2 July 2009

RAC/M/06/2009 Final

Minutes of the 6th meeting of the Committee for Risk Assessment
21-23 April 2009

Part I Summary record of the proceedings

Item 1 Welcome and apologies

The Chair welcomed participants to the meeting, including six advisers (from NL, IT, PL, FI and NO) and five stakeholder representatives (from EEB, EUROMETAUX, ETUC, CEFIC and ECETOC). Participants were informed that the meeting would be recorded solely for the purpose of writing the minutes and that this recording would be destroyed after the adoption of the minutes.

Apologies were received from six members and three regular observers (from OECD, ECEAE and HEAL). One member was absent. The list of attendees is given in Part III of these minutes.

The Secretariat introduced the participants to the housekeeping rules of the ECHA conference centre.

Item 2 Adoption of the Agenda

Revision 1 of the Agenda was adopted as proposed by the Secretariat. 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

The Chair asked the members and their advisers whether there were any conflicts of interest to be declared specific to the meeting. No conflicts of interest to the Agenda were declared.

Item 4 Adoption of the draft minutes of the RAC-6

4a Adoption of the draft minutes of RAC-5

The Chair introduced the revised minutes, incorporating the comments received from three members. RAC adopted the revised minutes. The Secretariat would make the final version available through the RAC CIRCA IG and the ECHA website.

4b Status report on the RAC-5 Action points

The Chair reported that all action points from RAC-5 (document RAC/06/2009/15) had been completed, with the exception of two issues that had been carried over to actions from this meeting and one issue that would be completed at the next RAC meeting (see action points RAC-6).

The Chair also clarified a few outstanding points from the previous meeting, such as the implications of not providing the conformity check report within the deadline of 30 days, due to the failure of the rapporteur or the Committee to reach a decision. It was confirmed that if the Committee did not carry out the conformity check in time, the Annex XV dossier would be considered to be in conformity and the restriction procedure would continue.

With regard to the clarification of the meaning of ‘public services’ in the rules for remuneration of co-opted members and invited experts adopted by the Management Board 18 December 2008 (MB/77/2008 final**)**, the Chair explained that this was not meant to include experts from universities or public research institutions, who would normally be eligible for remuneration.

Item 5 Administrative issues

5a Feedback on using the KALEVA services

The members have been requested to provide the Secretariat with their feedback on using the KALEVA travel agency's services when making their travel and hotel arrangements for RAC meeting participation. The Chair informed the participants that all comments and questions received prior the meeting had been collected and transferred to the KALEVA contact points in ECHA and in the travel agency for further actions.

Many of the members expressed appreciation for the new system and their satisfaction with the offered services. However, a few important recommendations were given with regard to further improvement of the KALEVA on-line booking system and communication when participants choose, confirm and receive their electronic tickets.

5b Current status of the RAC competence grid

The Chair informed the participants of the current status of the RAC competence grid (document RAC/06/2009/16) and noted that irrespective of the changes in the RAC composition in 2008, there were no real gaps or big changes in the committee's overall expertise.

It was also highlighted that RAC will be regularly informed (probably once per year) of the status of the committee's competence grid.

Item 6 Feedback from other ECHA bodies and activities

Feedback from MB-12, SEAC-3 and MSC-7 meetings

The Secretariat reported on the last meeting of the Management Board which had taken place on 25-26 February 2009 and noted its main highlights these being: decisions on appointments for Board of Appeal (incl. Chair of Board of Appeal); adoption of the revised Rules of Procedures of the Committees and Forum (available on ECHA website); and Management Board request for regular updates on the work of the Committees and Forum.

The Secretariat also provided feedback from the third meeting of the Committee for Socio-economic Analysis (SEAC) held on 23-24 February. The main discussion points at the plenary were: working procedure on processing of a restriction dossier (that mirrored respective RAC procedure), terms of reference for restriction rapporteurs, and draft opinion template. The outcome of the first RAC/SEAC arrangement meeting was also presented by one of the members and the SEAC working procedure for appointment of restriction rapporteurs was adopted. SEAC was also informed about the last update on the transitional dossiers and of the expected proposals for restrictions notified by the Member State Competent Authorities (MSCAs) to ECHA so far. It was mentioned that a refresher course on socio-economic analysis for SEAC had been organised back-to-back to the plenary, which had been highly appreciated by the SEAC.

The Secretariat referred also to the seventh meeting of Member State Committee (MSC), held on 2-3 April, at which discussion on substances subject to authorisation for inclusion in Annex XIV had taken place, as first MSC opinion on this topic is expected to be agreed in May.

Item 7 SEAC / RAC arrangement

One of the members of the SEAC/RAC arrangement reported on the 2nd meeting of the SEAC/RAC arrangement, held on 20 April 2009, back-to-back to RAC-6. The member reported that the meeting was intended to act as a test run of the procedures, this was done in the form of a role play exercise where two Rapporteurs (one from RAC and one from SEAC) and other members simulated the way both committees would go through a possible restriction proposal, using a transitional dossier submitted by the UK according to Article 136(3) of the REACH Regulation on MCCPs (medium-chain chlorinated paraffins) as a test case. Although the original transitional dossier had not proposed a restriction, relevant parts of the dossier related to use of MCCPs in leather fat liquors and metalworking fluids had been used as material for the role play.

The role play had highlighted a number of issues including: the difficulties surrounding the transfer of the current output of the risk assessment into terms that could be easily understood and used in a socioeconomic context; the utility of a structured dialogue focusing on problem identification, identification of strengths and weaknesses and issues for clarification; the fact that both RAC and SEAC rapporteurs held similar views on the strengths and weaknesses of the dossier; the advantages of involving the dossier submitter in the dialogue between the rapporteurs; and a preliminary view on the need of rapporteurs' working days required from conformity check up to first rapporteur's dialogue for a restriction dossier.

Based on the collected experience, the members of the SEAC/RAC arrangement, supported by the Secretariat, made a recommendation to RAC and SEAC to repeat the role play in a more streamlined mode at the upcoming joint RAC-SEAC meeting, with the rapporteurs supported by facilitators who took part in the role play. It was also reported that although the arrangement mandate had been fulfilled, organising a preparatory meeting in reduced composition might be needed in the end of May in support of the role play rapporteurs who volunteered to prepare short background document (mini-Annex XV dossier) for break out groups. Afterwards, the arrangement would be closed.

Other participants in the role play also provided feedback on the usefulness of this exercise in creating a better understanding of the need for working interactions and early communication between SEAC and RAC in the formulation of coherent opinions that could facilitate the further decision-making process.

In the following discussion, it was pointed out that the current Guidance on information requirements and chemical safety assessment has risk characterisation ratios (RCRs) as an output. If this and other information which can be used to describe the extent and severity of the risk were not sufficient for SEAC, then substantial resources for further development of methodology and data generation may be required to translate the RCRs into input for a socio-economic analysis.

In relation to the proposal for an extension of the role play to allow all members to participate at the joint plenary meeting in such an exercise, most members were in favour, particularly as it gave an opportunity to focus and discuss on the effectiveness of risk management measures, in addition to the risk assessment.

The Chair thanked members for their contributions and informed the committee that the mandate of the arrangement was now considered to be fulfilled and the Chair's report of the 2nd SEAC/RAC Arrangement meeting was under preparation and would be uploaded to RAC CIRCA IG when available.

Item 8 Working procedures – Annex XV restriction dossiers

8a Working procedure for processing a restriction dossier

The Secretariat introduced the revised draft working procedure document (RAC/06/2009/17) and noted that the revision was closely linked to progress with the mirrored SEAC restriction working procedure. The document had been revised according to considerations at RAC-5 and SEAC-3 and subsequent discussions via RAC and SEAC CIRCA Newsgroups. For the latter, RAC was provided with a response to RAC members' comments from the Secretariat (RAC/06/2009/18).

In the opening discussion on the document, one member pointed out that the issuance of a third version of the opinion just before the end of the public consultation might give an impression that comments submitted might not to be taken fully into account. The Chair acknowledged that clear communication to the public on the process when launching the public consultation would be key to the success of the process. Part of this communication should aim to encourage early contributions by explaining that the rapporteurs first formulate their opinions based on the proposal itself, and then modify them as necessary on the basis of the comments submitted through the public consultation by three and a half months and the following discussions at the first RAC and SEAC plenaries. Further comments submitted by the end of the sixth month would be reflected in a further revision of the opinion, if necessary, after a final discussion at RAC and SEAC plenary meetings. So, whilst comments received by the sixth month would thus not be ignored, the earlier the comments are submitted the more time the Committees will have to reflect upon them.

RAC supported the document without changes. The Chair concluded that there was a preliminary agreement on the working procedure, pending possible further input from other affected parties (dossier submitter, SEAC and Forum), for confirmation at the next RAC meeting

8b Draft template on the restriction opinion

The Secretariat presented the document RAC/06/2009/19 laying down the ECHA Secretariat's view on the purpose and content of the RAC and SEAC opinions on a restriction proposal and making a proposal for a format of the opinion in which both RAC and SEAC opinions would appear in one document supported by one shared background document. The Secretariat had already presented the proposal to SEAC-3 and the current version was modified based on the SEAC comments received. The document described the role of SEAC and RAC opinions and the background document (BD), the basic content of the opinions and the way of documenting them. It was highlighted that RAC and SEAC opinions should aim to provide a solid basis for the Commission's decision for amendment of Annex XVII. The most common combinations of RAC and SEAC opinions were also presented. The Secretariat also clarified the importance of the BD in providing transparent technical and scientific reasons justifying the opinion and thus further facilitating the decision-making process.

In the following discussion, some members sought clarification on the ways of presenting two potentially diverging opinions in one BD and anticipated difficulties in agreeing on only parts of documents, particularly when the opinions were adopted at different points of time. The Secretariat, supported by the Commission, underlined the importance of producing one common BD. Furthermore, it was noted that according to the procedures, BD should be jointly developed by ECHA, RAC and SEAC rapporteurs and the dossier submitter, and that both Committees should endorse separately their

relevant parts respectively in month 9 and month 12. Moreover, one of the changes made in the new Annex XV report format was to make a clearer separation of the sections which are in the remit of RAC from those which are in the remit of SEAC. This aimed to ensure that each committee has its own sections for comments and justifications clearly marked as emanating from either RAC or SEAC in each section of the BD. The Secretariat was requested to consider further sub-headings within the sections of the Annex XV report format which are relevant to both Committees so that the distinction between RAC-relevant and SEAC-relevant information can be made even clearer. One member made a recommendation to include a definition or reference to the definition of "restriction" in the introduction section of the document.

To a question on the need for interaction between RAC and SEAC to develop a view on proportionality the Secretariat replied that the risk needs to be understood before the benefits of a restriction could be properly assessed. However, it is SEAC that is tasked with giving a view on proportionality of the costs (related to the suggested restriction) compared with the benefits (related to the suggested restriction), based on the RAC's view of the description of risk.

Another member proposed that the BD should be a complementary document to the opinion instead of an Annex to it. The Secretariat replied that the opinions and BD should not be separated, since for example in the public consultation on the SEAC draft opinion, the opinion as proposed would make no sense without the supporting BD.

The Chair stressed that irrespective of whether the BD was an Annex or a complimentary document what was important was that RAC supported what was written in the RAC-relevant parts, as it represented the justification behind the RAC opinion. The Chair concluded with the suggestion to apply the proposed approach but to keep flexibility for further revision after first practical experience is collected.

Following one member's query, the Chair clarified that any minority opinions (even if from only one member) could be documented in an Annex to the opinion, after consultation with the member(s) with minority view(s).

Following the discussion, preliminary agreement was reached on the Secretariat's proposal.

8c Working procedure on appointment of RAC (co-) rapporteurs for restrictions

The Secretariat introduced document RAC/06/2009/20 and explained that the current RAC working procedure for appointment of RAC rapporteurs had been split into two more specific process-related procedures. In this document for the selection of rapporteurs for restriction dossiers, the main principles and selection criteria had been taken over from the current procedure, with addition of a more detailed stepwise working procedure with specific timelines and method for RAC agreement.

Some members expressed their concerns on a procedure that requests volunteers for a dossier on the basis of expected dates of submission indicated in the Registry of intentions (RoI). This requires a member to make a commitment to a task that will probably only begin one year later when the dossier is actually submitted. The Secretariat acknowledged the potential problems in requesting a commitment far in advance, however, as a dossier may be submitted at any point after notification, and expected submission dates may be revised, the current procedure was drawn up to reduce the risk of a dossier being submitted before a rapporteur was appointed. The Secretariat was requested to re-consider the most appropriate timeframe for

rapporteurs' appointment and the option of creating a pool of potential rapporteurs, followed by actual appointment in closer proximity to the expected date of submission.

In conclusion, the Chair summarised that a review of the draft procedure reflecting the comments received will be made and the revised procedure will be circulated to RAC for further comments, in particular with regard to introducing the concept of a pool of rapporteurs and timeline considerations.

8d Draft Terms of reference for restriction RAC (co-) rapporteurs

The Secretariat presented the revised draft terms of reference document (RAC/06/2009/21) and noted that the document had been revised and restructured according to considerations received at RAC-5 and SEAC-3 and subsequent newsgroup discussions. The main modifications were, as follows: a proposal was made for the RAC rapporteur to give a view as early as possible on whether the opinion was likely to diverge significantly from the original proposal as a basis for ECHA deciding whether to extend the time for SEAC to adopt an opinion with another 90 days, as foreseen by Article 71(3) of the REACH Regulation; timelines were taken out of the main text and removed to an Annex; and the section on deliverables was focused on those specifically required by the REACH Regulation. A response to RAC comments on the previous version (RAC/06/2009/22) had been provided by the Secretariat to the Committee.

Several members queried whether the letter of appointment could be considered as a contract for a rapporteurship. The Secretariat replied that the letter of appointment would confirm the appointment that RAC had decided in the meeting. It should be seen as of a one-sided nature, even though it requests confirmation of the member's commitment and availability for rapporteurship. However, it would not constitute a contract in relation to remuneration, which would be arranged via the transfer of funds to the MSCAs. The Secretariat proposed to return to this issue at a subsequent meeting after the Management Board decisions on transfer of funds and scale of payments to MSCAs had been made.

In response to a question from one member on how the rapporteur's independence from the MSCAs would be ensured (when they should be remunerated via MSCAs) the Secretariat explained that the rapporteur's independent status is described in the declaration of commitment which the rapporteur signs.

Preliminary agreement was reached on the proposed document, requesting early reconsideration of the relevant documents in the light of first collected practical experience, in particular with regard to division of tasks between rapporteurs and co-rapporteurs, and expected deliverables in the fixed procedural timeframe.

The Chair thanked members for their contributions and informed them that the final RAC procedural documents related to the restriction process are expected to be agreed by the next Joint RAC/SEAC plenary meeting in June/July.

Item 9

Preparation for the forthcoming Joint RAC-7 & SEAC-4 plenary meeting

The Secretariat introduced its ideas on structure and content of the Joint RAC & SEAC session. The main elements of the proposal were to have a plenary meeting organised in two sessions: a separate RAC session for discussing CLH issues (for 1-1.5 days) and a joint RAC & SEAC session in two parts (for 1-1.5 days). The first part would focus on mimicking the role play exercise of RAC/SEAC arrangement (see Item 7) via

discussion in small break-out groups on the basis of selected parts of the MCCPs transitional dossier (Mini-Annex XV dossiers) following approval of the dossier author (UK MSCA). The second part was to include the Committees' final agreement on the procedural documents for the restriction processes, as well as an information session on topics of interest to both Committees such as the scope and role of other Community-level risk management options (e.g. Integrated Pollution Prevention and Control, Water Framework Directive and Indicative Occupational Exposure Levels) to assist in evaluating justifications as to why a restriction under REACH is the most appropriate measure.

Based on the experience with the role play exercise, the members of the RAC/SEAC arrangement supported the involvement of all the members in the role play of RAC and SEAC rapporteurs. RAC supported the proposal and some members came with concrete suggestions on the practical organisation of this joint exercise, such as a well-balanced composition of each break-out group, including members from RAC with different areas of expertise (human health, environment, occupational health, etc.); allocation of members to groups as far in advance of the meeting as possible and discussion documents prepared and circulated well in advance.

The Secretariat agreed, following one member's suggestion, to consider organising the training in risk assessment for SEAC members prior to the joint plenary meeting, as an important tool for increasing the level of understanding and familiarity with the risk assessment terminology used by RAC in scientific discussions.

With regard to the information session on Community-level risk management measures other than a REACH restriction, the Secretariat was requested to invite relevant Commission services to give presentations and to consider inclusion of a session on what a restriction in Annex XVII of the REACH Regulation exactly means and how restrictions under Directive 76/769/EEC were developed in the past.

In conclusion, RAC supported the Secretariat suggestion, but also highlighted the need for well-balanced and prioritised organisation of the joint and separate committees' sessions ensuring sufficient time for CLH issues.

Item 10 Dossiers proposing harmonised classification & labelling (CLH)

10a Feedback on accordance checks of the on-going CLH dossiers

The (co-) rapporteurs for chloroform (EC No.: 200-663-8; CAS No.: 67-66-3), tetrahydrofuran (EC No.: 203-726-8; CAS No.: 109-99-9) (THF), indium phosphide (EC Number: 244-959-5; CAS Number: 22398-80-7), cryolite (two substances: EC No.: 237-410-6; CAS No.: 13775-53-6 and EC No.: 239-148-8; CAS No.: 15096-52-3), di-tert-butyl peroxide (EC No.: 203-733-6; CAS No.: 110-05-4) (DTBP) and gallium arsenide (EC No.: 215-114-8; CAS No.: 1303-00-0) presented their summary of the lessons learnt from the accordance checks of their respective dossiers.

None of the dossiers had been found to be fully complete for various reasons. The technical dossier for chloroform lacked key information such as data about its purity and the impurities present; the CAS name was absent; information on mutagenicity as an attachment was requested to be included within the Annex XV report; and it was unclear whether the RAC were being requested to consider other hazard classes, in addition to the main one (mutagenicity category 3).

In the case of THF, three new hazard classes/categories had been proposed: in relation to the proposal for category 3 carcinogen it was reported that the data presented in the dossier contained insufficient rationale according to the rapporteurs for this classification; there were also proposals for acute oral toxicity and skin irritation, both of which lacked a justification for why these hazard classes should be harmonised at Community-level. Data had also been presented in the dossier in relation to other hazard classes which were considered to be unnecessary by the rapporteurs and were proposed to be removed to clarify the focus of the proposal. There was a limited assessment of reproductive toxicity but no proposal for classification, and it was unclear whether or not the submitter intended the data to be considered by RAC. The format and scope of the citations and reference lists were noted to be problematic.

The dossier for indium phosphide lacked sufficient justification for some of the proposed hazard classes and required some further expansion and clarifications on the data presented. The dossier also lacked data on purity and impurities, the size of the particles tested and whether flammability could be a problem.

The two cryolite dossiers lacked justification for some of the proposed hazard classes/categories (acute oral toxicity, eye irritation) and as in the case of indium phosphide, information on other hazard classes had been provided that was not relevant to the proposals and reduced the overall clarity of the dossiers. The rapporteurs also reported that it was unclear whether the substance tested was the same as the substance for which classification was being proposed, because synthetic cryolite was presented as >95% pure, whilst natural cryolite was only 75-95% pure (also conflicting with the figure of 54% reported in the technical dossier). The rapporteur queried whether one or two entries should eventually appear in Annex VI to the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation).

Three new hazard classes/categories: chronic toxicity, reproductive toxicity category 2 and carcinogenicity category 3 were proposed in the gallium arsenide dossier. Necessary information or a justification for a proposed hazard class/category was reported to be missing from the dossier and there was also a lack of consistency of data within the dossier.

The information presented in the DTBP dossier had been sufficient for it to be in accordance, but it also contained data which was not directly relevant. In addition there had been concern over an impurity present up to 1% which itself was classified as a category 3 mutagen.

The rapporteurs reported that they had appreciated the support of the ECHA Secretariat during the accordance check and requested the Secretariat to provide advanced warning of an imminent need for an accordance check to confirm the availability of the rapporteurs

The Chair concluded that there were a number of recurring issues common to these accordance checks such as the general absence of justifications, of the need for harmonisation of those hazard classes not normally subject to harmonised classification and labelling according to Article 37 of the CLP Regulation, the need for a better description of the substance identity, particularly with respect to the impurity profile, and the inclusion of data on endpoints for which no classification was proposed and lack of clarity on why the information was presented. These consistently recurring issues in these and the previous accordance checks suggested that the guidance on preparing an Annex XV report might not have explained such points with enough clarity and it was agreed that the Secretariat would take the various lessons learnt into

account during the development of the new ECHA guidance on the preparation of a CLH dossier. The Secretariat undertook to consult RAC on this draft guidance.

Specifically, when information that is not directly relevant to the proposed classification, or for which there is no rationale for its inclusion, is presented in the dossier it was suggested that this could be placed in the technical dossier, rather than the CLH report. However, it was clarified that it is indeed up to the dossier submitter to judge which additional information that would be relevant as support to the proposed classification. Information and assessments from other regulatory programmes (i.e. secondary sources) may be used on a case-by-case basis without the need to refer to the original studies, depending upon the original assessment and level of detail provided. The CLH report template should be adjusted in order to ensure the reports serve the dual purpose of providing *sufficient scientific justification* (in summary format as specified in REACH, Annex I) for the proposed classification, whilst *clearly communicating* the proposals to concerned parties. The full Robust Study Summaries of the relevant studies should be provided in the IUCLID 5 dossier. More detailed guidance should be given to MSCAs on how to prepare their CLH reports to meet this dual need.

The Secretariat was thanked for its support given to the rapporteurs and asked to ensure accordance check reports are provided in advance of RAC meetings. Concerning the use of IUCLID 5, the Secretariat reported that this format had been agreed with the competent authorities and future registration dossiers will be provided in this format and hence proposals for classification will also be presented in this format. The Secretariat also advised that all attachments to CLH reports are incorporated directly into the report (unless confidential), in order to ensure the public consultation can take place with a single comprehensive document that is easily understandable to concerned parties. Questions concerning impurities were to be considered later in the Agenda (see item 10c).

10b Lessons learnt from accordance checks that may be transferred to conformity checks

The Secretariat presented an overview of the lessons learnt from the recent accordance checks. These included: the need to have full clarification of the substance identity (e.g. is the test substance the same as the substance for which a classification is proposed?); the need for the Committee to develop a common understanding of the contents and level of detail required in CLH reports to ensure sufficient data and information are present to commence the opinion forming process; the need to avoid entering too deeply into the evaluation process when checking accordance; the need for the Rapporteurs to pass on clear and consistent instructions via the accordance check report to MSCAs on how to bring their dossiers into accordance with the CLP Regulation; and the need to specify which data should be provided in the CLH report and which in the technical dossier.

The Secretariat proposed that all of these aspects could be usefully read across in varying degrees in a manner tailored to the conformity check process. For example, the ECHA Secretariat could assist rapporteurs by clarifying the substance identity in advance of the conformity check process. Similarly, the messages to be communicated back to an MSCA following a negative conformity check should be clear on what the submitter of a restriction dossier needed to do to bring a dossier into conformity with Annex XV of the REACH Regulation. The 15 day period following a failed conformity check provided for by the REACH Regulation could be used for the purpose of increasing clarity of the conformity check report.

Members supported the proposals by the Secretariat and in addition, suggested that the conformity check template is drawn to the attention of MSCAs that are preparing Annex XV reports so that the link is drawn at this stage between the report and its conformity assessment. The Secretariat was requested to share these recommendations with the SEAC Secretariat.

10c Substance identity in relation to impurities

The Secretariat introduced this item by reminding participants of the definition of a substance as described in Article 2(7) of the CLP Regulation and that information on substances for the purposes of harmonised classification and labelling should relate to substances as placed on the market. If the information used does not directly relate to substances placed on the market, a justification for the use of this information should be provided. A room document (RAC/06/2009/30) was also distributed by one member setting out the issue of impurities in relation to substance identity and how they had been dealt with in the past, and how they should be dealt with under the CLP Regulation when RAC draws up its opinion on proposals for harmonised classification and labelling.

Several other members explained how the system of classification and labelling had taken into account impurities in the past. One member considered that the simple scenario where the tested substance, with a certain impurity profile, was identical to that substance which was placed on the market was not the usual situation; instead differences were often apparent between the tested substances and those placed on the market. These tested substances were to be the basis of discussions at RAC which eventually would lead to their listing in Annex VI of the CLP Regulation with their name, CAS, EC and index numbers. For the vast majority of cases impurity profiles would not be referred to in the entry in Annex VI. RAC members would need to take impurities into account from the perspective of ensuring that the test data provided in CLH reports, was relevant for the substance for which a harmonised classification and labelling was proposed.

The responsibility of industry in relation to classification and labelling was clearly set out. Industry has the duty to classify and label substances that have been manufactured with differing impurity profiles. Manufacturers use Annex VI of the CLP Regulation as a basis for classification and compare the main component of their substances to decide how relevant the entries therein are for this purpose. Other components of the manufactured substances such as impurities may themselves also be listed in Annex VI of the CLP Regulation and would also be taken into account by manufacturers when classifying their substances. Industry therefore has the responsibility to ensure the appropriateness of classifications and labelling of substances that will be listed in the *Classification and Labelling Inventory*.

In order to assist dossier submitters, one member proposed to make some changes to the format of CLH reports and the template for accordance checks. These included: clarifying that the chapters on scientific evaluation are concerned with tested substances; the formal proposal for CLH should be limited to that which will appear in Annex VI of the CLP Regulation and not include the registration number of substances or information about impurities; and information about the impurity profile of substances placed on the market should be placed in a section about manufacture and use.

RAC members agreed with the explanation provided and supported the continuation of this approach in the work of RAC. The Secretariat was requested to take the recommended approach from this discussion into account when revising the ECHA

guidance for preparing a CLH dossier, revising the format for CLH reports and of the accordance check template. The Secretariat agreed to pass on the main points from the discussion to the Commission to assist in the preparation for a discussion at the forthcoming meeting of the Competent Authorities for REACH and CLP (CARACAL).

10d Revised format for CLH reports

The Secretariat introduced document RAC/06/2009/23 by explaining that there was a need to modify the report format for CLH proposals to take into account the changed legal basis with the introduction of the CLP Regulation, also providing an opportunity to address the proposals made by RAC for improvements arising from practical experiences with the first dossiers. The current proposal also was based upon being able to transfer information readily from IUCLID 5, via the chemical safety report plug-in tool to produce a CLH report.

Members appreciated the opportunity to comment on the proposed format of the CLH report and noted the importance of being able to capture the lessons learnt from the accordance checks that had taken place thus far. One member requested a format which would offer sufficient flexibility to be able to rearrange fields for the purpose of revising the background document. Other members requested that additional headings be inserted to direct the dossier submitters to provide a rationale for the proposed classification for each hazard class. Similarly, the format should be modified to clearly differentiate between information about the hazard classes that were the subject of the proposal and data for other supporting hazard classes. Another member requested that provision is made for the new hazard class, specific target organ toxicity (STOT) that appears in the CLP Regulation.

The Secretariat thanked RAC members for their comments. To continue collecting comments a RAC CIRCA IG newsgroup was to be established to capture any further comments by the end of April 2009. The Secretariat agreed to take comments received, including those in relation to the lessons learnt from accordance checks and in relation to impurities (see section 10a and 10c), into account when revising the format of the CLH report. A revised version would then be prepared for a forthcoming CARACAL meeting for endorsement.

10e Revised template for accordance checks

The Secretariat presented document RAC/06/2009/24 explaining that modifications were considered necessary for the same reasons as for the CLH report format. Principal changes included inclusion of a summary table of the proposed harmonised classification at the beginning of the document and the removal of the 'ECHA accordance check' table.

Members thanked the Secretariat for its efforts and made a number of further editorial suggestions for improvement. The Secretariat agreed to take these into account, together with those from sections 10a, c and d above. A revised template was to be uploaded to the RAC CIRCA IG after the meeting.

10f State of play of the submitted CLH dossiers

The Secretariat reported on the state of play of the 16 submitted CLH dossiers (document RAC/06/2009/25), pointing to the expected re-submission dates provided by MSCAs for those dossiers previously found to be not in accordance. The Secretariat explained that the members would be provided with the information after the meeting via CIRCA IG in an update of the status document referred to under item 12 of the Agenda.

10g First feedback from the public consultation of diantimony trioxide (DAT) and epoxiconazole

The Secretariat explained that the consultation of concerned parties had ended on 9 April 2009. Comments had been received from MSCAs, industry, academic institutions and one individual. Most commentators on epoxiconazole did not agree with the proposed classification of reproductive toxicity category 2, whilst for DAT there was a mixed response, both for and against, to the proposed classification for skin irritation. The next steps were to send the comments to the MSCA that submitted the dossiers and await the response to comments (RCOM).

Members thanked the Secretariat for the information and one member queried the timetable of the next steps. The Secretariat confirmed that the working procedure indicated that the 42 day period in which the dossier submitter was requested to provide responses to the comments would start from the end of the public consultation. However, since there was a delay in providing the compiled comments due to a holiday period, the 42 days could begin from the receipt of the comments by the MSCA. The Secretariat also indicated it would consider revising the working procedure for processing a CLH dossier to allow time to compile the comments at ECHA after some more experience with the public consultations.

Another member noted that the web form for commenting on the substances had appeared to dissuade comments supporting the proposals. The Secretariat confirmed it would examine the web form to ensure all comments are encouraged.

The compiled comments table was to be uploaded to the RAC CIRCA IG by the end of the current week.

10h Feedback from the CARACAL document on CLH dossiers proposing not to classify a substance

The Secretariat presented the feedback on the discussion that had taken place at the CARACAL meeting of 16-17 March 2009. The Commission had prepared a paper on the basis of the discussion that had taken place at RAC-5 in relation to CLH dossiers proposing not to classify a substance (see item 10c of the minutes of RAC-5). The Commission document stating that, except proposals for *de-classification* of a substance, dossiers that contain *no classification* proposals should not be submitted to RAC, had been supported by CARACAL. The rationale for this was to ensure that RAC focuses its resources on substances of highest concern instead of confirming a substance is not hazardous.

Item 11 Working procedure on the appointment of RAC (co-) rapporteurs for a CLH dossier

The Secretariat introduced the paper RAC/06/2009/26 by explaining that the proposed working procedure was based upon the procedure agreed at RAC-4 in document RAC/04/2008/13_rev 1. It had however been updated to take into account the new CLP Regulation; modified to include a more detailed stepwise working procedure; and tailored specifically for the purposes of appointing rapporteurs for CLH dossiers and therefore would be distinct from the working procedure for appointing rapporteurs for restriction dossiers. The overall aim of the working procedure was to keep it as flexible as possible.

One member queried what would happen where an appointed rapporteur was no longer available once the time had arrived to process the dossier. The Secretariat explained

that where a rapporteur is no longer available, they would need to resign from their position and the procedure for appointment would need to be repeated to select a new rapporteur. Another member expressed an interest to be made aware of all of the nominations the Secretariat had received for rapporteurships when considering whether to agree to a recommended candidate for a rapporteurship. The Secretariat agreed to provide members with the names of all candidates for a particular rapporteurship, when seeking agreement on a recommended rapporteur. Subject to these points, the document was agreed and the Secretariat was to modify the document and upload the final version to the RAC CIRCA IG after the meeting.

Item 12 Appointment of (co-)rapporteurs for newly registered intentions

The Secretariat introduced document RAC/06/2009/27 including new intentions with possible submission dates as appearing in the registry of intentions (RoI) up to 31 March 2009. A rapporteur and a co-rapporteur were proposed for flocoumafen and a rapporteur for acrylamide and two other substances with acrylamide as a main impurity. With respect to flocoumafen, there were another three anticoagulant rodenticides (difethialone, chlorophacinone and difenacoum) already listed in the RoI, and it was proposed that the same two members were to serve as either rapporteur or co-rapporteur for all four substances. The proposal was agreed by members. The Secretariat undertook to update and upload to the RAC CIRCA IG the status document, listing the rapporteurs for all submitted and intended dossiers

Item 13 Stakeholder commenting

This item was held in closed session but was reported on under any other business, item 14b.

Item 14 Any other business

14a Proposal to update ECHA guidance

One of the members introduced paper RAC/06/2009/28 which was a proposal for a modification of chapters R.10.5 and R.10.6 of the ECHA guidance document on information requirements and chemical safety assessment under REACH. The member explained that the guidance offers two possible alternatives for setting the predicted no-effect concentration (PNEC) for sediment and soil, one of which was using equilibrium partitioning based upon extrapolation from the PNEC water for aquatic organisms. However, according to the Scientific Committee on Health and Environmental Risks (SCHER) this method may not be sufficient when a chemical substance is particularly toxic for micro organisms. Therefore in these circumstances a $PNEC_{STP}$ (sewage treatment plants) can be derived which is based on the functionality of micro organism populations in the STP. The member proposed to modify the guidance to recommend the use of both the PNEC water and $PNEC_{STP}$ and then take the lowest value.

Other members thanked the member for the proposal indicating that whilst it sounded quite reasonable, the consequences on the guidance as a whole needed to be carefully considered before recommending the modifications. Reservations were also expressed by members whether RAC had a mandate to discuss such a proposal for guidance revision based upon the proposal of one RAC member and whether there was currently a possibility to bring this issue into the guidance update process. The Secretariat proposed to establish a newsgroup in CIRCA to collect any further comments by the end of May, and would also further investigate how to take forward such initiatives

from individual members for updating the ECHA guidance, and report back to the Committee.

14b Stakeholder commenting

The Chair reported that a discussion had taken place in closed session on the mechanism by which the regular stakeholder observers participating to the meetings could provide written comments on either general or dossier-specific issues. The outcome of the discussion had been to request the Secretariat to establish specific newsgroups to collect comments from stakeholders per meeting or per substance dossier, as appropriate. Any comments on general issues (e.g. minutes) were to be sent by stakeholders to the Secretariat by email to the RAC functional mailbox. It was also pointed out that in relation to dossiers, stakeholders should submit their comments, like the MSCAs, through the public consultation via the webforms on the ECHA website, and that these comments need not and should not be repeated via the Newsgroups.

14c CIRCA Newsgroup instructions

The Secretariat presented the various functionalities of the RAC CIRCA IG, including some recent changes that had occurred in switching to the secure CIRCA platform. These were also summarised in document RAC/06/2009/29.

Members were asked about their preference for receiving notifications of a batch upload of documents – either one notification per document or one per batch. Members preferred one notification per batch, but requested an email as well to inform them of the batch upload.

Item 15 Action points and main conclusions

The Secretariat presented a draft table of the conclusions 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 main conclusions and 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.

Item 16 Information session on IUCLID 5 for RAC

The Secretariat gave a presentation to RAC participants on IUCLID 5 and its various functionalities.

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II. MAIN CONCLUSIONS AND ACTION POINTS

RAC-6 ACTION POINTS & MAIN CONCLUSIONS– 21-23 April 2009

(as adopted at the RAC-6 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the RAC-6 Agenda	• RAC adopted the Draft RAC-6 Agenda without changes	• Adopted RAC-6 Agenda to be annexed to RAC-6 Minutes (SECR / after the meeting)
4. Draft Minutes **4a.** Adoption of the RAC-5 Final draft Minutes	• RAC adopted the Draft final minutes with minor changes	• Adopted minutes of RAC-5 to be uploaded to CIRCA and ECHA website (SECR / after the meeting)
4b. Status report on the RAC-5 Action points	• There was one outstanding action identified from RAC-5 which was transferred to these action points	• (AP 6, RAC-5 minutes) SECR to present the recommendations from the MSCAs workshop on restriction and authorisation at a forthcoming RAC plenary meeting after presentation to the REACH CA meeting (For RAC-7/SEAC-4 joint session)
5. Administrative issues **5a**. Feedback on using the KALEVA services		• Members to submit comments in writing to SECR to collect further feedback on using the KALEVA services (continuous) • SECR to reply on questions received.
7. SEAC/RAC arrangement. Further progress of the SEAC-RAC arrangement (oral report of the second meeting held on 20 April 09	RAC took note of feedback from SEAC/RAC arrangement on outcome of the role play mimicking part of the restriction process using MCCPs transitional dossier concluding that: • it was a very valuable exercise • recommended to repeat the exercise in a smaller scale for joint RAC/SEAC session	• Chair's report of 2nd SEAC/RAC meeting to be prepared and uploaded to RAC CIRCA IG when available (SECR) • Depending on permission of UK, SERAC role play rapporteurs to prepare short background document (mini-Annex XV dossier) for break out groups for joint RAC/SEAC session
8. Restriction **8a.** WP on processing of an	• Preliminary agreement on WP (doc RAC/06/2009/17) was reached.	• SECR to upload the preliminary agreed procedure to the RAC CIRCA IG (after the meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
Annex XV restriction dossier		• SECR to inform CARACAL on the proposed timelines in the WP affecting them as dossier submitters (June 2009)
8b. Draft opinion and background document template	• RAC suggested a definition of "restriction" to be included in the introduction to the document (doc RAC/06/2009/19) • RAC supported a common BD with RAC-specific sections and SEAC specific sections in line with the division in conformity check report • Preliminary agreement on the opinion template was reached.	• SECR to prepare revised version considering the comments received and to upload preliminary agreed document to RAC CIRCA IG
8c. WP on appointment of RAC (co-) rapporteurs for restrictions	• RAC suggested to provide in WP a concept of a pool of volunteers to be potential rapporteurs at the RoI's stage, and then select later from the pool when the dossier submission date was clearer.	• SECR to consider the comments received, revise the document and provide the revised document by RAC-7
8d. Draft terms of reference for restriction (co-) rapporteurs	• Preliminary agreement on the document RAC/06/2009/21 was reached.	• The final version of the document to be uploaded to RAC CIRCA IG (SECR/ after the meeting)
9. Preparation for the forthcoming Joint RAC-7 & SEAC-4 plenary meeting (continuing the discussion)	• RAC supported the ideas of the SECR on the structure and content of the Joint RAC & SEAC session planned for the end of June	• SECR to consider the comments received and to continue planning of the Joint session • SECR to consider including a presentation(s) on common understanding of what a restriction in Annex XVII exactly means and how they have they have been developed in the past • SECR to consider inviting COM to give presentation on other Community RMMs (such as IPPC, WFD, OEL, Waste Directive)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
10. CLH dossiers **10a.** Feedback on the accordance checks of the on-going CLH dossiers	RAC made some general observations, as follows: • Information in the CLH report that is not related to the proposed classification may be suggested to be removed from the CLH report but retained in the IUCLID 5 dossier, if there is no rational for its inclusion, i.e. relevance of the data to the proposal to be specified. • Request the SECR to ensure that the accordance check reports are available before the meeting • Information and assessment from other regulatory programmes (i.e. secondary sources) may be used on a case-by-case basis without the need to go into the original studies, depending on the purpose of the original assessment and level of detail provided • More guidance should be provided to MSCAs on how to describe justification for classification proposal, mere data description is insufficient. • The CLH report serves two purposes: providing the scientific justification for the proposal and communication to parties concerned. Thus, the report should be specifically tailored to the proposal	• SECR to take into account the comments from RAC during the revision of the Guidance Documents on preparing a dossier on harmonised classification and labelling and accordance check templates
10b. Learnings from the accordance checks useful to be transferred in the conformity check procedure	RAC supported the Secretariat's view on what lessons learned from the accordance check could be transferred to the conformity check and suggested in addition to ensure that MSCAs were aware of the conformity check template when preparing Annex XV report, i.e. how conformity would be assessed by RAC and SEAC	• SECR to communicate the recommendations to SEAC (by SEAC-4)
10c. Substance identity in relation to presence of impurities	RAC made the following observations: • It is the same substance incl. its impurities that is manufactured, tested, registered, evaluated, proposed to be classified and included in Annex VI • Annex VI does not normally refer to impurities, and industry as responsible for classification and labelling of their substances should consider the impact of any impurities present • The submitter of the proposal when evaluating the studies, should consider the relevance of the studies to the substance for which classification is proposed	• SECR to consider how to provide clear rules in the guidance on what information MSCA should provide on impurities in relation to proposals for C&L • SECR to inform COM on the outcome of the discussion for COM's preparation of a document for next CARACAL

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
10d. Revised format for CLH reports	RAC made a number of suggestions on improving the draft format including: • Rational for classification to be included under each endpoint • The format should direct the MSCA to indicate clearly which endpoint(s) to be discussed by RAC, which ones are for support • Further instructions on how to fill in the format to be added • Lessons learned from the accordance checks	• Members to submit additional comments on the proposed format in writing to SECR via Newsgroup (by 30 April 2009) • SECR to consider the comments received, revise the format and to submit the revised format to CARACAL for endorsement
10e. Revised template for accordance check	RAC agreed to the proposed template with some editorial changes incl. instructions on how to fill in the template	• SECR to upload revised template to the RAC CIRCA IG (after the meeting)
10g. First feedback from the public consultation based on the comments received from the concerned parties	RAC was informed of nature and number of comments received in first public consultation on 2 substances diantimony trioxide and epoxiconazole.	• Table with compiled comments received from public consultation to be uploaded to RAC CIRCA IG (SECR/ by end of week) • SECR to consider improving the clarity of the webform for providing comments (SECR/ by next consultation) • SECR to consider revision of the working procedure to take into account the time ECHA needs to compile the comments.
11. Working procedure on appointment of RAC (co-) rapporteurs for a CLH dossier	• RAC agreed document RAC/06/2009/26 on working procedure on appointment of RAC (co-) rapporteurs for a CLH dossier as it was proposed by the SECR with some changes	• SECR to consider the comments received, revise the document and to upload the final WP on appointment of RAC (co-) rapporteurs for a CLH dossier on the RAC CIRCA IG (SECR/after the meeting)
12. Appointment of (co-) rapporteurs	• RAC agreed to appoint the proposed rapporteurs & co-rapporteurs for the newly registered intentions (see document RAC/06/2009/27_rev. 1).	• SECR to upload in RAC CIRCA IG the updated status document (SECR/ after the meeting)
14.AOB **14a.** Proposal for revision of Chapters R.10.5 and R.10.6 of the Guidance document on information requirements and chemical safety assessment	• RAC generally in favour but proposed that the implications on testing strategy and the environmental risk assessment methodology as a whole should be further considered before making a recommendation for update of the guidance.	• SECR to create a newsgroup for collecting comments by end of May (after the meeting) • SECR to consider how to bring forward such initiatives for guidance update from individual RAC members where further input required from RAC members to reach an agreed text.
14b. Stakeholder commenting	RAC proposed separate section of RAC CIRCA Newsgroup for	• Stakeholder newsgroups to be established per meeting

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
– Report from closed session	stakeholders to place dossier-specific comments before a meeting	or per dossier by SECR. • Comments on general issues (e.g. minutes) to be sent by e-mail to SECR. (RAC functional mailbox).
14c. CIRCA newsgroups	RAC agreed to receive just one automatic notification when a batch of documents is uploaded to the RAC CIRCA IG	• SECR to prepare and send a separate e-mail notification to RAC following the uploading of a batch of documents to the RAC CIRCA IG
GENERAL	-	• All presentations and room documents on CIRCA (SECR/by 24 April 09) • Conclusions and action points (i.e. this doc) to be uploaded to Circa (SECR /by 24 April 09)

III. List of Attendees

Members		**ECHA staff**
ANDERSSON Alicja		BERNASCONI Roberta
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
GREIM Helmut		KULJUKKA-RABB Terhi
JENSEN Frank		LIPKOVA Adriana
KADIKIS Normunds		LOGTMEIJER Christiaan
KREUZER Paul		LUOTAMO Marita
LARSEN Paul Bo		MUNN Sharon
LE CURIEUX-BELFOND Olivier		NYLUND Lars
LEINONEN Riitta		PEDERSEN Finn
LOSERT Annemarie		PELTOLA Jukka
LUND Bert-Ove		RÖCKE Timo
MULLOOLY Yvonne		RUOSS Jurgen
NUNES Céu		SADAM Diana
PICHARD Annick		SIHVONEN Kirsi
POLAKOVICOVA Helena		SPJUTH Linda
POSPISCHIL Erich		VAINIO Matti
PRONK Marja		VASILEVA Katya
RUPPRICH Norbert		YLÄ-MONONEN Leena
SCHULTE Agnes		
SMITH Andrew		**Stakeholder observers**
STOLZENBERG Hans-Christian		ANNYS Erwin (CEFIC, replaces J. HOLMQVIST)
SULG Helen		MEISTERS Marie-Louise (ECETOC)
TARAZONA Jose V.		SANTOS OTERO Tatiana (ETUC)
VAN DER HAGEN Marianne		LEENAERS Joeri (EUROMETAUX)
VAN MALDEREN Karen		WEFERS Heribert (EEB)
ZGLOBIU Mariana-Elena		
		Representatives of the Commission
Advisers to the RAC members		GRODZKI Karola (DG ENV)
ALESSANDRELLI Maria (adviser to Paola Di PROSPERO)		PUOLAMAA Maila (DG ENTR)
ANNOLA Kirsi (adviser to Paul KREUZER)		IAGHER Raluca (DG ENV)
GRACZYK Anna (adviser to Boguslaw BARANSKI)		
MORKA Heidi (adviser to Marianne van der HAGEN)		
LEIKOSKI Mervi (adviser to Riitta LEINONEN)		
Other participants		
GEORGIOU Stavros (SEAC Member, for 21 April only)		

IV. List of Annexes

ANNEX I	Final RAC-6 Agenda
ANNEX II	List of RAC-6 meeting documents submitted to the RAC Members

ANNEX I

21 April, 2009
RAC/A/06/2009

Final Agenda

Sixth meeting of the Committee for Risk Assessment

21 -23 April 2009
Helsinki, Finland
21 April: starts at 09:00
23 April: ends at 12:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/06/2009
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the draft minutes of the RAC-5

a. Adoption of the draft minutes

RAC/M/05/2009 draft final
For adoption

b. Status report on the RAC - 5 Action points

RAC/06/2009/15
For information

Item 5 – Administrative Issues

a. Feedback on using the Kaleva services

For information

b. Current status of the RAC overall competence grid

RAC/06/2009/16
For information

Item 6 – Feedback from other ECHA bodies and activities

For information

Item 7 – SEAC / RAC arrangement

- Further progress of the SEAC-RAC arrangement (including oral report of the 2nd meeting of 20 April 2009)

For information

Item 8 – Working Procedures - Restrictions dossiers

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

RAC/06/2009/17

For discussion and preliminary agreement

(Response to comments table) RAC/06/2009/18

For information

b. Draft opinion and background document (BD) template

RAC/06/2009/19

For discussion

c. Working procedure on appointment of RAC (co-) rapporteurs for a restriction dossier

RAC/06/2009/20

For discussion and preliminary agreement

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

RAC/06/2009/21

For discussion and preliminary agreement

(Response to comments table) RAC/06/2009/22

For information

Item 9 – Preparation for the forthcoming Joint RAC-7 & SEAC-4 plenary meeting

- RAC expectations from the Joint plenary meeting

For discussion

Item 10 – CLH dossiers

a. Feedback on Accordance Checks of the on-going CLH dossiers

For information and discussion

b. Learnings from the accordance checks useful to be transferred in the conformity check procedures

For discussion

c. Substance identity in relation to presence of impurities

RAC/06/2009/30
Room document
For discussion

d. Revised format for CLH reports

RAC/06/2009/23
For consultation

e. Revised template for accordance check

RAC/06/2009/24
For discussion and agreement

f. State of play of the submitted CLH dossiers

RAC/06/2009/25
For information

g. First feedback from the public consultation based on the comments received from the concerned parties

For information and discussion

h. Feedback from the CARACAL discussion on the document on CLH dossiers proposing not to classify a substance

For information and discussion

Item 11 – Working procedures – CLH dossiers

- Working procedure on appointment of RAC (co-) rapporteurs for a CLH dossier

RAC/06/2009/26
For agreement

Item 12 – Appointment of RAC (co-) rapporteurs for newly registered CLH intentions

- Appointment of RAC (co-) rapporteurs for the newly registered intentions in the RoIs

RAC/06/2009/27
For decision

Item 13 – Stakeholder commenting (CLOSED SESSION)

For discussion

Item 14 – AOB

a. Proposal for revision of Chapters R.10.5 and R.10.6 of the Guidance document on information requirements and chemicals safety assessment

RAC/06/2009/28
For discussion

b. Stakeholder commenting - report from the closed session

For information

c. CIRCA Newsgroup instructions

RAC/06/2009/29

For information

Item 15 – Action points and main conclusions of RAC-6

- Table with Action points and conclusions from RAC- 6

For adoption

Item 16 – Information session on IUCLID 5 for RAC

a. Presentation of IUCLID 5 and its application to RAC activities

For information

b. Practical hands-on exercise focused on RAC work

ANNEX II.

List of RAC-6 meeting documents submitted to the Members of the Committee for Risk Assessment

1	RAC/06/2009/15	Status report for RAC-5 Action Points
2	RAC/06/2009/16	Competence coverage-RAC Overall Competence Grid
3	RAC/06/2009/17	Revised draft WP for processing an Annex XV proposal for restrictions
4	RAC/06/2009/18	RCOM to RAC comments on the Preliminary draft RAC WP on processing of an Annex XV proposal for restrictions
5	RAC/06/2009/19	The opinion of RAC on restriction proposal and BD template
6	RAC/06/2009/20	WP on appointment of RAC (co-)rapporteurs for a restriction dossier
7	RAC/06/2009/21	Revised draft ToRs for RAC (co-)rapporteurs (Restrictions)
8	RAC/06/2009/22	RCOM to RAC comments on the letter of appointment and draft RAC ToRs for (co-)rapporteurs (restrictions) for Annex XV dossiers proposing restrictions
9	RAC/06/2009/23	Revised format for CLH reports
10	RAC/06/2009/24	Revised template for accordance check
11	RAC/06/2009/25	State of play of the submitted CLH dossiers
12	RAC/06/2009/26	WP on appointment of CLH rapporteurs
13	RAC/06/2009/27	Appointment of rapporteurs for the newly registered intentions
14	RAC/06/2009/28	Proposal for revision of Chapters R.10.5 and R.10.6 of the Guidance document on information requirements and chemicals safety assessment
15	RAC/06/2009/29	Updated CIRCA Newsgroups guidance
16	RAC/06/2009/30	ROOM Doc- Consideration on impurities presents (individual member's view)