Helsinki, 5 October, 2009
RAC/M/07/2009 final

Final

Minutes of the 7th meeting of RAC
(30 June – 3 July 2009)

Part I. Summary Record of the Proceeding of the joint session of the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) within the 7th meeting of RAC and the 4th meeting of SEAC (30 June – 1 July 2009)

1. Welcome notes by RAC and SEAC Chairs

Ms Sharon Munn (Chair of the Committee for Risk Assessment, ECHA), who chaired the first half of the meeting, welcomed the participants of the joint session of the Committee for Risk Assessment and the Committee for Socio-economic Analysis held within the seventh meeting of RAC and the fourth meeting of SEAC. The Chair informed the meeting that among the participants of the joint session there were 30 RAC members and 26 SEAC members, two replacements of RAC members and four replacements of SEAC members, four advisors of RAC members and five advisors of SEAC members as well as three representatives of the Commission services and nine representatives of stakeholder organisations participating in the meeting as observers. The list of attendees is given in Part III of the minutes.

The Chair informed the participants that the meeting would be recorded.

2. Adoption of the Agenda for the joint session

The Agenda of the joint session (RAC/A/07/2009, Part I and SEAC/A/04/2009_rev.1, Part II) was adopted without any changes.

No participants declared any conflict of interest to the items on the Agenda of the joint session.

3. Preparatory session for the role play

The Chair explained that prior to and during the second meeting of the SEAC-RAC Arrangement on 20 April 2009 its members participated in a role play of rapporteurs' tasks based on a transitional dossier on MCCPs (medium-chain chlorinated paraffins). The participants of the Arrangement suggested repeating the role play in the joint RAC-SEAC meeting using a simplified Annex XV dossier. A presentation was then given by the Secretariat describing the purpose of the role play, suggesting how to structure the discussions in the break out groups, explaining the roles of different players as well as providing other useful advice on how to work during the role play. The main aim of the role play was to simulate the discussions between the RAC and SEAC rapporteurs during their first dialogue foreseen in the working procedures on developing RAC and SEAC opinions on Annex XV restriction dossiers. Each group was assigned to exchange views and form a preliminary opinion on the appropriateness of the proposed restriction on MCCPs in leather fat liquoring and not proposing a restriction on the use of MCCPs in metal working fluids.

4. Role play in break out groups

Parallel discussions were held in eight break out groups on a simplified MCCP dossier.

5. Welcome notes by Executive Director

Mr Geert Dancet, the Executive Director of ECHA, welcomed the participants of the joint plenary session of RAC and SEAC. He explained that such a joint meeting was the first of its nature and that ECHA considered it was important to bring these two key ECHA Committees together at an early stage as their future work on authorisations and restrictions will be very closely linked.

The Restrictions title of REACH provides that the Committees for Risk Assessment and Socio-economic Analysis shall each formulate an opinion on a restriction proposal, which will then be submitted by ECHA to the European Commission for a decision. Therefore, the need to find a "common language" for the two Committees is core. Mr Dancet recalled that it was with this objective in mind that a crash course on socio-economic analysis was provided for the members of RAC in early 2009 and a chemical safety assessment course was provided for the SEAC members

prior to the joint RAC-SEAC session. The Executive Director expressed his hope that these training sessions had served to broaden the common understanding of the respective roles of the Committees.

Mr Dancet also stressed that the joint plenary session provided a unique opportunity for the members of both Committees to get to know each other and try to understand each others concerns and needs in their work. He added that the meeting would hopefully enable a fruitful and successful collaboration between the Committees and the individual members so that the Agency, of which the two Committees are part, can deliver high quality opinions to the decision makers.

6. Lessons learnt from the role play

A presentation on the lessons learnt from the role play, prepared together with the facilitators of the break out groups, was given by the Secretariat. The discussion on the lessons learnt as well as the presentation given by the Secretariat have been summarised and presented in Annex III of the minutes.

The Secretariat proposed to finalise the presentation and upload it to CIRCA by 7 July 2009 and would also upload to Circa the Chair's summary from the second meeting of the SEAC-RAC Arrangement.

7. Common restriction issues

a) Overview of current restrictions in Annex XVII

A presentation was given by the Secretariat describing the Annex XVII restrictions. According to the REACH Regulation (Article 3(31)), a restriction means any condition for or prohibition of the manufacture, use or placing on the market. This definition is broad and open and gives a lot of possibilities to build up a restriction. Article 68(1) of REACH sets the basic conditions for the introduction of a restriction and these are unacceptable risk to human health or the environment, and Community-wide action required to address this risk. Important restriction characteristics are effectiveness (targeted to the effects, capable of reducing these effects to an acceptable level and within a reasonable period, proportional to the risk), practicality (implementable by the actors concerned, enforceable and manageable by the authorities) and monitorability (possible to monitor the result of the implementation). The content of the updated Annex XVII, which entered into force on 27 June 2009, was explained as well as the main elements of the Annex XVII entries. The Secretariat explained the difference in regulatory approach between a total ban and a targeted restriction, and illustrated both types with examples. Possible restriction conditions were also described and examples were given. Finally, some reasons for the diversity of restrictions were highlighted. It was concluded that the approaches and conditions are likely to be diverse in the future restrictions, too.

A participant asked whether it is possible to set conditions under REACH which would be very close or even the same as they would be under other legal instruments, such as the Water Framework or IPPC Directives. The Secretariat replied that as a restriction is defined as "any condition" under REACH, it would be in principle possible to introduce such a condition. However, for legal coherence and consistency, it would not be appropriate to propose conditions under REACH if they would be more appropriately addressed under other legislation.

b) Examples of process in the past for development of these Annex XVII entries

The Secretariat presented an example of how the restriction had been developed in the past, based on the organotins case. Organotins are mono-substituted organotins (e.g. used as plasticisers, catalysts), di-substituted organotins (e.g. stabilizers, catalysts) and tri-substituted organotins (historically used e.g. as biocides in anti-fouling products, consumer products, wood treatment and as pesticides). Exposure to certain organotin compounds has been scientifically proven to disrupt the endocrine system and cause harm to human health and the environment. Organotins are used in a

large number of different applications, including many consumer products; consumers are therefore exposed to a range of different products containing organotin compounds. The starting point was the restriction on placing on the market and use of organotins through amendments to the Marketing and Use Directive (76/769/EEC – "Limitations Directive"), which covered the main biocidal uses of organotins. The Commission Directive 2002/62/EC of 9 July 2002 restricted the use of all organostannic compounds in quite general terms, but specified the use – in biocides – in some detail and was thus practically directed towards tri-substituted organotins. Further work in years 2002-2009 was prompted by national concerns and the amended broader restriction was adopted on 28 May 2009 (Commission Decision 2009/425/EC). The actors and the main documents in the restriction process were described as well as observations given regarding the discussions, the process, the stakeholders` participation and the progress. Finally, equivalent points in the REACH process were identified.

A participant observed that for a lot of other substances under the Directive 76/769/EEC, almost the same discussions took place in the working group of the Council as in the Limitations Working Group. The process was therefore very time-consuming in the past. Another participant emphasised the preparatory work of the dossier and expressed the concern that REACH does not give much possibility for involvement of other MS competent authorities (CAs) or stakeholders in the preparatory phase. The Secretariat responded that the Registry of Intentions (RoI), which is publicly available, provides information on the restrictions under preparation and gives thus a possibility to the parties concerned (including stakeholders) to contribute early in the process. Stakeholder consultation during the preparation of a restriction dossier is highly recommended. A participant asked how many restriction dossiers the Committees and the Secretariat will have to handle. The Secretariat replied that the number of dossiers will depend on MS CAs (how active they are) and on the Commission who can ask ECHA to prepare the restriction dossiers. The Secretariat added that a discussion forum had been created for MS CAs to discuss their intentions before submitting them officially into the RoI. Such an informal RoI provides a good possibility for ECHA to know well in advance which dossiers are coming and when.

c) Draft opinion and background document template

The Secretariat recalled that SEAC had discussed the document "The opinion of SEAC on a restriction proposal" (SEAC/03/2009/05) in its third meeting in February 2009. In April 2009, RAC discussed a parallel document "The opinion of RAC on a restriction proposal" (RAC/06/2009/19), prepared as a revision of the SEAC document. In drafting the document for RAC, ECHA had carefully taken into account the results of the discussion in the SEAC-3 meeting as well as the written comments submitted by SEAC afterwards. In addition, the Secretariat had consulted the Commission services as the opinion ultimately needed to be useful in the "comitology" process (with parliamentary scrutiny reservation). The meeting document (RAC/07/2009/31 and SEAC/04/2009/17) had been updated on the basis of the discussion in the RAC-6 meeting and was now presented to both Committees for agreement. The Secretariat explained that the template aimed to provide a general outline and structure for the opinions and it was proposed to be used as a starting point for the work. Once experience had been gained on preparing the opinions and the background documents, the template could be modified as appropriate. Furthermore, the Secretariat stressed that as dossiers would probably vary considerably, the template needed to be used in a flexible manner (e.g. how the exact wordings were formulated).

RAC and SEAC agreed on the proposed Opinion and Background Document template.

d) Clarification of the support available to RAC and SEAC rapporteurs

The Chair explained that the meeting document RAC/07/2009/32 for RAC and SEAC/04/2009/18 for SEAC summarised the sources of support that would be available to RAC and SEAC (co-)rapporteurs within the process of development of RAC and SEAC opinions on Annex XV restriction dossiers. The Chair recalled that the need for such a summary was flagged by the

Committees within their discussions on the terms of reference for (co-)rapporteurs (ToR) and originally the intention was to include it in the ToR as an annex. However, it was later not considered appropriate to include it in the ToR and it was decided to produce a separate document on this topic instead. A brief presentation was then given by the Secretariat describing all sources of support available to RAC and SEAC rapporteurs listed in the document - MS, dossier submitter, ECHA Secretariat, other Committee members, ad hoc working groups, invited experts, members' advisors and observers. It was stressed that the main support to a (co-)rapporteur should be provided by his/her MS and thus, before accepting the nomination to become a (co-)rapporteur, the Committee member should make sure that the MS would be ready to provide adequate support to execute his/her tasks.

A participant proposed to make this document available also to MS CAs. It was agreed that the Secretariat would forward the document to CARACAL for their next meeting.

8. Information on the registered intentions for submitting Annex XV dossiers proposing restrictions

The Secretariat informed the meeting that Title VIII of REACH had entered into force from 1 June 2009 and that there was already a few intentions registered in the RoI (by Norway and France). The RoI is publicly available on the ECHA website1. The Secretariat asked RAC and SEAC members to consider volunteering for rapporteurships and co-rapporteurships on the basis of the information provided in the RoI. It was also noted that according to the Committees' working procedures, the appointment of rapporteurs and co-rapporteurs should be done at the earliest possible stage and further formalised at the latest after the Annex XV dossiers proposing restrictions have been submitted.

A participant asked whether it was possible to clarify from the MS CAs who have submitted their intentions whether the dossiers under preparation are mainly related to human health or environmental risks or both. Such information would be helpful for RAC and SEAC members in deciding whether to volunteer for the rapporteurship. The Secretariat agreed to clarify this with the MS CAs concerned.

9. Joint information session

Starting from the Agenda Point 9, the meeting was chaired by Ms Ann Thuvander, Chair of the Committee for Socio-economic Analysis, ECHA.

a) Process for guidance updates

The Chair explained that the Agenda Point on the process for guidance updates was introduced in the Agenda of the joint session as a result of the request from RAC expressed in the RAC-6 meeting to clarify the possibilities for the Committee to initiate an update of ECHA guidance relevant to RAC tasks. The ECHA Secretariat agreed to raise the issue with the ECHA guidance team and to bring forward a proposal for a procedure to address this possibility which would feed into the currently agreed process for guidance updates.

The Secretariat then presented the meeting document RAC/07/2009/33 for RAC and SEAC/04/2009/19 for SEAC, which described the process for guidance updates and the role of the Committees in this process. The legal basis for ECHA to provide guidance is given in Article 77(2)(g) of the REACH Regulation, according to which ECHA's task is, where appropriate, to provide technical and scientific guidance and tools for the operation of REACH for industry, especially SMEs, and for other stakeholders. Guidance is not a legally binding document, but it provides industry and authorities with a commonly agreed view on how to implement the REACH

[1] http://echa.europa.eu/chem_data/reg_int_tables/reg_int_curr_int_en.asp

Regulation. The Secretariat informed the meeting that a few months ago the ECHA's Framework for the Governance of Guidance Management had been adopted, which gave a general structure on how to implement the process of developing or updating guidance. According to this framework, an important step in guidance development/update is the consultation process. The Committees were informed that during the consultation procedure on a specific guidance document the consultation of stakeholders takes place through a Partner Expert Group (PEG), ECHA Committees and/or the Forum, and finally MSCAs (CARACAL). The Committees also have a possibility to raise issues themselves and were advised to channel these issues via the ECHA Secretariat. However, the Secretariat emphasised that the Committees should raise only such issues which have an impact on the Committee's work.

One participant asked whether ECHA foresees the same procedure for the updating of the guidance on CLP. The Secretariat confirmed that the same procedure will be used for the CLP Regulation.

b) Conclusions and recommendations from the authorisation workshop of January 2009
The Secretariat reported on the workshop on the Candidate List and Authorisation as Risk Management Instruments under REACH held in January 2009. Reasons for organising such a workshop, main conclusions as well as recommendations and follow-up actions were described. The Secretariat informed the meeting that the link to the report of this workshop had been uploaded to both RAC and SEAC CIRCA Interest Groups.

10. Feedback from other ECHA bodies and activities
The Chair of the Committee for Risk Assessment summarised the recent developments in RAC. With regard to classification and labelling, 16 accordance checks had been completed on the submitted dossiers and six were still in process. Three public consultations were ongoing and two have already been completed. The meeting was informed that RAC would discuss its first draft opinion (on diantimony trioxide) within the RAC separate session following the joint RAC-SEAC plenary meeting. The Chair of RAC also mentioned that the working procedures on classification and labelling were being revised due to the change in the legal basis with the entry into force of the CLP Regulation.

The Chair of the MSC gave feedback from the last two meetings of the Committee – the MSC-7 held in April and the MSC-8 held in May 2009. During these meetings, the Committee discussed mainly its opinion on ECHA's draft recommendation for the inclusion of substances into Annex XIV. The opinion was drafted by the rapporteur with the help of a working group consisting of six members of the Committee, and was based on the following input: ECHA's original draft recommendation and supporting documents, comments submitted within the public consultation (altogether 365 comments were received), ECHA's response to these comments and ECHA's draft recommendation revised on the basis of the comments. The Chair of the MSC described the challenges which the Committee had faced in the preparation of the opinion and informed the meeting that ECHA's final recommendation took into account the opinion of the MSC and that the establishment of the Annex XIV by the Commission can be expected in late 2009 – early 2010. The MSC work plan for the second half of 2009 was also briefly introduced.

The Secretariat then made a brief report from the last two meetings of the ECHA Management Board (MB). In its meeting in April 2009, the MB adopted ECHA's general report of 2008 as well as the Executive Director's annual activity report of 2008. Both reports had been published on the ECHA website. The rules of reimbursement of REACH tasks to MSs were discussed and agreed. It was also noted that four new stakeholder organisations were added to the list of eligible stakeholders (the names of the organisations have been published on ECHA's website). In the June 2009 meeting, the discussion was mainly concentrated on the access of MSCAs to REACH-IT. The enforcement authorities' access to REACH-IT was also touched upon and the MB had agreed to a document concerning the list of data in REACH-IT to which the enforcement authorities should

have access. The Secretariat mentioned that the appointment of three new members of the Committees took place in the June MB meeting.

A report was also given by the Secretariat from the last Forum meeting. One of the main discussion points was the access of the enforcement authorities to REACH-IT. Co-operation with the customs was also discussed and a working group was decided to be created to facilitate this co-operation. The Forum adopted its working procedure for development of the Forum advice on enforceability of the Annex XV proposals for restriction and established a working group on Restrictions to facilitate the elaboration of the Forum advice.
Finally, a brief report was provided from the June 2009 CARACAL meeting. The access of MSCAs to REACH-IT was extensively discussed also in this meeting. Timelines for the processing of a restriction dossier as foreseen in the working procedures of the Committees were introduced to the CAs, foreseeing four possible submission dates in a year according to the cycle of Committee meetings but with a request to aim to avoid one of the dates which would lead to difficulties in one of the critical steps which would fall in the summer holiday period. The dossier submitter's tasks in the working procedures of RAC and SEAC were also presented, which MSCAs agreed to. The workshop on Evaluation planned for MSCAs for September 2009 was announced by ECHA. The Secretariat also informed the meeting that a document on the RoI was provided to the MSCAs and proposed to make this document available also to RAC and SEAC for information.

11. Co-operation with other Community bodies

The Secretariat explained that the REACH Regulation contains legal provisions that address the co-operation with and co-ordination of the work between ECHA and other European Community agencies and scientific committees of relevant EC institutions and bodies (like the European Food Safety Authority and the Advisory Committee on Safety, Hygiene and Health Protection at Work). The scope of co-operation and co-ordination of the work should embrace the opinions adopted by the ECHA Committees but also possibly other types of co-operation. The Secretariat informed the meeting that the REACH Regulation calls also for formally adopted Rules of Procedure (RoPs) on the aspects of co-operation. As Committees are to be consulted when establishing these RoPs, the meeting document RAC/07/2009/34 for RAC and SEAC/04/2009/20 for SEAC presented a roadmap towards their adoption with the indication of involvement of the Committees in the process. Possible elements for the RoPs were introduced to RAC and SEAC.

12. Administrative issues

a) Remuneration of RAC and SEAC rapporteurs for Annex XV dossiers proposing a restriction

The Secretariat recalled that in line with the REACH Regulation, a proportion of fees collected by ECHA under the Fee Regulation should be transferred to MSCAs to compensate them for certain REACH tasks (substance evaluation and rapporteur work done in RAC and SEAC on restrictions and authorisations). According to the Fee Regulation, it is for the MB of ECHA, following a favourable opinion from the Commission, to establish financial arrangements for such transfers, including the amounts to be transferred. The Committees were informed that the MB had discussed in its meeting in February 2008 the reimbursement of tasks executed by MSs and had appointed a working group chaired by the ED of ECHA, consisting of representatives from DE, UK, SE, the Commission and ECHA. The final report of this working group, together with the proposal for a Decision on the financial arrangements for transfer of a proportion of fees to the MSs, was presented to the MB at its meeting in April 2009, where the MB approved the proposed draft decision after which it was sent to the Commission for opinion. The Secretariat added that after receiving an opinion from the Commission, the MB will have to adopt the decision. The Secretariat presented the legal framework of the draft decision, the principles followed in the development of the draft decision as well as the scale of payments set in it.

b) RAC/SEAC members` access to information in REACH-IT
The Chair informed the meeting that the Room document RAC/07/2009/46 for RAC and SEAC/04/2009/23 for SEAC had been distributed to the participants of the meeting summarising RAC and SEAC members' information needs for data in REACH-IT. The presentation was then given by the Secretariat describing what kind of access to REACH-IT MS CAs, enforcement authorities and members of the Committees will have. The MS CAs will have a full access to the REACH-IT database (with the exception of the PPORD). However, as it contains confidential business data, very strict security requirements will have to be applied. The enforcement authorities will have an access limited to an extract of REACH-IT called RIPE. The Committees were informed that the MB had approved in its June 2009 meeting the list of RIPE data compiled by the Forum. The Committees' members should have access to the data needed for their work but this has to be defined. The Secretariat informed the meeting that for the moment CIRCA is going to continue to be used for sharing of data. However, more precise security rules will have to be applied on the handling of the data by members. The Secretariat noted that for 2010 ECHA is going to prepare a new secure system to replace CIRCA.

It was agreed that the Secretariat will open a written commenting round on the Room document RAC/07/2009/46 for RAC and SEAC/04/2009/23 for SEAC.

13. AOB
The Secretariat informed the meeting that the MB revised in its last meeting the ECHA Guide for the Reimbursement of travel and accommodation expenses and payment of subsistence allowances and that the only change concerned the amount of deduction for lunches and dinners organised by ECHA.

14. Action points and main conclusions of the joint RAC-7 and SEAC-4 session
RAC and SEAC agreed on the conclusions of the joint session and the action points to follow the joint session as laid down in Part II of these minutes.

Part II Summary record of the proceedings of the RAC separate session (2-3 July)

1. Welcome and apologies
The Chair welcomed participants to the meeting, including six advisers and four stakeholder representatives (from EEB, EUROMETAUX, CEFIC and ECETOC). A representative from the MSCA that proposed the CLH dossier for diantimony trioxide (DAT) was present for item 7c. Two invited experts attended the meeting replacing members, Thomasina Barron and Paola Di Prospero. 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 four members and four regular observers (from OECD, ECEAE, ETUC and HEAL). Two members were absent. The list of attendees is given in Part III of these minutes.

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.

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 meeting2. Two members from SE declared they were from the same Agency where the dossier to be discussed at agenda point 7c was prepared.

4. Approval of the draft minutes of RAC-6

4a Approval of the draft minutes of RAC-6

The Chair introduced the revised minutes, incorporating the comments received from two members. RAC approved the revised minutes without further changes. The Secretariat was to make the final version available on the RAC CIRCA IG and the ECHA website.

4b Status report on the RAC-6 Action points

The Chair reported that all action points from RAC-6 (document RAC/07/2009/36) had been completed, with the exception of one issue that had been carried over to actions from this meeting (see action points RAC-7).

5. Working procedures – Annex XV restriction dossiers

5a Working procedure for processing an Annex XV restriction dossier

The Secretariat introduced the revised draft working procedure (document RAC/07/2009/37) and noted that the revision was very similar to the version on which preliminary agreement had been reached at RAC-6. The document had been revised to take into account the working procedure for developing Forum advice on enforceability for Annex XV restriction proposals that had been agreed at Forum-4. Some minor editorial changes had also been made. The Secretariat noted that, if necessary, the working procedure would be reviewed in the light of experience of its application to restriction dossiers.

RAC agreed the document without further changes. The final version was to be uploaded to the RAC CIRCA IG and to the ECHA website after the meeting.

5b Working procedure on appointment of RAC (co-) rapporteurs for restrictions

The Secretariat introduced the revised working procedure (document RAC/07/2009/38) and explained that the main difference between this version, and the version presented at RAC-6, on the request of members, was the creation of a pool of eligible rapporteurs in the working procedure. The revised procedure now involved inviting nominations for rapporteurs as early as possible, creating a pool of eligible rapporteurs, and then to finally appoint a rapporteur closer to the expected time of dossier submission. The Secretariat noted that, if necessary, the working procedure would be reviewed in the light of experience of its application to restriction dossiers in practice.

The working procedure was agreed subject to making the submission of supporting documents to nominations optional (step c in the working procedure). The final version was to be uploaded to the RAC CIRCA IG and to the ECHA website after the meeting.

5c Draft terms of reference for restriction RAC (co-) rapporteurs

The Secretariat presented the revised draft terms of reference document (RAC/07/2009/39) and explained that the revised version was very similar to the version on which preliminary agreement had been reached at RAC-6. Several modifications had been introduced to the document to be consistent with the changes introduced in the working procedures for processing an Annex XV

[2] According to Article 9(2) of the RAC Rules of Procedure (RoPs).

restriction dossier and the working procedure for the appointment of rapporteurs (see items 5a and 5b above). The document also included some editorial changes.

RAC members agreed the terms of reference document with a minor editorial change. The final version was to be uploaded to the RAC CIRCA IG and to the ECHA website after the meeting.

6. CLH procedural documents

6a Draft procedure for delivering opinions for CLH proposals for substances previously agreed at TC C&L

The Secretariat gave a presentation to introduce this item (documents RAC/07/2009/40 & RAC/07/2009/47). It was explained that the Technical Committee for Classification and Labelling (TC C&L) at DG JRC had agreed on the final recommendations for harmonised classification and labelling (CLH) for inclusion in the 31st Adaptation to Technical Progress (ATP) amending Annex I to Directive 67/548/EEC by its May 2006 meeting. However, as these classifications could not be formally adopted before the first reading agreement in the legislative process of the CLP Regulation, they were not included in the CLP Regulation adopted on 16 December 2008. The classifications are now included in the proposal for the 1st ATP of the CLP Regulation and will be included in Annex VI.

After May 2006, TC C&L continued its activities for an additional year and during this period final recommendations for CLH of a further 87 substances were made. This group of substances included new and existing substances, pesticides and biocides. It also included 33 new or revised classifications for carcinogenicity, mutagenicity, toxic for reproduction (CMR) or as respiratory sensitizers, as well as 54 substances with classifications for other hazard classes. The inclusion of these substances in Annex VI of the CLP Regulation was therefore considered urgent. However, according to the Commission, as confirmed at the recent CARACAL meeting held on 15-16 June 2009, since there were no transitional provisions in the CLP Regulation for these substances there was no other possibility than to apply the normal procedure according to Articles 36-38 of the CLP Regulation. Therefore, Member States should submit a dossier with a proposal for harmonised C&L to ECHA for each of the 87 substances and, despite these substances being regarded as having been finalised at EU expert level, RAC has to formulate an opinion on the proposals, including a consultation of concerned parties.

A long discussion took place in which members expressed their opposition to the duplication of work previously done by TC C&L and their concern that processing these 87 substances should not delay work on the new CLH proposals being considered by RAC. Several members queried why the substances could not be incorporated directly into the 2nd ATP to the CLP Regulation, without the need for a RAC opinion. In particular, members expressed concern about holding public consultations on the substances which had already been extensively discussed and commented on by all stakeholders. Members proposed that wherever possible, efficient methods for processing the TC C&L agreed substances should be found. The members suggested first of all that the ECHA Secretariat identifies the lead MSCAs on each of the dossiers and provides advice on how to make best use of the existing documentation in the compilation of the dossiers, along the lines described in RAC/07/2009/40. It was also supported to fully utilise the previous work from TC C&L and focus any discussions on the impact of any new information on the TC C&L agreed proposal. Whilst accepting that a rapporteur would need to be appointed for each dossier, grouping of similar substances with one rapporteur could be considered, as well as the use of written procedures to agree on opinions. Some members suggested that it might be beneficial to draw up minimum information requirements in a dossier that RAC would need in order to form an opinion on these substances, possibly by a working group. Several members also highlighted the importance of carefully presenting the proposals for public consultation, possibly in a separate section to the other standard dossiers, and ensuring via an introductory text that the background to these substances is

understood. It was the general opinion that if no new data were brought forward during the public consultation, the RAC would confirm the conclusions of the TC C&L. A statement on this could be included with the public consultation in order to avoid resubmission of information already considered by TC C&L. The text of the opinion may also be modified to explain and reflect the special case of these substances. In relation to accordance checks, some members were in favour of omitting this step.

The Secretariat thanked members for their constructive suggestions for the efficient processing of these substances. The Secretariat agreed it would further consider how best to proceed in the most efficient way possible, keeping RAC informed and, if appropriate, submit proposals to CARACAL. In particular, the Secretariat may: identify the lead Member State for each dossier; provide additional assistance with the substance identification aspects of dossiers; and consider options for supporting dossier submitters to prepare dossiers. In addition, it was also agreed to consider: the careful presentation of proposals for public consultation; to streamline the procedure for processing these proposals by RAC, including possibly waiving the accordance check; as well as considering tailoring the contents of the opinion template for these dossiers.

6b Revised working procedure for the accordance check of a CLH dossier and template for the outcome of an accordance check

The Secretariat introduced the revised working procedure (document RAC/07/2009/41) and noted that changes had been made: to take into account the new EC Regulation on Classification, Labelling and Packaging ('the CLP Regulation', Regulation (EC) No. 1272/2008); in the light of experience with the first 16 CLH dossiers processed in the period June 2008-June 2009; and to include some editorial changes.

RAC members discussed the revised working procedure and posed several questions. One member requested (co-) rapporteurs be informed when the dossier is first received by ECHA in order to be alerted that an accordance check would be required several weeks later. It was agreed to add this point to the first step of the working procedure. Another member noted that a dossier submitter may decide that it wishes a dossier that had failed the accordance check to be processed without modification. In this scenario, the member requested clarification whether a rapporteur could withdraw from rapporteurship. Another member queried how the substance identification aspects would be addressed if the dossier submitter was not willing to modify and resubmit the dossier.

The Chair explained that (co-) rapporteurs would be alerted when a CLH dossier had been received at ECHA. In response to the second question, the Chair pointed out that the scenario of a dossier submitter requesting a failed dossier to be processed was expected to be rare. However, if it did occur, the rapporteur should proceed with the formulation of a draft opinion as required by the terms of reference. This draft opinion may state, where appropriate, that there was insufficient or unclear information to assess the proposed classification. Where the reason for failure was related to substance identification, the Secretariat would engage the dossier submitter in a discussion to clarify the issues as far as possible prior to public consultation.

The working procedure was agreed subject to the minor change noted above. The final version was to be uploaded to the RAC CIRCA IG and to the ECHA website after the meeting.

A discussion also took place on the template for recording the outcome of an accordance check that was annexed to the working procedure. It was explained that a slightly revised version to the one annexed to the working procedure taking into account comments made by the members at RAC-6 had been uploaded to the RAC CIRCA IG before the meeting. The revised template was agreed by RAC following presentation of the changes.

In addition, one member raised the issue of whether the requirements for robust study summaries (RSS), in relation to proposals for CLH for pesticide active substances, was now clear. The Secretariat replied that for an undefined time period (cut-off still under discussion) waiving of the requirement for RSS in the technical dossier was accepted for certain hand-over dossiers from the old legislation including proposals for biocide and pesticide active substances, provided the relevant information which might normally be found in the RSS was included in the CLH report, or in attachments to the IUCLID 5 technical dossier. A standard text had been adopted in the template in relation to this concession, which was inserted where relevant by the scientific dossier manager when filling the preliminary accordance check template for the rapporteurs.

Another member queried whether a question could be added to the accordance check template to emphasise the importance of the relationship between the identity of the substance which was the subject of the classification proposal and the identity of the substances used as a test material in the studies on which the classification is based (particularly with regard to level and nature of impurities present) (see discussion on impurities - item 10c RAC/M/06/2009 final). The Chair suggested that this aspect should be reflected initially in the CLH guidance for preparing a CLH dossier (see item 8) and the accompanying CLH report template and subsequently in the accordance check template.

7. CLH dossiers

7a Feedback on the accordance checks of the on-going CLH dossiers

Abamectin (CAS No.: 71751-41-2; EC No.: Not applicable)

It was clarified that the CLH proposal for this not currently classified substance aims to cover identified environmental and human health (acute, repeated dose and reproductive toxicity) hazards. The following details were reported: for classification purposes, the dossier submitter proposed the trade name abamectin to be used as this is the name of the plant protection product used in society; however, in contradiction with the defined composition for ISO name and CAS number for abamectin, it was identified that the tested substance contains more than 80 % avermectin B1a as main component and less than 20 % avermectin B1b. In such case, according to the substance identity rules under REACH, the substance should be considered as mono-constituent and named as avermectin B1a. Therefore, although the rapporteurs had found that sufficient information is provided for formulating an opinion, the dossier was not in accordance in relation to the substance identity. The rapporteurs suggested considering whether the dossier may be further processed with two names and CAS numbers (possible leading to two entries to be included later in Annex VI) while the problems related to substance identification and naming are solved in parallel.

The Secretariat provided more details of the nature of the problem of an incorrect ISO name as raised under the pesticides programme (due to the different MERCK definition) and that the dossier submitter is aware of the ISO naming problem and currently working on the solution. The Secretariat highlighted the importance of substance identification and correct substance naming, in particular with regard to the registration process under REACH.

RAC and the Secretariat agreed with the rapporteurs' proposal that for the purposes of the public consultation, abamectin could be referred to as abamectin and avermectin B1a and the correct name should be further clarified with the dossier submitter in parallel.

7b State of play of the submitted CLH dossiers

The Secretariat reported on the state of play of the submitted CLH dossiers and registered intentions by the date of the meeting, including new information which had become available since the status report (document RAC/07/2009/42) had been distributed. The Secretariat pointed to the withdrawal of the intention on n-hexane. The CLH dossier for chloroform had been postponed due to a need for inclusion of new data on mutagenicity and the dossier re-submission was expected in September 2009. The CLH dossier for abamectin had failed the accordance check due to substance identity

issues (see item 7a); for seven newly submitted dossiers the accordance check was in progress and public consultation was ongoing for four CLH dossiers (trixylyl phosphate, indium phosphide, di-tert-butyl peroxide and gallium arsenide). The Secretariat explained that the members would be provided with the most recent information after the meeting via RAC CIRCA IG in an update of the status document referred to under item 9 of the Agenda.

7c. First discussion on draft opinion on CLH dossier for Diantimony Trioxide (DAT) (CAS No. 1309-64-4, EC No. 215-175-0)

The Chair introduced the members to the procedural status of the CLH dossier for diantimony trioxide (DAT), submitted by Sweden, by explaining that following the public consultation on the proposal, Sweden had provided responses to comments and incorporated some changes in the background document. On this basis the rapporteur and co-rapporteur had drafted an opinion. The ongoing step was commenting by RAC on the rapporteurs' draft opinion on DAT. Some additional comments had been received and uploaded to CIRCA from the International Antimony Association (IAA) on request for clarification on certain aspects from the co-rapporteur. One written comment had been submitted from Eurometaux, on behalf of IAA, on the draft opinion, which had been uploaded to RAC CIRCA IG before the meeting and was presented as a Room Document. A representative of the dossier submitter from the Swedish MS CA had been invited for the plenary discussion for this agenda item as an observer. The Chair proposed to have a first discussion on the draft opinion and if possible to reach a conclusion and adopt the opinion at the meeting. She invited the rapporteurs for DAT and the dossier submitter to present the dossier as an introduction to the discussion.

The rapporteur for DAT introduced the discussion by explaining that the current classification for DAT in Annex VI is Carc. Cat. 3, R40 and that the proposal is to add classification for skin irritancy (Xi, R38). The rapporteur and co-rapporteur were both in agreement that the data provided in the dossier were insufficient to support classification as a skin irritant and this view was reflected in the draft opinion, and the background document had been revised in support of this opinion. The rapporteurs initiated a discussion by highlighting the most salient issues leading to their conclusions. The proposal was on the almost pure substance marketed as a white crystalline powder; there were negative results from all animal studies carried out with this substance although most of the studies were inadequate or inconclusive in some way; the evidence cited by the dossier submitter in support of classification was based on human experience from three factories as described in four cited papers, where exposure to fumes and dusts containing DAT in hot, sweaty conditions provoked irritant reactions. In the view of the rapporteurs, these data did not provide clear evidence that the substance itself had the inherent capacity to cause skin irritation, because substantial heat and sweat were required in addition to chemical exposure in all of the cases of skin effects described. Furthermore, the composition of the fume was not fully characterised and it was likely that DAT was not the only chemical species present in the fume to which these cases were exposed.

In conclusion, the rapporteurs whilst recognising that DAT-containing fumes had been related to irritant reactions in workers involved in smelting and processes involving molten antimony did not consider that this justified additional classification of pure diantimony trioxide as skin irritant at the Community wide level. The rapporteurs considered that the hazards posed by dust and fumes at antimony smelting plants should be addressed by use of appropriate risk management measures in accordance with the Chemical Agents Directive 98/24/EC and other appropriate local workplace risk assessment systems rather than via classification.

The representative of the dossier submitter was then invited to present the grounds for submitting the proposal and to respond to the rapporteurs' comments. The dossier submitter explained that DAT had been subject to a risk assessment under the Existing Substances Regulation (EC) No 793/93 and one of the conclusions had related to identification of skin irritation as a risk during production which could be addressed by appropriate classification and labelling as a skin irritant. In

the dossier submitter's view, classification did apply to substances during manufacture and considering all physical forms of the substance. Furthermore, the International Antimony Association (IAA), also indicated a need for classification of the substance as irritant due to the exposure at the working place (as 0-5 cases per year in the working place had been reported by the IAA). In addition, the dossier submitter emphasised the importance of the use of human data by providing examples of cases where the animal model had been demonstrated to be insensitive to an effect found in humans.

The dossier submitter remarked that industry currently makes self-classification on the basis of existing data and covered such hazards in the Safety Data Sheet. Nevertheless, there was a need to ensure harmonised classification and labelling for DAT at the Community level. The Secretariat suggested that RAC focus first on whether the data fulfilled the classification criteria and then, if necessary, consider whether there was sufficient justification for a harmonised classification at Community level.

The dossier submitter also referred to recent correspondence from IAA submitted after the public consultation in response to a request for clarification from the co-rapporteur in which it was indicated that cases of skin irritation had also occurred in workers involved in packaging operations, where less extreme conditions of heat might be expected than in production. In response, the Eurometaux observer underlined that the observations in workers performing production and packaging operations were only in relation to direct contact with dust containing DAT in hot and sweaty conditions.

One RAC member expressed concerns on disregarding the human data based on lack of validation of the methods for generating human data. Furthermore the negative results from animal studies were not convincingly conclusive that DAT was not irritating since none of the studies were of a high reliability. The rapporteurs reiterated that they were not contesting the evidence of skin irritation under the specific conditions described but did not consider that the substance itself would produce irritation in the absence of these specific conditions and, since classification related to the forms or physical states in which the substance was placed on the market, classification was not warranted. It was agreed to modify the wording in the background document to emphasise the low reliability of the animal studies.

One member pointed out the very low water solubility of DAT would support that it was unlikely that free antimony species would be generated under the conditions under which DAT was marketed and used. Furthermore, by comparing with similar discussions on nickel compounds he suggested that the effect seen would more likely have been caused by antimony ions, which are corrosive, than by DAT. Therefore, he supported the view of the rapporteurs.
In response to one member's request on the significance of the cases of hyperpigmentation, which could not be recognised in animal studies, the rapporteur clarified that hyper pigmentation was observed in only one of the studies in which there was the poorest information on exposure and where the fume may have contained only 40 % DAT thus the cause of the hyperpigmentation was very unclear.

Some members queried whether it can be expected that the use of DAT, as placed on the market, can lead to exposures under similar conditions that led to irritation in the case reports and whether there is any information available from downstream users on human exposure under different conditions. The Eurometaux observer responded that about 150 people were exposed during production processes, and in downstream user industries there were approximately 8 000 people exposed, but there were no reports of irritancy collected from these downstream users. Another member referred to a report, not cited in the CLH dossier, from Toxicological Risk of Selected Flame Retardant Chemicals, 2000 in which human patch tests had not indicated irritant properties of this substance.

One member asked if it would be possible to ask IAA for further clarification on the reference to cases arising from packaging operations. The Secretariat responded that the practice of submission of further data after the public consultation was not to be encouraged unless necessary and that the RAC discussion and opinion should be based on the provided data.

Following the discussion, RAC reached a consensus in favour of the rapporteurs' view not to support the proposed classification of irritating to skin and adopted the opinion for DAT and the background document with a few minor editorial changes.

The Secretariat thanked the rapporteurs and members for their efforts and informed the Committee that the adopted opinion and its annexes would be uploaded to the RAC CIRCA IG, forwarded to the Commission and published on the ECHA web site after the meeting.

7d Feedback from the last CARACAL meeting

The Secretariat presented feedback from the second meeting of the competent authorities for REACH and CLP held on 15-16 June 2009. The main discussion issues were: confirmation of deadlines for C&L notifications according to Article 40(3) of the CLP Regulation; discussions on the Commission's view on classification only due to the presence of impurities (initiated due to the proposal for V6); PBT classification criteria according to Article 53(2) of the CLP Regulation; the Guidance developed by JRC under module 2 of the REACH Implementation Project (RIP) 3.6; and the ECHA initiative on Communication strategy on CLP. With respect to the second issue mentioned above, the Commission had prepared a paper on the basis of the discussion that had taken place at RAC-5 on CLH dossiers containing proposals to classify a substance only on the basis of the presence of impurities (see item 10c of the RAC-5 minutes). The Commission document stated that a substance containing constituents already classified in Annex VI as carcinogenic, mutagenic or toxic to reproduction (CMR), and present at levels above the indicated general or specific concentration limits, should be classified as CMR by manufacturers and importers on the basis of the classified constituent and therefore it was not necessary to introduce an entry for the substance in Annex VI. When substances classified as CMR due to constituents are present in mixtures, the mixture should be classified as CMR when the concentration of the classified constituent in the mixture is above the general or specific concentration limits.

One member enquired when the criteria for environmental hazard classification based on chronic toxicity data are expected to be incorporated in the CLP Regulation. The Commission confirmed that such discussion is ongoing and when agreed it would be proposed for inclusion in the CLP Regulation.

8. CLH Guidance document

Update on progress with revision of the Guidance document for preparing and submitting a CLH dossier

The Secretariat informed the Committee of the current progress with the revision of the Guidance document for preparing a CLH dossier. The revision is required owing to the new CLP Regulation in force, as well taking account of experience gained with the dossiers already submitted within the last year. The process of drafting and consultation was outlined, following the guidance consultation procedure as adopted by the MB,, including the expected RAC contribution in this regard. Members were also introduced to the preliminary content of the draft Guidance.

One member suggested new aspects to be considered and covered with the revision, as follows: substance ID aspects specifically in relation to proposals for biocides and pesticides and further requirement for dossier submitter's justification when re-opening an existing classification on the basis of new data.

9. Appointment of RAC (co-) rapporteurs for CLH dossiers

9a Appointment of RAC (co-) rapporteurs

The Secretariat introduced document RAC/07/2009/43_rev.1 (distributed as a room document) including new intentions for CLH proposals with expected submission dates as registered in the Registry of intentions (RoI) up to 30 June 2009 and provided more details on the expected CLH hazard classes. Members were requested to volunteer for (co-) rapporteurship.

RAC agreed to appoint as rapporteurs and co-rapporteurs for these new intentions identified candidates who expressed their interest prior to or during the meeting.

As one vacant position for co-rapporteur remained, the Secretariat was requested to identify the appropriate members with expertise in the environmental field and to encourage one of them to volunteer for rapporteurship for this substance.

The Secretariat undertook to update and upload to the RAC CIRCA IG the status document, listing the appointed rapporteurs and co-rapporteurs for all submitted and intended dossiers.

9b Status report on RAC rapporteurships

The Secretariat presented to RAC as a room document (RAC/07/2009/44) an updated status report on the distribution of rapporteurships in the Committee and assigned rapporteurships and co-rapporteurships per individual member and encouraged those members who had not volunteered yet, to consider their candidatures for the newly registered and forthcoming intentions.

10. Outcome from the written procedures

The Chair informed RAC of the outcomes of the launched written procedures in the period between RAC-6 and RAC-7 meetings, as follows: two members were appointed by the Committee as RAC rapporteurs for two intentions for submission of CLH dossiers.

11. Any other business

RAC meeting calendar for 2010

The Chair presented document RAC/07/2009/45 (Room document) by explaining that six meetings are tentatively scheduled for 2010 and two of them (September and December) are fixed on the basis of submission dates in the restriction process. However, it was underlined that the total number of the meetings and their duration are tentative and will depend on the real workload in 2010.

12. Main conclusions and Action points of RAC-7

The Secretariat presented the main conclusions and action points of the RAC-7 plenary meeting for final comments and agreement by the Committee. All suggestions were reflected accordingly and RAC agreed the document. The main conclusions and action points are attached as Part II of these meeting minutes.

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Part III. Conclusions and action points

1. JOINT SESSION OF RAC AND SEAC (30 June - 1 July 2009)
MAIN CONCLUSIONS & ACTION POINTS
(Adopted at the Joint Session of RAC and SEAC)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the Agenda for the Joint session	The Agenda (RAC/A/07/2009, Part I, SEAC/A/04/2009_rev.1, Part II) was adopted without any changes. No declarations of conflict of interest declared.	SECR to upload the adopted Joint session Agenda to Circa as a part of the Joint session minutes.
3. Preparatory session for the role play	Members took note of the instructions and recommendations for the role play.	-
4. Role play in break out groups	-	-
5. Welcome notes by Executive Director	-	-
6. Lessons learnt from the role play	-	-
a) Presentation with highlights from the discussions in the break out groups	Members took note of the presentation given by the Secretariat prepared together with the facilitators of the break out groups.	SECR to finalise the presentation (by 7 July). SECR to upload Chairman's summary from the second meeting of the SEAC-RAC Arrangement to CIRCA (2 July).
b) Lessons learnt from the role play		SECR to include the conclusions of the role play in the Joint session minutes (after the meeting)
7. Common restriction issues		
a) Overview of current restrictions in Annex XVII	Members took note of the presentation given by the Secretariat.	-
b) Example of process in the past for development of these Annex XVII entries	Members took note of the presentation given by the Secretariat.	-
c) Draft opinion and background document (BD) template	RAC and SEAC agreed the document on the opinion and background document (BD) template (RAC/07/2009/31 or SEAC/04/2009/17).	-
d) Clarification of the support available to RAC and SEAC rapporteurs	Members took note of the sources of support available to the rapporteurs.	SECR to forward the meeting document (RAC/07/2009/32 or SEAC/04/2009/18) to CARACAL (by next

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
		CARACAL meeting).
8. Information on the registered intentions for submitting Annex XV dossiers proposing restrictions - Registered intentions for submitting an Annex XV restriction dossier (by 30 June 2009)	Members took note of the report given by the Secretariat.	SECR to clarify whether the dossiers under preparation are related to human health and/or environmental risks. SECR to launch the procedure for the appointment of (co-) rapporteurs in RAC and SEAC based on the current list of registered intentions (after receiving the information mentioned above).
9. Joint information session		
a) Process for guidance updates	Members supported the proposal of the Secretariat for the Committees' involvement in the initiation of guidance update and in the guidance consultation process.	-
b) Conclusions and recommendations from the authorisation workshop of January 2009	Members took note of the outcomes of the authorisation workshop.	-
10. Feedback from other ECHA bodies and activities	Members took note of the feedback reports from the recent developments in RAC, MSC, the Forum, the MB and CARACAL.	SECR to forward the document on the registry of intentions presented at CARACAL to RAC and SEAC.
11. Co-operation with other Community bodies - Presentation of the possible elements of rules of procedure (Article 110(2) and (4) of REACH) for co-operation with EFSA and ACSHW	Members took note of the elements of the RoPs for co-operation with EFSA and ACSHW and their role in the process towards their adoption.	
12. Administrative issues		
a) Remuneration of RAC & SEAC rapporteurs for Annex XV dossiers proposing a restriction	Members took note of the principles of remuneration of RAC & SEAC rapporteurs.	
b) RAC/SEAC	Circa will be used for the distribution	SECR to launch a Circa

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
members` access to information in REACH-IT	of confidential data to RAC and SEAC until a new more secure IT tool is available. Additional security measures will be applied.	newsgroup on the document (RAC/07/2009/46 or SEAC/04/2009/23). RAC and SEAC to provide comments in writing within 2 months from launching of the Circa newsgroup.
13. AOB **General**		SECR to upload all Joint session presentations and the action points to Circa by 2 July.

2. RAC SESSION (2-3 July 2009)

MAIN CONCLUSIONS & ACTION POINTS

(Adopted at the RAC-7 meeting)

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
2. Adoption of the RAC-7 Agenda	RAC adopted the Draft RAC-7 Agenda without changes.	Adopted RAC-7 Agenda to be annexed to RAC-7 Minutes (SECR/ after the meeting).
4 Draft Minutes **4a Approval of the RAC-6 final draft Minutes**	RAC approved the Draft final minutes with minor changes.	Approved minutes of RAC-6 to be uploaded to CIRCA and ECHA website (SECR/ after the meeting).
4b Status report on the RAC-6 Action points	There were several actions identified from RAC-6 which were transferred to these action points or were ongoing.	Stakeholder newsgroups to be established per meeting or per dossier by SECR and comments on general issues (e.g. minutes) to be sent by e-mail to SECR (ongoing).
5 Restrictions **5a WP on processing of an Annex XV restriction dossier**	Agreement on WP (doc RAC/06/2009/17) was reached.	SECR to upload the agreed procedure to the RAC CIRCA IG and publish on ECHA web site (after the meeting).
5b WP on appointment of RAC (co-) rapporteurs for restrictions	WP agreed subject to making provision of supporting documentation to rapporteurship optional.	SECR to upload the agreed procedure to the RAC CIRCA IG and publish on ECHA web site (after the meeting).
5c Draft terms of reference for restriction (co-) rapporteurs	Document RAC/07/2009/39 was agreed subject to a minor change.	SECR to upload the agreed document to the RAC CIRCA IG and publish on ECHA web site (after the meeting).

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
6 CLH Procedures **6a Draft procedure for CLH substances already agreed at TC C&L**	RAC & SECR to carefully consider how to proceed in the most efficient way possible. This may include the following: – SECR identifying the lead MS for each dossier – SECR providing additional assistance with the substance ID aspects – Consider options for supporting dossier submitters to prepare dossiers – The way in which proposals are presented in the public consultation – Streamlining the procedure for processing these proposals by RAC and consider waiving the accordance check – Fully utilise the previous work from TC C&L and any new data – Tailoring the contents of the opinion template for these dossiers.	SECR to consider these aspects further and inform RAC on the way forward after the meeting. Submit proposals to CARACAL
6b WP for accordance checks	Agreement was reached on the WP (doc RAC/07/2009/41) subject to a minor change. The revised template (annexed to the WP- version already uploaded to RAC CIRCA IG) was agreed with minor changes.	SECR to upload the agreed procedure to the RAC CIRCA IG and publish on ECHA web site (after the meeting).
7 CLH Dossiers **7a Feedback on accordance check**	For the purposes of the public consultation abamectin will be referred to as abamectin and avermectin B_{1a} and the correct name will be further clarified with dossier submitter in parallel.	SECR to clarify the correct name with dossier submitter.
7c DAT	RAC reached a consensus and adopted the opinion for DAT and the background document. RAC members agreed with the view of the rapporteurs <u>not</u> to support the proposed classification of irritating to skin.	The adopted opinion and its annexes to be uploaded to the RAC CIRCA IG, forwarded to COM and published on the ECHA web site (SECR/after the meeting).

Agenda point	Conclusions / decisions / minority opinions	Action requested after the meeting (by whom/by when)
8 CLH Guidance document	RAC proposed that the following aspects are covered in the revised guidance: - substance ID aspects specifically in relation to proposals for biocides and pesticides - dossier submitter to justify re-opening an existing classification on the basis of new data.	SECR to include in the guidance revision (SECR ongoing).
9 Appointment of CLH (co-) Rapporteurs	RAC agreed to appoint the rapporteurs & co-rapporteurs for some of the newly registered intentions (doc RAC/07/2009/43.rev1).	SECR to upload in RAC CIRCA IG the updated status document to reflect appointments (SECR/ after the meeting). SECR to identify potential rapporteurs and encourage them to fill the vacant position.
GENERAL		All presentations and room documents to be uploaded to RAC CIRCA IG (SECR/by 7 July). Conclusions and action points (i.e. this doc) to be uploaded to Circa (SECR /by 7 July).

Part IV. Lists of Attendees

1. List of Attendees of the joint session (30 June – 1 July)

SEAC members:		**RAC members:**
BASTOS, Henri		ALESSANDRELLI, Maria*
BENDL, Jiri*		ANDERSSON, Alicja
BRIGNON, Jean Marc		BARANSKI, Boguslaw
BROKAITE, Kristina		BORGES, Maria Teresa
COSTEA, Ion		DUNAUSKIENE, Lina
DALTON, Marie **		DUNGEY, Stephen
DE GIGLIO, Franco		GRUIZ, Katalin
ECONOMIDES, Aristodemos		GREIM, Helmut
FAHERTY, Mark		HUTORAN, Svetlana**
FANKHAUSER, Simone		JENSEN, Frank
FEYAERTS, Jean-Pierre		KADIKIS, Normunds
FOCK, Lars		LARSEN, Poul Bo
FORKMAN, Mats		LE CURIEUX-BELFOND, Olivier
FURLAN, Janez		LEINONEN, Riitta
GEORGIOU, Stavros		LOSERT, Annemarie
HAJAS, Martin		LUND, Bert-Ove
KOZAK, Kristof		MELANITOU, Maria
LANGTVET, Espen		MULLOOLY, Yvonne
LOURENÇO, João		NUNES, Céu
LUTTIKHUIZEN, Cees		ORPHANOU, Maria
RECCHIA, Luca Maria		PICHARD, Annick
RYDLEWSKA-LISZKOWSKA, Izabela		POLAKOVICOVA, Helena
SALONEN, Heikki		PRONK, Marja
SCHUCHTAR, Endre		SCHULTE, Agnes
SIMON, Franz-Georg		SMITH, Andrew
SUSNIK, Marko		STOLZENBERG, Hans-Christian
TELLING, Aive		SULG, Helen
THEOHARI, Maria		TARAZONA, Jose V.
THIELE, Karen		VAN DER HAGEN, Marianne
VANDERSTEEN, Kelly***		VAN MALDEREN, Karen
*replacing BIZKOVA, Rut		VILANOVA, Eugenio
**replacing McGUINNESS, Sharon		ZGLOBIU, Mariana-Elena
***replacing DANTINNE, Catheline		*replacing DI PROSPERO, Paola
		**replacing RUPPRICH, Norbert
Advisors to the SEAC members:		**Advisors to the RAC members:**
DOMINIAK, Dorota (advisor to RYDLEWSKA, Izabela)		ANNOLA, Kirsi (advisor to LEINONEN, Riita)
BEEKMAN, Martijn (advisor to LUTTIKHUIZEN, C.)		GRACZYK, Anna (advisor to BARANSKI, Boguslaw)
KIISKI, Johanna (advisor to SALONEN, H.)		HAKKERT, Betty (advisor to PRONK, Marja)

FIORE, Karin (advisor to BASTOS, H.)	MORKA, Heidi (advisor to VAN DER HAGEN, Marianne)
GRANDI, Silvia (advisor to RECCHIA, L)	
Representatives of the Commission: GIL, Sebastian (DG ENV) ROZWADOWSKI, Jacek (DG ENT) WISTUBA, Christine (DG ENV)	**Stakeholder observers:** ANNYS, Erwin (CEFIC) DINTCHEVA, Ralitza (UEAPME) HOLLAND, Mike (EEB)
	LEENAERS, Joeri (Eurometaux)
ECHA staff:	MÄKELÄ, Kari (EMCEF)
BLENCOWE, Tom	MEISTERS, Marie-Louise (ECETOC)
DANCET, Geert	MUSU, Tony (ETUC)
DE BRUIJN, Jack	VAN SLOTEN, Rene (CEFIC)
FUHRMANN, Anna	WEFFERS, Heribert (EEB)
HERDINA, Andreas	
HOLLINS, Stephen	
KARHU, Elina	
LEFEBVRE, Alain	
LEFEVRE, Remi	
LIPKOVA, Adriana	
LOGTMEIJER, Christiaan	
MUNN, Sharon	
PELTOLA, Jukka	
RODRIGUEZ IGLESIAS, Pilar	
SADAM, Diana	
STOYANOVA, Evgenia	
SUNDQUIST, Anna-Liisa	
THUVANDER, Ann	
VAINIO, Matti	
VASILEVA, Katya	
YLÄ-MONONEN, Leena	

2. List of Attendees of the RAC session (2 – 3 July)

Members		**ECHA staff**
ANDERSSON Alicja		HOLLINS Steve
BARANSKI Boguslaw		HONKANEN Jani
BORGES Maria Teresa		FUHRMANN Anna
DUNAUSKIENE Lina		KNIGHT Derek
DUNGEY Stephen		KULJUKKA-RABB Terhi
GREIM Helmut		LIPKOVA Adriana
GRUIZ Katalin		LOGTMEIJER, Christiaan
JENSEN Frank		LUOTAMO Marita
KADIKIS Normunds		LUSCHÜTZKY Evita
KREUZER Paul		MUNN Sharon

LARSEN Poul Bo		NYLUND Lars
LE CURIEUX-BELFOND Olivier		PEDERSEN Finn
LEINONEN Riitta		RÖCKE Timo
LOSERT Annemarie		SADAM Diana
LUND Bert-Ove		SCHÖNING Gabriele
MELANITOU Maria		SPJUTH Linda
MULLOOLY Yvonne		THUVANDER, Ann
NUNES Céu		VAHTERISTO Liisa
ORPHANOU Maria		VASILEVA Katya
PICHARD Annick		YLÄ-MONONEN Leena
POLAKOVICOVA Helena		
POSPISCHIL Erich		
PRONK Marja		
RUPPRICH Norbert		
SCHULTE Agnes		
SMITH Andrew		
STOLZENBERG Hans-Christian		
SULG Helen		
TARAZONA Jose V.		
VAN DER HAGEN Marianne		
VAN MALDEREN Karen		
VILANOVA Eugenio		
ZGLOBIU Mariana-Elena		
Replacements		**Representatives of the Commission**
ALESSANDRELLI Maria (replacement to Paola DI PROSPERO)		IAGHER Raluca (DG ENV)
MURRAY Brendan (replacement to Thomasina BARRON)		WISTUBA Christine (DG ENV)
Advisers to the RAC members		**Stakeholder observers**
ANNOLA Kirsi (adviser to Riitta LEINONEN)		ANNYS Erwin (CEFIC)
DUSSART Aurelie (adviser to Karen VAN MALDEREN)		LEENAERS, Joeri (Eurometaux)
GRACZYK Anna (adviser to Boguslaw BARANSKI)		MEISTERS, Marie-Louise (ECETOC)
HAKKERT Betty (adviser to Marja PRONK)		WEFFERS, Heribert (EEB)
MORKA Heidi (adviser to Marianne VAN		

DER HAGEN)		
PASQUIER Elodie (adviser to Annick Pichard)		OHLSSON Agneta (Representative of Sweden for DAT dossier) for item 7 c)

Part V. LIST OF ANNEXES

ANNEX I. Final Agenda of the RAC-7 meeting

ANNEX II. Lists of documents submitted to the Members of the Committee for Risk Assessment for the joint RAC-SEAC session and for the RAC session

ANNEX III. Conclusions of the role play

ANNEX I

2nd July 2009
RAC/A/07/2009_rev.1

Final Agenda
Seventh meeting of the Committee for Risk Assessment

30 June – 03 July 2009
Helsinki, Finland

Part I

JOINT SESSION OF RAC and SEAC

30 June: starts at 14:00
01 July: ends at 18:00

Item 1 – Welcome notes by RAC & SEAC Chairs

Item 2 – Adoption of the Agenda for the Joint session

RAC/A/07/2009, part I
For adoption

Item 3 – Preparatory session for the role play

For information

Item 4 – Role play in break out groups

a. Parallel discussion in break out groups on the mini Annex XV dossier

For discussion

b. Meeting of break out groups' facilitators for preparing of a presentation with highlights from the discussions in the groups

For preparation

Item 5 – Welcome notes by Executive Director

Item 6 – Lessons learned from the role play

a. Presentation with highlights from the discussions in the break out groups

For information

b. Lessons learned from the role play

For discussion

Item 7 – Common restriction issues

a. Overview of current restrictions in Annex XVII

For information

b. Example of process in the past for development of these Annex XVII entries

For information

c. Draft opinion and background document (BD) template

RAC/07/2009/31

For discussion and agreement

d. Clarification of the means of support available to RAC and SEAC rapporteurs from ECHA

RAC/07/2009/32

For information

Item 8 – Information on the registered intentions for submitting Annex XV dossiers proposing restrictions

- Registered intentions for submitting an Annex XV restriction dossier (by 30 June 2009)

For information

Item 9 – Joint information session

a. Process for guidance updates

RAC/07/2009/33

For discussion

b. Conclusions and recommendations from the authorisation workshop of January 2009

For information

Item 10 - Feedback from other ECHA bodies and activities

For information

Item 11 – Co-operation with other Community bodies

- Presentation of the possible elements of rules of procedure (Article 110(2) and (4) of REACH) for co-operation with EFSA and with ACSHW

RAC/07/2009/34
For information

Item 12 – Administrative issues

a. Remuneration of RAC & SEAC rapporteurs for Annex XV dossiers proposing a restriction

RAC/07/2009/35
For information

b. RAC/SEAC members' access to information in REACH-IT

RAC/07/2009/46 (Room document)
For information

Item 13 – AOB

Item 14 – Action points and main conclusions of Joint RAC-7 & SEAC-4 session

- Table with Action points and conclusions from the Joint session

For adoption

Part II

RAC SESSION

02 July: starts at 9:00
03 July: ends at 14:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

Item 3 – Declarations of conflicts of interest to the Agenda

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

a. Adoption of the draft minutes

RAC/M/06/2009 draft final
For adoption

b. Status report on the RAC - 6 Action points

RAC/07/2009/36 (Room document)
For information

Item 5 – Final agreement of the RAC working procedures for restrictions

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

RAC/07/2009/37
For final agreement

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

RAC/07/2009/38
For agreement

c. Terms of reference for restriction (co-) rapporteurs

RAC/07/2009/39
For final agreement

Item 6 – CLH procedural documents

a. Draft procedure for delivering opinions for CLH proposals for the substances previously agreed at TC C&L

RAC/07/2009/40
For discussion

RAC/07/2009/47 (Room document)
For information

b. Revised working procedure on the accordance check of a CLH dossier

RAC/07/2009/41
For agreement

Item 7 – CLH dossiers

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

For information and discussion

b. State of play of the submitted CLH dossiers

RAC/07/2009/42

For information

c. First discussion on CLH dossiers after public consultation (diantimony trioxide)

For discussion and possible adoption of the opinion

d. Feedback from the last CARACAL meeting

For information and discussion

Item 8 – CLH Guidance document

- Update on progress with revision of the Guidance document for preparing and submitting a CLH dossier

For information

Item 9 – Appointment of RAC (co-) rapporteurs for CLH dossiers

a. Appointment of RAC (co-) rapporteurs

RAC/07/2009/43

For decision

b. Status report on RAC rapporteurships

RAC/07/2009/44 (Room document)

For decision

Item 10– Outcomes from the written procedures

For information

Item 11 – AOB

- RAC meeting calendar for 2010

RAC/07/2009/45 (Room document)

For information

Item 12 – Action points and main conclusions of RAC-7

- Table with Action points and decisions from RAC- 7

For adoption

ANNEX II

1. Documents submitted to the Members of the Committee for Risk Assessment and to the Members of the Committee for Socio-economic Analysis for the joint RAC-SEAC session

Revised Draft Agenda of the joint RAC-SEAC session (Agenda Point 2)	RAC/A/07/2009, Part I	SEAC/A/04/2009_re v.1, Part II
The opinion of RAC and SEAC on restriction proposals (Agenda Point 7c)	RAC/07/2009/31	SEAC/04/2009/17
Clarification of the support available to RAC and SEAC rapporteurs (Agenda Point 7d)	RAC/07/2009/32	SEAC/04/2009/18
Process for guidance updates (Agenda Point 9a)	RAC/07/2009/33	SEAC/04/2009/19
Possible elements of rules of procedure (Article 110(2) and (4) of REACH) for co-operation with EFSA and ACSHW (Agenda Point 11)	RAC/07/2009/34	SEAC/04/2009/20
Remuneration of RAC and SEAC rapporteurs for Annex XV dossiers proposing a restriction (Agenda Point 12a)	RAC/07/2009/35	SEAC/04/2009/21
RAC/SEAC members` information needs for data in REACH-IT (Agenda Point 12b)	Room document RAC/07/2009/46	Room document SEAC/04/2009/23

2. Documents submitted to the Members of the Committee for Risk Assessment for the RAC session

RAC/07/2009/36	Status report on the RAC - 6 Action points. Room document
RAC/07/2009/37	WP on processing of Annex XV restrictions dossiers
RAC/07/2009/38	WP on appointment of rapporteurs (Restrictions)
RAC/07/2009/39	Terms of reference for restriction (co-)rapporteurs
RAC/07/2009/40	Draft procedure for delivering opinions for CLH proposals for the substances previously agreed at TC C&L but not included in Annex VI of Regulation (EC) No 1272/2008
RAC/07/2009/41	Revised working procedure on the accordance check of dossiers proposing harmonised classification and labelling-first revision
RAC/07/2009/42	State of play of the submitted CLH dossiers
RAC/07/2009/43	Appointment of rapporteurs for the newly registered intentions
RAC/07/2009/44	Status report on the assigned CLH (co-)rapporteurships to RAC members
RAC/07/2009/45	Proposed RAC meeting calendar for 2010. Room document
RAC/07/2009/47	French comments on the procedure for TC C&L substances. Room Document

ANNEX III

Conclusions of the role play

List of documents provided to the members for the role play:

Mini-dossier
Executive summary of the mini dossier
Description of the role play
SEAC/04/2009/22

The description of the role play can be found in the aforementioned documents. These documents can be found on CIRCA in the section "role play" of the joint session. A total of eight break-out groups were organized, in each group there was one facilitator, one RAC rapporteur and one SEAC rapporteur3. In some cases a co-rapporteur or a co-facilitator was also used.

After the presentation was given to the joint session of RAC and SEAC on the results of the role play, those members who played the role of rapporteurs exchanged their experiences on the role play. The discussion that followed focused on the following items: how easy it was to be a rapporteur, were the remits of RAC and SEAC clear and what to do if not all information needs were fulfilled.

How easy was it to be a rapporteur?

Rapporteurs indicated that the task of being a rapporteur should not be underestimated. Rapporteurs need to be knowledgeable and have the appropriate experience in order to function well in their task. It was thought that a good preparation of the rapporteurs is essential for the success of the first dialogue. The experience from the groups was that having a teleconference prior to the first dialogue contributed to the success of the dialogue.

During the discussion at the plenary the point was made that a good communication and understanding between RAC and SEAC rapporteurs is needed. Rapporteurs should communicate frequently and preferably meet (at least once) face-to-face.

Rapporteurs indicated that it would be desirable that the other members of RAC and SEAC could be asked to help out rapporteurs.

Rapporteurs mentioned that it was good to have a structure available for the dialogue as it led them through the dossier. Another way to work would be to go section by section through a dossier.

Were the boundaries between RAC and SEAC clear?

The feedback from the breakout groups was mixed on this issue. In some groups the remits of both committees was clear and participants acted accordingly. In other groups there were many 'border-crossings'. However, often these crossings happened in an attempt to seek further clarification of the issues at hand, or were an attempt to seek a common understanding of the problem.
What if most of the information needs were not fulfilled?

[3] In one group (F), the RAC rapporteur was absent due to the cancelled flight.

During the role play many participants suggested that further information was required. They felt that the information in the mini-dossier was not sufficient enough to come to an opinion. This provoked in some groups a discussion on what kind of information one needs to know, the minimum information needs required to formulate an opinion and the role of the submitting member state in providing additional information.

It was agreed that the dossier submitter plays a crucial role in the process since the quality of the dossier is deemed to be an important success factor in the process of coming to an opinion. During the discussion the rapporteurs mentioned that it is important that the dossier submitter should remain at the disposal of the rapporteurs throughout the process. It was thought that the submitter could be one of the main sources to provide further clarification and additional information where needed.

The provided information was often thought to be insufficient to come to an opinion. This was partly due to the "mini-dossier bias": the provided information being compressed and kept to a minimum level for the purposes of the role play. It was pointed out that in the future rapporteurs should be able to focus more on reviewing the information in the dossier rather than identifying information gaps.

Further to the issue of information needs, participants pointed out that industry and stakeholders can play a role in providing additional information e.g. on alternatives. This information can be provided preferably prior to submission or, otherwise, during the 6-month public consultation.

Comparison with lessons learnt in the SERAC role play.

The experience of the role play seemed to have reinforced most of the lesson learnt from the role play that was held during the second SERAC meeting, which had been distributed to the participants prior to the meeting (as part of the report of SERAC)4.

[4] The full Chair's summary of the 2nd meeting was distributed to the members of both RAC and SEAC after the joint session.