21/4/2009

RAC/M/05/2009 Final

Minutes of the 5th meeting of the Committee for Risk Assessment
10-11 February 2009

Part I Summary record of the proceedings

Item 1 Welcome and apologies

The Chair welcomed participants to the meeting, including the two new members appointed by the Management Board (MB) since the previous meeting (see agenda item 5c). The Chair also introduced six advisers (from NL, IT, PL, FI, DE and NO) and six 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 two members and three members were absent. The list of attendees is given in Part III of these minutes.

The Chair noted that there had been two recent additions to Unit A.2 at ECHA, Liina Naur who was working in the Secretariat for the Member State Committee (MSC) and Tom Blencowe, a trainee.

Item 2 Adoption of the agenda

Revision 2 of the agenda was adopted as proposed by the Secretariat and the Chair introduced the room documents. The final agenda and list of all meeting documents are attached to these minutes as Annexes I and II, respectively.

Item 3 Declarations of conflicts of interest to the Agenda

Chair asked whether there were any conflicts of interest to be declared specific to the meeting. One member noted that they were employed by a Member State Competent Authority (MSCA) that had prepared some of the dossiers for harmonised classification and labelling (CLH) to be discussed under item 10d.

Item 4 Follow up to RAC-4

4a Adoption of the draft minutes of RAC-4

The Chair introduced the revised minutes, incorporating the comments received from five 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.

4b Status report on the actions arising from RAC-4

The Chair reported that all actions from RAC-4 (document RAC/05/2009/12) had been completed, with the exception of two issues that had been carried over to actions from this meeting (see action points RAC-5).

4c Status of the adoption of the first revision of the Rules of Procedure

The Chair explained that the changes of the Rules of Procedure proposed at the last meeting had been implemented. In addition, there had been several changes to Article 2 to take into account the adoption of the EC Regulation on classification, labelling and packaging (‘the CLP Regulation’, Regulation (EC) No. 1272/2008), as well as a minor editorial change in Article 15. The document was now expected to be presented to the

meeting of the MB on 26-27 February, along with the corresponding Rules of Procedure from the other ECHA Committees and the Forum.

Item 5 Administrative issues

5a Change in the composition of RAC

The Chair presented document RAC/05/2009/01 on the changes to the composition of RAC. Two members Daphne Hoyaux and Margita Tomsone (nominated by Belgium and Latvia, respectively) had resigned since the last meeting and two new members Milan Paulovic (nominated by Czech Republic) and Thomasina Barron (nominated by Ireland) had been appointed by the MB at its last meeting (17-18 December 2008). The newly-appointed member who was present, nominated by Ireland, introduced herself.

5b Revised rules for the reimbursement of travel, hotel and subsistence expenses

The Chair presented document MB/78/2008 final that had been adopted by the MB at its last meeting. The rules applied to all members of the MB, Committee and Forum members, invited experts, observers fulfilling criteria laid down in the document and to other attendees at ECHA meetings. Principal changes from the previous version, included: payment of accommodation expenses on the basis of a hotel invoice; reference to pre-paid flight or other tickets, signalling the future use by ECHA of a private travel company for the benefit of participants in meetings; and specific rules concerning stakeholder observers.

5c Remuneration of co-opted members and invited experts

The Secretariat presented a decision (see document RAC/05/2009/02) adopted by the MB at its last meeting on the remuneration of co-opted members and experts invited by the ECHA Committees and the Forum. The decision is intended to implement Articles 87(3) of Regulation (EC) No 1907/2006 (the REACH Regulation) and 15 of Regulation (EC) No 340/2008 ('the Fee Regulation'), respectively. The decision establishes a scale of fees for the remuneration of the work of co-opted members and of experts invited by the Committee or requested by ECHA. Remuneration was not payable to individuals who are employed in the public service of a Member State. A uniform rate of EURO 300 per day had been set which was consistent with the principles of economy and sound financial management.

One member requested clarification of the meaning of 'employed in the public service of a Member State' and whether this applied to universities. The Secretariat agreed to consider this question further and report back on progress to the next RAC plenary.

Item 6 Feedback from other ECHA bodies and activities

6a Member State Committee (MSC)

The Chair of the MSC summarised developments in the MSC which met for the sixth time on 17-18 December. She explained that the first recommendation of substances to be included in Annex XIV of the REACH Regulation (Authorisation List) has to be submitted by ECHA to the Commission by 1 June 2009. Towards this, a public consultation was underway of ECHA's proposed prioritisation of substances to be included in Annex XIV, recommendations for each inclusion, including corresponding

sunset dates, and supporting documents. The consultation was to close on 14 April after which the MSC was to be formally consulted, before submitting to the Commission. In total 7 substances have been proposed to be prioritised. It was estimated that this first Authorisation List may be finalised by the end of 2009 and that the first application date would be in 2011/2012. The Chair also noted the MSC was to meet four times in 2009 and the next meeting was scheduled for 1-2 April.

One member enquired about the workshop concerned with the Candidate List and authorisation as risk management instruments that had taken place on 21-22 January at ECHA's conference facilities. The Secretariat explained that the workshop had been aimed at reaching a common understanding on the intention and scope of both the Candidate and Authorisation Lists and factors to take into account when making a choice between authorisation, restriction and other Community legislation to address the risks posed by substances of very high concern. The Secretariat agreed to present the recommendations from the workshop at a forthcoming RAC meeting.

6b Feedback from the MB and Forum-3 meetings

The Secretariat reported on the meeting of the MB that had taken place on 17-18 December. In addition to issues mentioned above (item 5), it was noted that a brief report on the activities and progress of the Committees and the Forum had been provided to and appreciated by the MB.

Forum-3 took place on 2-4 December 2008, to discuss enforcement of REACH in the Member States, immediately following the closure of the pre-registration window. Forum-3 agreed, *inter alia*, the mandate and terms of reference for the first co-ordinated enforcement project which will focus on pre-registration, registration and safety data sheets for phase-in substances across 20 countries, including Norway and Iceland. It also held a brief discussion on the CLP Regulation, Forum's role in the restriction process and its interaction with RAC and SEAC.

Item 7 SEAC / RAC arrangement

One of the members of RAC reported on the first meeting of the SEAC/RAC arrangement that had taken place on 27 January 2009 in Helsinki (see document ECHA/SEAC-RAC ARGMNT/M/01/2009). The member reported that the meeting was intended to consider the interaction between SEAC and RAC to ensure the opinions of the two Committees are prepared in a co-ordinated manner and with the full understanding of the overall requirements of REACH.

The highlights of the discussion included: the need for RAC and SEAC rapporteurs to interact informally and exchange their views throughout the restriction process; rapporteurs to hold face-to-face meetings; good lines of communication between RAC and SEAC e.g. by rapporteurs attending the sister Committee meeting and by using common newsgroups in CIRCA; establishment of joint working groups; the need for careful scheduling of plenaries and creation of submission windows in order to manage the workload effectively; and the usefulness of testing the parallel RAC/SEAC processes with a test case prior to receiving the first real one. Participants particularly noted the tight timeline in which the restriction process takes place and therefore highlighted the importance of receiving comments early on draft opinions, the need for introducing interim timings for the different steps in the process (see document RAC/05/2009/03) and for repeated liaison between rapporteurs and learning from their

experience. The next steps were reported to be presentation of progress to both RAC and SEAC, and to continue working together electronically on the remaining issues in the mandate and then to meet again on 20 April prior to RAC-6.

Members discussed the matters raised and agreed on the usefulness of the work carried out thus far. They concurred with the observations made and in particular, pointed out that the quality of the final opinions from each Committee will also be dependent upon that of the sister Committee. Several members also confirmed the need to test the processes in each Committee and it was proposed that elements of the transitional dossier, medium-chain chlorinated paraffins (MCCP), could be considered as a test case.

Item 8 Working procedures – Annex XV restriction dossiers

8a Working procedure for processing a restriction dossier

The Secretariat presented a first preliminary proposal for a working procedure on processing a restriction dossier (see document RAC/05/2009/03). The legal basis for the procedure is Article 70 of the REACH Regulation and the working procedure is intended to follow directly after the working procedure for a conformity check (RAC/04/2008/44 final). The parallel aspects of the RAC and SEAC processes were highlighted in the presentation.

A lively discussion followed the presentation in which a number of issues were considered. Several members expressed the need to ensure (co-) rapporteurs are given sufficient support to carry out their work in the short time available in the procedure, for example by the use of ad hoc working groups of interested members, managed by the rapporteur. The Secretariat confirmed that this was possible on a case-by-case basis, but would need to be considered in further detail.

Some members sought clarification on the background document (BD) e.g. who should draft the document and would there be sufficient time for rapporteurs to carry out the final edit of the document. The Secretariat confirmed that the dossier submitter is expected to produce the first draft of the BD and that it is in their interest to do so, even if there are no legal obligations for the MSCA to do so. The timing of the editing of the BD, i.e. updated in line with each draft of the opinion, or only updated at the end of the process in line with the final opinion, would be considered further by the Secretariat and may vary from case to case.

In order to improve the clarity of the process, several members queried whether it is appropriate to have 4 submission windows and hence 4 overlapping submission cycles. It was suggested instead to consider only two submission windows. Another member proposed that regular status reports with relevant deadlines should be made to members by the Secretariat for each substance being considered for a restriction.

Other points raised by members were suggestions to: include the timeline diagram from the presentation in document RAC/05/2009/03; extend the period referred to in step (f) in which RAC was to provide comments on the Rapporteur's first version of the opinion from 14 to 21 days; and generally to consider including further flexibility in the procedure to allow it to be modified according to case-specific parameters such as the complexity of the dossier.

The Chair thanked members for their contributions and proposed to upload the document to CIRCA for a further round of commenting in a newsgroup. SEAC was expected to review the document at its third meeting 23-24 February, after which all comments would be collected and a further version circulated to RAC for final adoption at the RAC/SEAC joint meeting in June.

8b Draft terms of reference for (co-) rapporteurs (restrictions)

The Secretariat introduced the revised draft terms of reference document (RAC/05/2009/04) and noted that the drafting of this document was closely linked to progress with the working procedure for restrictions and the interaction between the two sister Committees. The document had been revised according to consideration at RAC-4 and a subsequent newsgroup discussion. For the latter, a response to comments document from the ECHA Secretariat (RAC/05/2009/13) had been provided to members.

Members generally supported the approach taken in the revised document. Several members sought clarification in relation to references to the work of the rapporteur on the Background Document (BD), i.e. whether it would undergo several revisions in line with each version of the opinion and which actor should do this (Rapporteur, dossier submitter or ECHA Secretariat) and who would have final ownership of the BD. Another member queried if there would be one or two BDs at the end of the RAC and SEAC process. The Secretariat confirmed that it was anticipated there would usually be several revisions of the BD during the opinion-forming process and that, according to the working procedure, the BD would be modified first by the dossier submitter and then by the rapporteur, however, ECHA would also assist the rapporteur to finalise the BD. Ownership of the final BD would be RAC for its parts of the document. It was also considered appropriate to have a single BD (i.e. joint document supporting both SEAC and RAC opinions) at the end of the restriction process.

The Chair thanked members for their comments and proposed to upload the document to a CIRCA newsgroup to collect further comments. SEAC was expected to review the document at its third meeting 23-24 February, after which all comments would be collected and a further version circulated to RAC for final adoption at the RAC/SEAC joint meeting in June.

Item 9 Transitional dossiers (Article 136(3) of the REACH Regulation)

9a&b Overview of dossiers and Community risk management options

The Secretariat presented an overview of the 25 transitional dossiers (for 26 substances) received by ECHA by the deadline of 1 December 2008 established in Article 136(3) of the REACH Regulation (see RAC/05/2009/05). None of the submitted transitional dossiers identified a need for a restriction under REACH and instead all proposed other measures to address the identified risks. However, one dossier (MCCPs) refers to the need for a restriction for the specific use of MCCPs in leather fat liquoring but this was not included in the Annex XV report format. A need for Community wide measures (other than restriction under REACH) were proposed for 21 dossiers; national or industry action was proposed in 22 dossiers; and 2[1] dossiers did not identify the need

[1] After the meeting the MSCA submitting these 2 dossiers requested that they be re-categorised into category 2 (need for Community-wide measures) since the current category (category 4) gave the impression of no risk, whereas in fact risks had been identified but the MSCA had proposed that current EU existing legislative measures provided an adequate framework to address the risks and thus no additional specific measures had been proposed.

for further risk management measures (N.B. a dossier can belong to more than one group).

The Secretariat explained that since none of the dossiers proposed a restriction under REACH in Annex XV report format, they could not readily be used as a test case. Nevertheless, some of the transitional dossiers discussed a restriction as one of the risk management options and hence were of interest to RAC. A characterisation sheet had been prepared providing a history and guide to the content of each dossier.

Several members enquired what would be the next steps with these transitional dossiers. The representative of the COM confirmed that these dossiers are presented to RAC for information only. In relation to MCCPs, another member noted that the Member State in question had been considering an action under REACH, but it was awaiting clarification of the outcome of the bioaccumulation testing requested from industry under the Existing Substances Regulation before making a specific proposal.

A member also noted a specific issue that one of the dossiers raised in relation to the methodology outlined in the REACH guidance for chemical safety assessments, and on which they would provide further detail in writing to the Secretariat and which could be useful for future revisions of the ECHA guidance documents. The Chair confirmed this document would be circulated to RAC members for their views.

9c&d Learnings from the transitional Annex XV dossiers

The Secretariat presented the dossiers from the perspective of increasing the common understanding of why Community measures, other than restriction, was the most appropriate measure for these substances. The emphasis was placed upon the aspects of the justifications that were most relevant to RAC. The justification for Community wide action was considered in terms of the risks to be addressed, including the baseline. The various risk management options in the dossiers were then examined in relation to three criteria: effectiveness, practicality and monitorability.

Members held a short discussion on issues arising from the presentation. Several members noted that some Community wide measures may not appear to be the most effective instruments to manage the risk of substances, particularly because of the time involved to apply them, or because their focus is not on regulating specific substances. Other members queried the relationship between other Community measures e.g. Community occupational exposure limits, the Environmental Liability Directive[2] and the REACH processes. The Secretariat confirmed that other Community instruments would operate in their usual way without prejudice to the REACH processes.

It was emphasised by the Secretariat that in the future members would receive proposals from the opposite aspect, i.e. justifying that a restriction was the most appropriate measure compared to other Community-wide measures, so the RAC would need to examine the proposals from the opposite point of view, and would clearly need knowledge on the other Community wide instruments and their effectiveness before proposing these as better options to the restriction.

[2] Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage.

Item 10 Dossiers proposing harmonised classification & labelling (CLH)

10a Draft terms of reference (ToR) for CLH (co-) rapporteurs

The Secretariat presented a revised terms of reference document (RAC/05/2009/09) which had been modified on the basis of comments from members during RAC-4 and the subsequent CIRCA newsgroup discussion (see response to comments document RAC/05/2009/10). In addition, the document had been amended to take into account the new legal base coming from the recent adoption of the CLP Regulation. The revised document also included various structural and editorial modifications to enhance its readability and to clarify the deliverables from rapporteurs and their support from the Secretariat. The Secretariat indicated the need to agree the document, preferably at the meeting, in order to provide rapporteurs that were currently operational with their terms of reference.

Members discussed outstanding issues arising from the document. Several members sought clarification that rapporteurs *perform* the accordance checks, with the Secretariat in a *supporting* role. There were also similar queries in relation to the role of the rapporteur in the preparation of the BD as arose in relation to the restriction process (see items 8a&b). There followed a detailed discussion on the purpose of the accordance check and respective roles of the Secretariat versus rapporteurs which is reported under Agenda item 10 d.

The terms of reference document was agreed with several modifications to highlight the roles of the rapporteur and ECHA in relation to accordance checks and concerning the BD. The final version was to be uploaded to CIRCA for information after the meeting. The Secretariat also undertook to send letters of appointment and terms of reference documents to RAC rapporteurs by 25 February 2009.

10b State of play of the CLH dossiers

The Secretariat reported on the state of play of CLH dossiers. Concerning notifications of intentions, the Registry of Intentions (RoI) was updated regularly with new notifications, revisions of forecasted dates of submission, and removal of entries after the dossiers had been submitted. An update of the public version on the ECHA website was expected shortly to reflect these changes. There had been 14 proposals for CLH in 2008 and none thus far in 2009. Of these 14, accordance checks had been carried out for 8 substances and the results either had been or were to be sent to MSCAs shortly. There had been one proposal for no classification which ECHA were considering to reject (see AP 10c) and therefore so far excluded from the accordance check process. Of the remaining 5, the Secretariat was currently carrying out the first draft of the accordance checks and would forward all documentation to the rapporteurs and co-rapporteurs in the week following the meeting. Clarifications or supplementation of data had been requested from the submitting MSCA in each of the accordance checks. Two of these dossiers had been re-submitted by the MSCA (epoxiconazole and diantimony trioxide) and were expected to be published shortly for comments from concerned parties. One proposal on MPA-TEA had been withdrawn as the planned manufacture had stopped.

Members thanked the Secretariat for the update. In relation to the public consultation, one member expressed the concern that the first dossier should be one in which the proposal was solely in relation to skin irritation which might give the wrong impression considering the objective under the new CLP Regulation to focus on CMRs and respiratory sensitisers. Another member enquired whether there would be a second accordance check of the re-submitted dossiers before publication. Another member suggested indicating in the RoI whether there is an environmental component to the dossier. Several members noted the difficulty of locating the RoI in CIRCA and also requested that regular status updates be sent to members to enable them to better plan their work.

The Secretariat confirmed a second accordance check does not take place on re-submitted dossiers, unlike the conformity check of a restriction proposal; and MSCAs had been requested to always indicate in the RoI in the future whether there would be a proposed environmental classification in the dossiers. It was agreed to consider a link from RAC CIRCA IG to the RoI (end February 2009) and to inform (co-) rapporteurs as soon as a dossier has been received and provide them the dossier if requested. The members suggested taking into account comments from RAC with regard to the CLH dossier development during the revision of the Guidance Documents on preparing a dossier on harmonised classification and labelling

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10c Dossiers for harmonised C&L proposing not to classify a substance and classification based upon the presence of constituents such as impurities

The Secretariat introduced the discussion on document RAC/05/2009/07. It was explained that the need for the discussion originated from three dossiers submitted by one Member State concerning substances in the hand-over file from the previous Regulation (EEC) No 793/93 (Existing Substances Regulation). One of the dossiers made a proposal that harmonised classification and labelling on the basis of the available data was not necessary (scenario 3.1 in the document). Another dossier proposed a classification solely on the basis of an already classified impurity (scenario 3.3.). A further question was whether RAC should review hazard classes other than those proposed by the MSCA (scenario 3.2). The Secretariat sought views from RAC to prepare for a discussion at the forthcoming REACH Competent Authorities meeting, 16-17 March.

Scenario 3.1

The Secretariat explained that the CLP Regulation does not provide for submission of dossiers proposing no classification and Annex VI of the Regulation does not contain unclassified substances. Therefore ECHA proposed to reject the dossier.

The members generally agreed with the analysis of the Secretariat, but several pointed to one scenario where discussion by RAC of such dossiers could be necessary, this being where it is proposed to de-classify a substance, i.e. remove from Annex VI on the basis of new data. The Secretariat agreed that de-classification should be brought into the paper as a case where a proposal for no classification could be considered as the basis for a no classification discussion at RAC.

There was also some support and understanding for the motivation of a Member State seeking confirmation of RAC for its proposal not to classify a substance. One member noted that if RAC does not allow such discussions, it could provoke MSCAs to propose

'over' classification of a substance, solely in order to enable a discussion of the case for which it had no fixed opinion. It was also noted that a RAC opinion stating that available data did not support classification for a particular hazard class may be useful information if these substances were ever under consideration as potential alternatives (e.g. in a restriction proposal). It was pointed out that RAC opinions supporting no classification for specific endpoints were in any case likely to arise, either because the RAC did nor support classification as given in the original proposal, or in the case of harmonisation of all hazard classes for pesticides and biocides, where it was inevitable that classification would not be required for all endpoints.

It was also pointed out that during the transitional phase between the old and new legislation, MSCAs were missing a forum for discussion of the outcome of the risk assessment process. In the future this activity would come under substance evaluation and it may be possible that within this activity a forum for such a discussion could be found, which could address questions on the need for classification, before the preparation of a proposal.

The Chair concluded that during the transitional phase, before substance evaluation, RAC members were not against having discussions on borderline cases for CLH. The representative from the COM undertook to check with legal experts whether the submission of a non-classification dossier is permitted and indicated that a RAC opinion of no classification will not be considered by the COM for inclusion into Annex VI.

Scenario 3.2

RAC was not in favour of recommending that MSCAs evaluate all the available data for each of the harmonised hazard classes when making a proposal, considering that this was entirely up to the submitting MSCA. Many situations were envisaged where it was recognised that it was important to give the MSCA this freedom when making a proposal. For instance where there were clear data indicating a concern for one endpoint but limited data of dubious reliability for the other harmonised endpoints, MSCAs should be allowed to focus their resources just on the endpoint of clear concern. Some members suggested that dossier submitters should be required to clarify if they had considered end points for hazard classes, other than those proposed for classification. It was suggested to revise the Annex XV report template to request dossier compilers to indicate whether the data for a hazard class were absent or not evaluated.

In cases where information was supplied in the dossier on other endpoints but without a clear conclusion on fulfilment of the classification criteria, members agreed that RAC should adopt a flexible approach to considering other hazard classes on the basis of the available information, such that a RAC opinion could go beyond the original proposal and include the view that the data in the dossier, or provided during the public consultation, supported classification in additional hazard classes to the ones proposed. A representative from COM confirmed that the CLP Regulation offered RAC this flexibility.

Scenario 3.3

The question raised in the document was how RAC should deal with proposals that are only based on the content of an impurity for which a harmonised classification already exists. The paper proposed that it was not necessary to make entries in Annex VI for

such substances since according to the CLP Regulation, based on the application of general or specific concentration limits, a substance with constituents that are classified at Community level and present in concentrations above the limits, must be classified accordingly. It was proposed that there would be no added value in including such a substance in Annex VI, since it could become overloaded with such substances, and resources used for the preparation of the proposal, organisation and response to the public consultation, and preparation of the RAC opinion would be unnecessary. One member requested that the guidance for preparing proposals for harmonised classification and labelling would need to be updated to reflect this as it currently does not distinguish between proposals where the impurity is already listed on Annex VI compared with when it is not listed.

In the discussion which followed some members were not so convinced that acceptance of such cases would give rise to overloading of the inventory as the proposals would be in the hands of the MS and there would probably not be that many made. Members considered that there may be cases where an Annex VI entry might provide added value and the proposing MSCA should provide a justification of the need for a harmonised entry. COM indicated that one example of a justification for harmonisation could be where there was some problem in the C&L Inventory for such a substance. It was agreed that these cases should involve no more then an automatic application of the concentration limits and therefore there was no necessity for the RAC to have any in depth scientific discussions, however COM pointed out that there was neither possibility to by-pass the RAC nor the public consultation.

In conclusion the members' view was that such cases should be dealt with on a case-by-case basis, following a 'light approach' where such proposals are passed through RAC without discussion.

The Secretariat thanked members for the discussion and undertook to take it into account when preparing the paper for the forthcoming CA meeting.

10d Feedback on the on-going CLH Dossiers

There was a general discussion on the experiences so far on the accordance checks. One member indicated that the accordance check appeared to be serving two purposes, one for the ECHA Secretariat's requests to the submitting MSCA (e.g. entering the data in the correct manner and place in the IUC5 dossier), and the other for the requests from the rapporteur, leaving it unclear, in the member's opinion, who made the final decision on accordance. Other members welcomed the discussion with the Secretariat on these first accordance checks and considered it a joint activity. Another member proposed that the most important outcome of the accordance checks should be that the MSCA understood what was being requested and thus some sort of overall check should be done in the end to ensure that requests made by the ECHA Secretariat were coherent with those from the rapporteur. The discussion also touched upon the purpose of the accordance check and the level of detail requested by rapporteurs in the dossiers, which from first experiences seemed to differ from one rapporteur to another. Several members noted the need to ensure that a baseline is established to ensure the accordance checks performed by rapporteurs are fit for purpose. By way of support, ECHA should play its role in defining a certain baseline of consistency in what was requested of the dossier submitter in the accordance check.

The Secretariat confirmed that the rapporteur made the final decision on accordance or non-accordance of a dossier. It was agreed that the accordance check report template would be modified to remove the box where the ECHA Secretariat made a proposal on accordance of the specific sections before the accordance check was finalised.

The (co-) rapporteurs reported back on matters arising from the accordance checks that had been carried out in relation to four CLH dossiers: lucirin, TXP, V6 and TDCP.

A number of issues were raised by the presenters as follows. On lucirin the study summaries were presented clearly in the Annex XV report and were sufficient to form a relevant basis for a discussion on the possible harmonised classification and labelling however there were inconsistencies between the data reported in the robust study summaries in the IUCLID 5 dossier prepared by industry and the study summaries in the Annex XV report prepared by the MSCA. On TXP further information was required on the identification of constituents and further quantitative data was required on the toxicity effects. For V6 the text of the Annex XV report sometimes did not correspond to the conclusions drawn, and there was also the more general query of how does RAC deal with classification based solely on impurities. For TDCP, the dossier was not in accordance due to deficiencies in substance identification and scientific justification.

In the following discussion one member cautioned against requiring unnecessary information from dossier submitters. For example, is information on impurities from different manufacturers important in carrying out the CLH process for a specific dossier? In addition, the member pointed out that studies found valid under other EC regulatory processes should generally be acceptable for the purposes of REACH. Several other members queried whether the pure substance was to be classified or the substance with all its impurities, at varying concentrations. The Secretariat concurred with the need to avoid requiring unnecessary information and reminded RAC members that REACH defines a substance to include "….any additive necessary to preserve its stability and any impurity deriving from the [manufacturing] process used…."(Article 3(1)).

The Chair thanked members for their contributions and proposed to receive any further comments on the accordance check reports via a CIRCA newsgroup by 2 March.

Item 11 Appointment of (co-)rapporteurs

11a Appointment of rapporteurs for new dossiers

The Secretariat introduced document RAC/05/2009/08 which set out new submissions and intentions registered in the RoI as of 23 January 2009. In particular, volunteers for a rapporteur were required for one intended dossier, indoxacarb. A member volunteered to be rapporteur for indoxacarb without objection from other members. The Secretariat agreed to upload an updated version of the status document by 13 February 2009.

11b Outcome of written procedures

The Chair noted that a written procedure had been carried out for the appointment of rapporteur and co-rapporteur for V6. Both had been appointed without objection.

Item 12 Information session on IUCLID 5 for RAC

This item was postponed due to insufficient time.

Item 13 Any other business

13a Overview of RAC learning needs

Document RAC/05/2009/11 was drawn to the attention of members by the Chair. One member suggested further details were required in the document in order to clarify the content and level of the training proposed. It was agreed to revise the document as proposed.

13b Meeting dates 2009

Document RAC/04/2008/33_rev3 was agreed without further discussion.

13c Collecting comments from stakeholder observers

The Secretariat agreed it would consider and bring to RAC a proposal for the provision of comments from stakeholder observers to the meetings.

Item 14 Action points and main conclusions of RAC-5

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-5 ACTION POINTS & MAIN CONCLUSIONS – 10-11 February 2009
(as adopted at the RAC-5 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the RAC-5 Agenda	• RAC adopted the Draft RAC-5 Agenda without changes	• Adopted RAC-5 Agenda to be uploaded to CIRCA and ECHA website (SECR / after the meeting)
4. Adoption of Draft RAC-4 minutes a. Adoption of the draft minutes	• RAC adopted the Draft final minutes without further changes	Adopted minutes of RAC-4 to be uploaded to CIRCA and ECHA website (SECR / after the meeting)
4. Adoption of Draft RAC-4 minutes b. Status report on the RAC - 4 Action points	There were two outstanding actions identified from RAC-4 which were transferred to these action points	• (Item 13 RAC-4 minutes) SECR to make available to RAC members and observers the health effects TC C&L "guidance" notes that were referred to in the presentation (e.g. the specialised experts' note in relation to animal thyroid tumours, etc). • SECR to clarify the implications of not providing the conformity check report within the REACH 30 day deadline
5. Administrative issues c. Remuneration of co-opted members and invited experts		• SECR to clarify the definition of "public services" in the MB Decision on remuneration of co-opted members and invited experts, in particular experts from public universities and public scientific institutions

6. Feedback from other ECHA bodies		• SECR will present the recommendations from the MSCAs workshop on restriction and authorisation at a forthcoming RAC plenary meeting after presentation to the REACH CA meeting
7. SEAC / RAC arrangement	• SEAC/RAC Arrangement to continue working to complete the tasks in the mandate • Elements of the MCCP transitional dossier may be used in developing a case for testing procedures	
8. Working Procedures - Restrictions dossiers a. Draft WP on processing of an Annex XV restriction dossier b. Draft terms of reference for restriction rapporteurs		• a&b. RAC is requested to provide written comments on RAC/05/2009/03 and RAC/05/2009/04 by 16th March 2009 via the respective Newsgroups in RAC CIRCA IG after RAC-5 meeting • a&b. Revised version of Doc RAC/05/2009/03 and Doc RAC/05/2009/04 will be circulated based on the comments received during the SEAC-3 meeting and written RAC comments (SECR/ in early April 2009)
9. Transitional dossiers (Art 136 (3)) of the REACH Regulation		• One member to prepare a paper for consideration by RAC concerning modification of the Guidance on CSA • SECR to disseminate the paper to RAC when it is received from the member
10. C&L Annex XV dossiers a. Draft terms of reference for CLH (co-)	• RAC agreed document RAC/05/2009/09 on Terms of reference (ToR) for CLH (co-) rapporteurs as it was proposed by SECR with some changes.	• SECR to upload the final ToR for CLH (co-) rapporteurs on the RAC CIRCA IG (SECR / after the meeting)

rapporteurs		• SECR to prepare and send letters of appointment to all appointed RAC rapporteurs &co-rapporteurs (SECR / 25 Feb 09)
10. C&L Annex XV dossiers b. State of play of the submitted C&L Annex XV dossiers	• After receipt of the CLH dossier at ECHA, SECR should enquire whether (co-) rapporteurs wish to receive it immediately, or only after provision of first draft accordance check.	• SECR to take into account comments from RAC with regard to the CLH dossier development during the revision of the Guidance Documents on preparing a dossier on harmonised classification and labelling • Link from RAC CIRCA IG to the Registry of intentions in REACH CAs CIRCA IG to be considered (SECR/end of February)
10. C&L Annex XV dossiers c. Annex XV CLH dossiers suggesting not to classify a substance (Non C&L) and C&L proposals based on the presence of constituents such as impurities	• RAC agreed that when a CLP dossier is submitted by a MS with a proposal for no classification: - If there is a proposal for de-classification on an entry of the Annex VI, this would be a clear case for forming a RAC opinion on a no classification proposal - RAC could consider having discussions on borderline cases when needed during the transitional phase prior to the substance evaluation • With regard to the issue whether all end-points should be covered in a CLP dossier, RAC agreed it has a flexibility to consider other end points on the basis of data in the dossier • RAC agreed that when a CLP dossier is submitted with a proposal based on the presence of impurities that are already classified in Annex VI, it should be consider on case-by-case basis and following a "light" procedure	• SECR to bring cases concerning non - classification proposals and proposals based on the presence of impurities to the MSCAs and propose a discussion in the forthcoming MSCA meeting in March.
10. C&L Annex XV dossiers d. Feedback on the on-		• RAC to provide further comments on the presented accordance check reports by 2nd March

going C&L Annex XV dossiers • Accordance Check • Public consultation		
11. Appointment of rapporteurs	• RAC agreed to appoint a number of rapporteurs & co-rapporteurs for the submitted dossiers and registered intentions (see document RAC/05/2009/08).	• SECR to upload in RAC CIRCA IG the updated status document (SECR/13 Feb 09)
13.AOB a. Overview of RAC learning needs		• SECR will revise Doc RAC/05/2009/11 and provide it to RAC • SECR to consider and bring to RAC a proposal for provision of comments from stakeholder observers to the meetings
GENERAL		• All presentations and room documents on CIRCA (SECR/by 13/02/09) • Conclusions and action points (i.e. this doc) to be uploaded to Circa (SECR /by 13/02/09)

III. List of Attendees

Members		**ECHA staff**
ANDERSSON Alicja		AJAO Charmaine
BARANSKI Boguslaw		BLENCOWE Tom
BARRON Thomasina		ERICSSON Gunilla
BORGES Maria Teresa		DE BRUIJN Jack
DI PROSPERO Paola		FUHRMANN Anna
DUNAUSKIENE Lina		HOLLINS Steve
DUNGEY Stephen		KARHU Elina
GRUIZ Katalin		KNIGHT Derek
HALKOVA Zhivka		KULJUKKA-RABB Terhi
JENSEN Frank		LIPKOVA Adriana
KADIKIS Normunds		LUOTAMO Marita
KREUZER Paul		MUNN Sharon
LE CURIEUX-BELFOND Olivier		NAUR Liina
LEINONEN Riitta		NYLUND Lars
LOSERT Annemarie		PEDERSEN Finn
LUND Bert-Ove		RÖCKE Timo
MELANITOU Maria		RUOSS Jurgen
MULLOOLY Yvonne		SADAM Diana
NUNES Céu		SIHVONEN Kirsi
ORPHANOU Maria		SUNDQUIST Anna-Liisa
PICHARD Annick		VAHTERISTO Liisa
POLAKOVICOVA Helena		VAINIO Matti
POSPISCHIL Erich		VASILEVA Katya
PRONK Marja		YLÄ-MONONEN Leena
RUPPRICH Norbert		
SCHULTE Agnes		**Stakeholder observers**
SMITH Andrew		Mr ANNYS Erwin (observer from European Chemical Industry Council (CEFIC) and replaces Jenny HOLMQVIST)
STOLZENBERG Hans-Christian		Ms. MEISTERS Marie-Louise (observer from ECETOC)
SULG Helen		Mr NEWBY John (observer from Health and Environmental Alliance (HEAL))
TARAZONA Jose V.		Ms. SANTOS OTERO Tatiana (observer from European Trade Union Confederation (ETUC))
VAN DER HAGEN Marianne		Ms. SUHONEN Eeva (observer from European Coalition to End Animal Experiments (ECEAE) and replaces Katy TAYLOR)
VAN MALDEREN Karen		Mr. WEFERS Heribert (observer from European Environmental Bureau (EEB))
VILANOVA Eugenio		
ZGLOBIU Mariana-Elena		
Advisers to the RAC members		

Ms. ALESSANDRELLI Maria (adviser to Paola Di PROSPERO)		
Ms. ANNOLA Kirsi (adviser to Paul KREUZER)		
Ms. GRACZYK Anna (adviser to Boguslaw BARANSKI)		
Ms. HAKKERT Betty (adviser to Marja PRONK)		
Ms. HERBEST Uta (adviser to Agnes SCHULTE)		
Ms. MORKA Heidi (adviser to Marianne van der HAGEN)		
Representatives of the Commission		
BINTEIN Sylvain (DG ENV)		
PUOLAMAA Majla (DG ENTR)		

IV. List of Annexes

ANNEX I Final Agenda

ANNEX II List of RAC-5 meeting documents submitted to the RAC Members.

ANNEX I

10th February, 2009
RAC/A/05/2009

Final Agenda
Fifth meeting of the Committee for Risk Assessment

10 -11 February 2009
Helsinki, Finland
10 February: starts at 13:00
11 February: ends at 18:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/05/2009
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

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

c. Adoption of the draft minutes

RAC/M/04/2008 draft final
For adoption

d. Status report on the RAC - 4 Action points

RAC/05/2009/12
Room document
For information

e. Status of the adoption of the 1st revision of the RAC Rules of procedure

RAC/04/38/2008 rev1
Room document
For information

Item 5 – Administrative Issues

a. Change in the RAC composition **RAC/05/2009/01**

For information

b. Revised Rules for reimbursement of travel, hotel and subsistence expenses of experts for members and experts attending the ECHA meetings

For information

c. Remuneration of invited experts serving the Committee working groups

RAC/05/2009/02
For information

Item 6 – Feedback from other ECHA bodies and activities

For information

Item 7 – SEAC / RAC arrangement

a. First results of the SEAC / RAC arrangement (including oral report of the 1st meeting of 27 January 2009)

For information

b. Work Plan till June 2009

For discussion

Item 8 – Working Procedures - Restrictions dossiers

a. Working procedure on processing of an Annex XV restriction dossier

RAC/05/2009/03
For discussion

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

RAC/05/2009/04
For discussion

RAC/05/2009/13 (Responses to comments table)
Room document
For information

Item 9 – Transitional dossiers (Art 136 (3)) of the REACH Regulation

b. General dossier characterisation

RAC/05/2009/05
For information

c. Risk Management Options at the Community level

RAC/05/2009/06
For information

d. Dossiers identifying a need for a Community-wide measures other than restriction

For discussion

d. Dossiers identifying a need for action at national/ local level

For information

Item 10 – C&L Annex XV dossiers

a. Draft terms of reference for CLH (co-) rapporteurs

RAC/05/2009/09
Room document
For agreement

RAC/05/2009/10 (Responses to comments table)
Room document
For information

b. State of play of the submitted C&L Annex XV dossiers

For information

c. Annex XV CLH dossiers suggesting not to classify a substance (Non C&L) and C&L proposals based on the presence of constituents such as impurities

RAC/05/2009/07
For discussion

d. Feedback on the on-going C&L Annex XV dossiers

- Accordance Check
- Public consultation

For information and discussion

Item 11 – Appointment of rapporteurs

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

RAC/05/2009/08
For decision

b. Outcome of written procedures

For information

Item 12 – Information session on IUCLID 5 for RAC

a. Presentation on the IUCLID 5 and its application with regard to RAC activities

For information

b. Practical demonstration on the main functionality of IUCLID 5

For information

Item 13 – AOB

a. Overview on the RAC learning needs

RAC/05/2009/11
Room document
For information

b. Meeting Dates for 2009

RAC/04/2008/33 Rev.3
Room document
For information

Item 14 – Action points and main conclusions of RAC-5

- Table with Action points and decisions from RAC- 5

For adoption

ANNEX II

Meeting documents submitted to the Members of the Committee for Risk Assessment (RAC-5)

Document Title	**Document number**
Draft Agenda (Rev 2)	RAC/A/05/2009
Draft minutes RAC-4	RAC/M/04/2008
Change in RAC composition	RAC/05/2009/01
Remuneration of co-opted members and invited experts	RAC/05/2009/02
Working procedure for processing an Annex XV restriction dossier	RAC/05/2009/03
Draft terms of reference (co-) rapporteurs (restrictions)	RAC/05/2009/04
Transitional dossiers – general dossier characterisation	RAC/05/2009/05
Transitional dossiers – risk management options at Community level	RAC/05/2009/06
CLH: Annex XV dossiers proposing no classification and CLH proposals based upon constituents	RAC/05/2009/07
Appointment of rapporteurs for submitted Annex XV dossiers	RAC/05/2009/08
CLH: Draft terms of reference (co-) rapporteurs	RAC/05/2009/09
CLH: Draft terms of reference (co-) rapporteurs response to comments table	RAC/05/2009/10
Overview of RAC learning needs	RAC/05/2009/11
Status of RAC-4 action points	RAC/05/2009/12
Draft terms of reference (co-) rapporteurs (restrictions) response to comments table	RAC/05/2009/13
Status of the adoption of first revision of the RAC rules of procedure	RAC/04/38/2008 rev1
Meeting dates 2009	RAC/04/2008/33 rev 3

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