is missed the procedure could probably be re-started from the beginning. Nevertheless, the Secretariat agreed to confirm the implications of not meeting the 30- day deadline.

As a means of providing additional time for rapporteurs, some members suggested shortening the time for RAC members to provide comments. Another member pointed out the difficulty of providing comments in a short time and the possible consequences this could have for the overall quality of the report. These comments were noted by the Chair, and it was agreed there is a need to find a balance between time allowed for rapporteurs and for members providing comments. The Chair also reassured members that their role as rapporteurs in the conformity check would be a screening role. On the basis of this discussion, RAC agreed the proposed document.

A brief discussion took place on the draft list of questions for a conformity check of an Annex XV dossier (document RAC/04/2008/45 which is a revised version of RAC/03/2008/15). The Chair explained the document had been modified following discussions at SEAC-2, in particular to clarify whether RAC, SEAC or both Committees should provide an answer to the questions. In the sections where both Committees should provide a view, it had been specified on which particular aspect each Committee should comment.

Some members asked the Secretariat for clarification whether a conformity check report concluding the dossier to be in conformity would allow the Committee to later conclude in the opinion-forming phase that there was insufficient information available. The Secretariat explained that the conformity check was a first screening of the dossier and it did not preclude the rapporteurs concluding on in-depth evaluation of a conforming dossier that the data were in some way insufficient to fully justify the conclusions drawn.

Members requested documents RAC/04/2008/44 and RAC/04/2008/45 be subject to possible future modification in the light of experience, in particular from transitional dossiers that may be used for testing purposes. This was agreed and RAC endorsed the revised document with minor changes. The Secretariat was to upload the slightly modified versions of the documents to RAC CIRCA IG.

9b. Handling transitional dossiers (Article 136(3))

The Chair updated members on the current status of the anticipated transitional dossiers arising from the Existing Substances Regulation (Regulation (EEC) No 793/93). She

recalled that the procedure for handling these dossiers had been agreed at RAC-3. Preliminary indications were that some transitional dossiers indicating a need for a restriction under REACH would be submitted; however these had not yet arrived at ECHA since the deadline for submission was 1st December 2008. All members were requested to consider their availability to volunteer as test rapporteurs or co-rapporteurs for these dossiers.

The Secretariat reported in this context on the work of the MB Sub Group examining the issue of transfer of funds to MSCAs. Members of this Group from DE, SE and UK had suggested that the members supported by these countries in RAC & SEAC could act as test rapporteurs for the transitional dossiers containing a REACH restriction. Principally this was to gain experience and provide feedback to the MB on the resources required of a rapporteur to apply the working procedures and develop an opinion on a restriction proposal.

RAC members from SE and DE confirmed their provisional interest to volunteer as test (co-) rapporteurs for transitional dossiers from the UK. However, they pointed out the short deadlines in the procedure would need to take account of the forthcoming holiday period. The Secretariat clarified that the timing would be adjusted accordingly for these transitional dossiers since the formal deadlines would not apply to these test cases and also noted the possibility for rapporteurs to work in tandem with their counterparts in SEAC. One member nominated by FR also expressed an interest in a test (co-) rapporteurship for one of the dossiers.

9c. Draft terms of reference (ToR) for (co-) rapporteurs for restriction proposals

The Chair introduced the draft terms of reference document (RAC/04/2008/39) and noted that this was a first draft and further modifications would be needed in the future to adapt to the working procedures, when agreed, and to elaborate, if necessary on the respective roles and responsibilities of rapporteurs and co-rapporteurs and to provide quality criteria against which the deliverables can be measured. There followed a brief discussion in which some members expressed the view that the current responsibilities of rapporteurs as described in the ToR appeared to entail a lot of administrative work. The Secretariat proposed to make clearer in a revised draft the support that was intended to be provided to the rapporteur by ECHA. Members were invited to provide their further comments on the document via CIRCA by 10 December.

9d. The role of the Forum on enforceability and for restriction proposals

The Secretariat gave a brief presentation introducing the role of the Forum, its tasks and activities carried out so far. According to REACH, one task of the Forum was examining proposals for restrictions with a view to advising on enforceability. It was however mentioned that the working procedure for providing advice on restriction proposals was not yet in place, but that the Forum was going to discuss the issue at its third meeting on 2-4 December 2008.

Item 10 Restriction dossiers - work plan for 2009

The Chair introduced the meeting document RAC/04/2008/41 which described a work plan for RAC and SEAC in relation to Annex XV restriction dossiers up to June 2009. RAC members noted the proposed work plan.

Item 11 Harmonised Classification & Labelling (CLH) - Annex XV dossiers

11a. ECHA overall presentation - feedback on first accordance checks

The Secretariat presented their overall observations and comments following the first 4 accordance checks of Annex XV dossiers for harmonised classification and labelling. The Secretariat expressed its appreciation to the submitting MS for coming forward with these dossiers thereby allowing the procedures to be tested. Several issues had emerged which required further attention in the future. This included providing clearer information with regard to the identity of the substance; providing a justification for a proposal for harmonisation of other endpoints; the need to highlight the new evidence being presented in the case of a proposal to modify an existing entry; and the need for a section related to the history of the substance prior to the submission, particularly the outcome of previous discussions in other regulatory fora.

11b. Presentations by rapporteurs - feedback on first accordance checks

The rapporteurs and co-rapporteurs for the four Annex XV dossiers presented their main observations and recommendations following their experiences of carrying out accordance checks. The issues that emerged were: the need for a clear understanding of the identity of the substance or substances for which a classification was proposed, including impurities and isomers; clear description of the test substance used in the reported studies and a clear link between study results and the fulfilment of the proposed criteria for classification for the identified substance(s). It was proposed that ECHA Secretariat following pre-registration (and later registration) would be in the best position to judge on the substance identification relevant to what was being produced and marketed and to what the C&L proposal should cover. In addition there seemed to be a need for clarification on which endpoints the rapporteur should give an opinion when there were data in the proposal covering endpoints which were not subject of the classification proposal. One member also raised the issue of how to deal with a proposal for classification when it was known that there were ongoing studies, the results of which might impact on the view of the proposal. Some members felt that the interaction between rapporteur and co-rapporteur had in most cases worked well, and supported to continue with this approach. Other members considered that there seemed to be no real need for a co-rapporteur in the accordance check procedure, because the combination of ECHA and rapporteur should already be sufficient.

A discussion followed in which some members suggested the template for the Annex XV report format could be improved to guide the submitting MS to provide the necessary data found to be lacking. It was also suggested that the ECHA Secretariat could communicate any significant difficulties, e.g. on substance identification, to the MS early in the procedure, rather than at the end of the accordance check; and to communicate the experience gained thus far to MS in the process of preparing dossiers for submission. The Secretariat agreed that this experience should be captured and conveyed to the MSCAs. In relation to the update of the template it was explained that this was planned as part of the adaptation of the guidance to the new CLP regulation but this would not be available within the very near future.

Another matter raised by members was the importance of receiving feedback from ECHA on the follow up after the accordance check had been carried out. The Secretariat agreed to keep RAC informed of progress after an accordance check.

11c. Working procedures - processing a C&L dossier

The Secretariat presented a revision to the working procedure (document RAC/04/2008/27_rev.1) which included a modification to the timelines. The Chair also summarised the previous comments received from members on proposed changes to the working procedure and the Secretariat's response to them (document RAC/04/2008/42).

One member asked whether the timeline of 18 months foreseen in the draft EC Regulation on harmonised classification and labelling of hazardous substances and mixtures (CLP Regulation) started once the Annex XV dossier had been submitted to RAC, or when it was delivered by RAC to the Commission. The Commission confirmed the 18 month period is for RAC to develop and deliver its opinion.

There was a further discussion of the proposed timelines in the working procedure and whether they could be adjusted to allow the rapporteurs to have more time for their responsibilities in the procedure. Other members noted the need to find a balance between the time allowed for rapporteurs to draft the opinion versus the time given for other RAC members to provide comments. Finally, RAC agreed with the proposed timelines, subject to their possible adjustment in the light of experience. The Secretariat would circulate the final version of the document.

11d. Draft terms of reference (ToR) for (co-) rapporteurs for CLH proposals

The Secretariat presented draft terms of reference for (co-) rapporteurs (ToR) for CLH proposals (document RAC/04/2008/43). The document included a substance–specific letter from the Chair to the (co-) rapporteur confirming their appointment, the Terms of Reference and declarations of commitment and interests in relation to the specific dossier, as required by the REACH Regulation. It was acknowledged that the current version may need to be modified in the future to further specify the roles and responsibilities of rapporteurs and co-rapporteurs; for deciding when a co-rapporteur is necessary; and to lay down some criteria for assessing the quality of the deliverables.

One member pointed out that there will be a new legal basis of the ToR in the near future when the draft CLP Regulation has been adopted which should be taken into account for future revisions. Another member expressed the view that the presentation of the draft opinion to RAC by the rapporteur should be seen as an opportunity -for discussion, rather than a formal defence of the draft opinion. Some members requested the document should provide further clarity on the deliverables expected from the rapporteur and the relative distribution of workload between rapporteurs and ECHA. The Chair noted the various points raised and agreed to include more detail on the contribution of the ECHA Secretariat to the drafting of the different documents.

One member also requested advice on how to deal with direct contacts to the rapporteurs from outside commentators when carrying out their required tasks. The Secretariat strongly recommended members to channel any comments or direct contacts they receive to ECHA.

There was general agreement that the ToR should be applied and then modified, if necessary, in the light of experience. The Chair concurred with this and indicated the document would be revised and circulated for agreement via the written procedure.

Item 12 Appointment of (co-)rapporteurs

12a. Revision of the procedure for the appointment of RAC rapporteurs and co-rapporteurs

The Secretariat introduced the revised version of Document RAC/02/2008/13 (see document RAC/04/2008/13_rev.1) and explained the reasons for the revision. RAC agreed the revised document with a minor change and the Secretariat indicated it would circulate the final version.

12b. Annex XV dossiers submitted to ECHA requiring appointment of rapporteurs

The Secretariat informed the Committee of an indication from one member who had volunteered to be a co-rapporteur for the anticipated Annex XV CLH dossier for Acequinocyl. This proposal was accepted by RAC.

12c. Outcome of written procedures

Following the requirements of Article 20 (6) of the RAC Rules of Procedure, the Secretariat reported to RAC on the appointment of rapporteurs and co-rapporteurs by written procedures in the period July – November 2008.

Item 13 Information Session on the CLP Regulation

The Secretariat presented an overview of the scope and requirements of the forthcoming CLP Regulation and its implications for REACH and the work of RAC. The presentation included a comparison of the physicochemical, human health and environmental classification and labelling criteria in the current legislation (Directive 67/548/EEC) with the future criteria to be introduced by the new EC Regulation.

The Commission updated RAC on the state of play with the guidance on the application of the CLP Regulation (RIP 3.6) that is currently under development. COM explained the guidance will assist users to understand the differences between the GHS and the current EU system, and provide guidance on application of the new classification criteria. The final draft is expected to be sent to the REACH CA meeting for approval at their meeting in summer 2009.

With regard to the forthcoming CLP Regulation, one member asked for clarification whether there would be a differentiation in the cases when CLH proposals will be prepared and submitted by a MSCA and by industry. The Commission clarified that the MSCAs can submit CLH proposals for any substances, while the industry could only provide such CLH proposals for hazard classes of substances without harmonised classification under either the current legislation (Annex I of Dir 67/548/EEC) or the forthcoming CLP Regulation (Annex VI).

One RAC member requested the Secretariat to make available to RAC members and observers the health effects TC C&L "guidance" notes that had been referred to in the presentation (e.g. the Specialised Experts' note in relation to animal thyroid tumours, etc).

Item 14 Any other business

14a. Collecting experience on classification and labelling (C&L)

The Chair invited the member who proposed this item to present their proposal on this issue. The member explained that as RAC develops its experience in dealing with C&L proposals, it would be helpful to have a procedure for collecting this knowledge and finding a mechanism to ensure that this feedback is taken up in any guidance update process. The Secretariat welcomed the initiative and suggested, as an initial mechanism, creating a CIRCA Newsgroup to collect the input from Committee members.

14b. Meeting calendar for 2009

The Chair presented a proposal for RAC meetings in 2009 (document RAC/03/2008/33_rev.2). It was explained, the number of meetings has been reduced to five taking into account the anticipated workload for 2009. RAC members noted the proposed dates and some members announced they may not be able to participate in the July meeting due to scheduling of a UN GHS meeting in the same week. The Secretariat explained the rationale for rescheduling the meeting in July is to have a joint plenary RAC/SEAC session.

14c. Training Needs

In addition to the SEA 'crash course' in SEA (see item 7c), RAC members were asked to indicate their wishes for additional and specific RAC-focused training. Some advisers and observers also expressed their interest in participation in such activities.

The Secretariat presented further suggestions for RAC- relevant specific courses, such as 'IUCLID 5 for RAC', and a 'QSAR specific course for RAC'. RAC supported the suggestion of the Secretariat to carry out a survey to collect views of RAC on additional training needs.

14d. Access to documents for stakeholders

In response to a query by one of the stakeholder observers, the Secretariat agreed to consider how best to facilitate their access to meeting documents. It was anticipated that access to the RAC CIRCA IG would be facilitated in early 2009.

Item 15 Action points and main conclusions of RAC-4

The Secretariat presented a draft table of the decisions and action points agreed at the meeting for each agenda item to be endorsed by RAC at the meeting. Participants commented on the table which was amended accordingly. The action points were endorsed. The Secretariat agreed to distribute the table to the members on the day after the meeting and it is attached as Part II of the meeting minutes.

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Part II Conclusions and action points

RAC-4 ACTION POINTS & MAIN CONCLUSIONS – 18-19 November 2008
(as adopted at the RAC-4 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
4. Adoption of Draft RAC- 3 minutes	• RAC adopted the Draft final minutes without changes	• Adopted minutes of RAC-3 to be uploaded to CIRCA and ECHA website (SECR / after the meeting)
6. Revision of RAC Rules of Procedure (RoPs)	• RAC agreed with the proposed revision of their RoPs with small changes	• Revised RoPs agreed by RAC to be sent to the MB for adoption (SECR/before the Feb MB meeting)
7. Feedback from other ECHA bodies		
c. Feedback from SEA Workshop	• c) RAC agreed with Secretariat's proposal for organising a crash course in SEA for RAC	• c.) SECR to organise and send an invitation to all RAC members, advisers and observers for a crash course in SEA for RAC (Feb 2008)
d. Draft mandate of Joint RAC/SEAC Activity	• d.) RAC agreed with the Secretariat's proposal for establishing Joint RAC/SEAC Interactions and the proposed Terms of reference for the Joint RAC/SEAC Activity (Doc RAC/04/2008/40) • d.) RAC agreed to nominate 3 representatives (Boguslaw Baranski, Olivier Le Curieux- Belfond and Hans- Christian Stolzenberg) in the Joint RAC/SEAC interaction • d.) Test rapporteurs for transitional dossiers are invited to contribute to the work of RAC / SEAC interaction	• d.) SECR to send an invitation to RAC representatives for the first meeting for Joint RAC/SEAC interactions (Jan 2009) • d.) SECR to upload in CIRCA final terms of reference for the Joint RAC/SEAC Activity (Doc RAC/04/2008/40) • d.) Role of observers to be clarified.
e. 4th Meeting of Chairs and Secretariats of Commission and Agency Scientific Committees and Panels involved in risk assessment		• e) SECR to upload to RAC CIRCA IG all documents concerning the cooperation with other Community bodies (when they are available) • e) SECR to consider future participation of other RAC members.

f. 1st Risk Assessment Conference		
8. Cooperation with OECD b. OECD terrestrial classification system under the Global Harmonised System (GHS) in relation to REACH	• b. RAC agreed at present there is no a mandate given to the committee to deal with this issue further.	
9. Working Procedures - Restrictions dossiers (including transitional (Art 136 (3)) dossiers) a. Conformity check b. Proposal for handling 793/93 transitional dossiers c. Draft terms of reference for restriction rapporteurs	• a.) RAC agreed with Doc 44 on working procedure for conformity check and Doc 45 on criteria for conformity check with small changes. The documents may be modified if necessary in the light of experience. • a.) RAC agreed the abovementioned documents to be used with restriction testing cases for transitional dossiers. • c) The RAC agreed to provide comments to Doc 39.	• a.) SECR to clarify the implications of not complying with providing the conformity check report within 30 day deadline. • a.) Final versions of Doc 44 and 45 will be circulated after the meeting (SECR/ after the meeting) • c.) RAC is invited to send comments on the draft terms of reference for restriction rapporteurs proposed in doc 39 within 3 weeks, i.e. by 10th December
10. Planning of the work for 2009	• RAC took note of the SECR proposal for work plan for 2009	
11. C&L Annex XV dossiers • Feedback on accordance check of the first C&L Annex XV dossiers (DAT, HBCD, MPA-TEA and epoxiconazole) • Working Procedures - C&L Annex XV dossiers		• RAC members to provide feedback with regard to revision of the Annex XV CLH template. • SECR to address substance ID issues before sending accordance check report to rapporteurs. • SECR to consider how to communicate the suggestions to the other MSCAs involved in preparing the dossiers. • SECR to upload the final WP on processing a

c. Processing a C&L dossier d. Draft terms of reference for CLH rapporteurs	c) RAC agreed to Doc 27 on processing a C&L dossier as it was proposed by SECR with a remark that the document may be modified if necessary in the light of experience, in particular with regard to timelines. d) Doc 43 to be revised on the basis of comments and then circulated to RAC members for agreement via written procedure.	C&L dossier to the RAC CIRCA IG • SECR to revise Doc 43 on ToR for CLH rapporteurs and to circulate the final version to RAC for agreement via written procedure (SECR/30 Nov 08).
12. Appointment of rapporteurs	• RAC agreed with the revision of Doc 13 on appointment of RAC (co-) rapporteurs with following change: delete the last sentence in last paragraph of section 2. Co- rapporteur for an Annex XV CLH dossier for acequinocyl was appointed by RAC.	• SECR to upload in RAC CIRCA IG the final version of the revised procedure (SECR/21 Nov 08).
14.AOB a) Need for a procedure for collecting experiences for improving the C&L procedure b) Meeting calendar for 2009 c Further training needs	• a) RAC agreed with the proposal for a Newsgroup for collecting the opinions on C&L procedure to be set up. • b) RAC agreed with the Meeting calendar for 2009 proposed in the second revision of doc 33. • c) RAC agreed with the SECR suggestion for a survey on learning needs to be carried out.	• SECR to create a permanent CIRCA Newsgroup in the RAC CIRCA IG for collecting the members' views regarding the possible improvement of the C&L procedure. • Survey on learning needs to be carried out (SECR/30 Nov 08)
GENERAL		• All presentations and room documents on Circa (SECR/by 21/11/08) • conclusions and action points (i.e. this doc) to be uploaded to Circa (SECR /by 21/11/08) • SECR to consider how to facilitate access of stakeholders to meeting documents (end Dec).

III. List of Attendees

Members		**Representatives of the Commission**
ANDERSSON Alicja		BERGGREN Elisabet (DG JRC)
BARANSKI Boguslaw		VAN HAELST Annick (DG ENV)
BORGES Maria Teresa		GRODZKI Karola (DG ENV)
DI PROSPERO Paola		PUOLAMAA Maila (DG ENTR)
DUNAUSKIENE Lina		
DUNGEY Stephen		**ECHA staff**
GRUIZ Katalin		BARANSKI Maciej
HALKOVA Zhivka		ERICSSON Gunilla
KADIKIS Normunds		FUHRMANN Anna
KREUZER Paul		HAUTAMAKI Anne
LARSEN Poul Bo		HOLLINS Steve
LE CURIEUX-BELFOND Olivier		KARHU Elina
LEINONEN Riitta		KLAUK Anja
LUND Bert-Ove		KNIGHT Derek
ESPOSITO Dania (replace Mezzanotte)		KULJUKKA-RABB Terhi
MULLOOLY Yvonne		LIPKOVA Adriana
NUNES Céu		MALM Jukka
ORPHANOU Maria		MUNN Sharon
PICHARD Annick		NYLUND Lars
POLAKOVICOVA Helena		PEDERSEN Finn
POSPISCHIL Erich		PELTOLA Jukka
PRONK Marja		POPESCU Raluca
RUPPRICH Norbert		ROCKE Timo
SCHULTE Agnes		RUOSS Jurgen
SMITH Andrew		SADAM Diana
STOLZENBERG Hans-Christian		SCHOENING Gabrielle
SULG Helen		SIHVONEN Kirsi
TARAZONA Jose V.		SUNDQUIST Anna-Liisa
TOMSONE Margita		VAHTERISTO Liisa
VAN DER HAGEN Marianne		VAINIO Matti
VAN MALDEREN Karen		VASILEVA Katya
VILANOVA Eugenio		YLÄ-MONONEN Leena
ZGLOBIU Mariana-Elena		
Advisers to the RAC members		**Stakeholder observers**
Ms. ALESSANDRELLI Maria (adviser to Paola Di PROSPERO)		Ms HOLMQVIST Jenny (observer from European Chemical Industry Council (CEFIC))
Ms. GRACZYK Anna (adviser to Boguslaw BARANSKI)		Ms. MEISTERS Marie-Louise (observer from ECETOC)
Ms. HAKKERT Betty (adviser to Marja PRONK)		Mr NEWBY John (observer from Health and Environmental Alliance (HEAL))
Other observers		Ms. SANTOS OTERO Tatiana (observer from European Trade Union Confederation (ETUC))
Ms GOURMELON Anne (observer from OECD)		Ms. TAYLOR Katy (observer from European Coalition

		to End Animal Experiments (ECEAE))
Mr PAULOVIC Milan (RAC candidate-member nominated by Czech Republic)		Mr. WEFERS Heribert (observer from European Environmental Bureau (EEB))

IV. List of Annexes

ANNEX I. List of RAC-4 meeting documents submitted to the RAC Members

ANNEX II. Final Agenda

ANNEX I.

Meeting documents submitted to the Members of the Committee for Risk Assessment (RAC-4)

Document Title	Document number
Draft Agenda (Agenda Item 2. Rev 2)	RAC/A/04/2008_rev. 2_room doc
Draft Final Minutes of RAC 3 (Agenda Item 4)	RAC/M/03/2008 draft final
Change in composition of the RAC (Agenda Item 5)	RAC/04/2008/37
Rules of Procedure of the Committee for Risk Assessment. Revision. (Agenda Item 6)	RAC/04/2008/38
Terms of reference of a Joint RAC/SEAC Activity (Agenda Item 7)	RAC/04/2008/40
Working procedure on conformity check (Agenda Item 9a)	RAC/04/2008/44
Criteria for conformity check - revision (Agenda Item 9a)	RAC/04/2008/45
Draft terms of reference for CLH rapporteur (Agenda Item 9c)	RAC/04/2008/39
Outline work plan for restriction dossiers (Agenda Item 10)	RAC/04/2008/41
Working procedure for processing an Annex XV dossiers proposing Harmonised Classification and Labelling (Agenda Item 11c)	RAC/04/2008/27_rev.1
Response to comments on RAC/04/2008/27_rev.1 (Agenda Item 11c)	RAC/04/2008/42
Draft Term of reference for CLH rapporteurs (Agenda Item 11d)	RAC/04/2008/43
Procedure on appointment of RAC (co-) rapporteurs (Agenda Item 12a)	RAC/04/2008/13_rev.1
Meeting calendar for 2009 (Agenda Item 14b)	RAC/04/2008/33_rev.2
Feedback from the first Risk Assessment Conference (Agenda Item 7f)	RAC/04/2008/46_room doc

ANNEX II.

18th November, 2008
RAC/A/04/2008 final

Final Agenda

Fourth meeting of the Committee for Risk Assessment

18 -19 November 2008

Helsinki, Finland

18 November: starts at 9:00
19 November: ends at 18:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/04/2008_rev. 2
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of the RAC-3

RAC/M/03/2008 draft final
For adoption

Item 5 – Administrative Issues

a. change in the RAC composition

RAC/04/2008/37
For information

b. ECHA code of conduct for stakeholder observers

For information

Item 6 – Rules of Procedure (ROPs) [*closed session*]

- Revision of the RAC Rules of Procedure

RAC/04/2008/38
For agreement

Item 7 – Feedback from other ECHA bodies/activities and other Agencies & Community bodies

Feedback from other ECHA bodies

a. Feedback from MSC meetings and outcome of the MSC discussion on establishment of a Joint MSC/RAC PBT WG

For information

b. Feedback from MB and SEAC-2 meetings

For information

c. Feedback from SEA Workshop

For information

d. Joint RAC/SEAC activity– terms of reference

RAC/04/2008/40
For endorsement

Feedback from other Community bodies

e. 4th Meeting of Chairs and Secretariats of Commission and Agency Scientific Committees/Panels involved in Risk Assessment (Parma, 4-5 Nov 2008)

For information

f. 1st Risk Assessment Conference (Brussels, 13-14 Nov 2008)

RAC/04/2008/46
Room document
For information

Item 8 – Cooperation with OECD

a. Presentation on the OECD main activities relevant to RAC

For information

b. OECD terrestrial classification system under the Global Harmonised System (GHS) in relation to REACH

For discussion

Item 9 – Working Procedures - Restrictions dossiers (including transitional (Art 136 (3)) dossiers)

a. Conformity check – working procedure

RAC/04/2008/44
RAC/04/2008/45
For agreement

b. Handling transitional dossiers (Article 136(3))

For information

c. Draft terms of reference for (co-)rapporteurs

RAC/04/2008/39
For discussion

d. The role of Forum to give advice on enforceability of a restriction proposal

For information

Item 10 – Planning of the work for 2009

- Outline work plan on restrictions

RAC/04/2008/41
For information

Item 11 – C&L Annex XV dossiers

Feedback on Accordance Check of the first C&L Annex XV dossiers

a. ECHA Overall presentation
b. Rapporteurs' presentations

For information and discussion

Working Procedures - C&L Annex XV dossiers

c. Processing a C&L dossier

RAC/03/2008/27_rev.1
RAC/04/2008/42
For agreement on timelines

d. Draft terms of reference for (co-) rapporteurs

RAC/04/2008/43
For agreement

Item 12 – Appointment of rapporteurs - where needed

a. Revision of the Procedure for appointment of RAC (co-) rapporteurs

b. Annex XV dossiers submitted to ECHA requiring appointment of rapporteurs

For decision

c. Outcome of written procedures

For information

Item 13 – CLP Regulation

- Presentations on the CLP Regulation - framework and classification criteria

For information

Item 14 – AOB

a. The need for a procedure for collecting experiences that could improve the C&L procedure

For discussion

b. Meeting calendar for 2009

RAC/03/2008/33_rev.2
For information

c. Further training needs

For discussion

Item 15 – Action points and main conclusions of RAC-4

- Table with Action points and decisions from RAC- 4

For adoption