RAC/M/17/2011

FINAL

26 October 2011

Minutes of the 17th meeting of the Committee for Risk Assessment (RAC-17) (13-16 September 2011)

Part I Summary Record of the Proceedings

1 Welcome and apologies

Dr Jose Tarazona, Chair of the Committee for Risk Assessment (RAC), ECHA, welcomed participants to the meeting. RAC was informed on the appointment of two new RAC members (the mandate of one starting from 25 September 2011). The newly appointed member (whose mandate has started from the nomination) was welcomed and invited to briefly introduce herself. RAC was also informed on the renewal of the memberships of three RAC members. Ten advisers, two invited experts, seven stakeholder representatives (from Business Europe, CEFIC, ECETOC, ECPA, EMCEF, EuCheMS, and Eurometaux), six observers accompanying stakeholder observers (STO), one representative of dossier submitters (RAC member) and five representatives from the Commission were welcomed.

For this meeting some participants took part in substance related discussions as remote participants. This included: two members, four advisers, one observer representative from EFSA stakeholder, and representatives of Member State Competent Authorities (MSCA) from France, Germany, Norway and the Netherlands.

Apologies were received from four RAC members and three regular observers (CONCAWE, ECEAE and ETUC). The list of attendees is given in Part III of these minutes.

Two members were absent.

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.

2 Adoption of the Agenda

The revised agenda (RAC/A/17/2011_rev.3) was adopted with the clarification that the RAC opinion on PHMB had been adopted by written procedure and some minor modifications. The final agenda and the 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 agenda items. Ten members and two stakeholder observers declared potential conflicts of interest to the substance-related discussions. In addition, one member declared involvement in a DG SANCO Scientific Committee dealing with similar substances. The Chair clarified the later involvement cannot be considered a conflict of interest and that potential divergences if any should be handled according to Art. 95 of the REACH Regulation.

4 RAC Manual of Conclusion and Recommendations

Apologies were presented from the Secretariat as due to lack of resources, there has not been progress on this issue. On behalf of the Secretariat the Chair indicated that efforts will be done for getting progress in the near future.

RAC members proposed to include in the manual the RAC agreement regarding the labelling for reprotoxic substances and the list of hazard classes that should be addressed in the different dossiers (including the case of active substances in PPP and BP already included in Annex VI of the CLP Regulation).

5 Administrative issues and information items

The Secretariat informed the Committee on administrative issues (room document RAC/17/2011/18) and in particular stakeholder organisations of the decision taken at the June meeting of the Management Board (MB) in relation to the Register of Interest Representatives ('the transparency register') established by the European Commission. Future invitations to meetings of this Committee will be dependent upon stakeholders having registered in the Commission's transparency register. STO observers are invited to take note of this change and provide confirmation of their registration by sending their registration number to the RAC Secretariat.

The Chair presented the document RAC/17/2011/19 covering a set of proposals for streamlining of RAC procedures. Members were requested to comment on these proposals.

RAC was informed on the on-going discussions regarding the ECHA policy on declaration of conflicts of interest (CoI) to be discussed by the MB, the new policy will be applicable to Committee members and ECHA staff.

The participation of Croatia as an observer. The Chair and the Secretariat introduced room document RAC/17/2011/20 in which the background was explained to a request from Croatia to attend RAC meetings as an observer. RAC agreed to this request and the Secretariat was to communicate the agreement to the MB to take a decision on whether Croatia can attend future Committee meetings.

6 Request under Article 77(3)(c) - gallium arsenide

The (co-)rapporteurs reported back on the RAC preparatory meeting held on 12th September and summarised the key issues arising from the public consultation (11th March – 27th April 2011) and from the first draft opinion and BD following the commenting round with RAC members. The key issues for consideration were in relation to: epidemiology; read across between arsenic oxides and gallium arsenide based on similar metabolites; the possibility of a threshold for carcinogenicity; the metabolism and bioavailability of gallium arsenide; and some other specific considerations. During the discussions RAC STO observers also raised for the first time a further consideration: the form in which gallium arsenide is placed on the market and the form to which workers may be exposed, as well as the forms used in the animal studies on bioavailability. STO observers were requested and provided available data on the form of gallium arsenide that was used in the principal studies in relation to carcinogenicity.

There was a common view on the need to carefully further consider these scientific issues and members were invited to provide any further reflections to the (co-) rapporteurs in the CIRCABC newsgroup after the meeting. The (co-)rapporteurs were invited to prepare a revised draft opinion for distribution to the Committee by Monday the 3rd October.

7 CLH[1] Dossiers

7.1a PHMB

The Chair informed RAC that the opinion on PHMB was adopted before RAC-17 by written procedure by majority with one minority position on carcinogenicity.

7.1.b Di-n-hexyl phthalate (DnHP)

The Chair invited the RAC rapporteurs to present the revised draft opinion on the CLH proposal submitted by France.

Currently there is for this substance no entry in Annex VI of the CLP Regulation. The classification proposal related to the reproductive toxicity of the substance. There was evidence to support the proposal for the developmental toxicity and also evidence of effects on fertility. As complementary information concerning the fertility classification, di-(2-ethylhexyl) phthalate (DEHP) has a similar chemical structure to DnHP, and in the submitted data comparable effects were observed with both DEHP and DnHP at identical doses, suggesting that logically they should have similar classifications.

RAC adopted by consensus the revised draft opinion on the CLH proposal for Di-n-hexyl phthalate. The proposed classification is presented in Table 1 of Part II of this document.

The Chair thanked the rapporteurs and the members for the work.

7.1.c MMTC (trichloride of methyltin) and
7.1.d EHMA (methyltin tri(2-ethylhexyl-mercaptoacetate MMT)

The Chair invited the RAC rapporteurs to present the revised draft opinions on the CLH proposals submitted by France.

At the RAC-16 meeting the relevance of the gastric simulation study showing the rapid hydrolysis of MMT(EHMA) to MMTC at low pH (0.6-07) had been discussed. After the studies on hydrolysis of several organotin compounds under environmental conditions have been checked and been found to support the hydrolysis argument, RAC agreed to accept the read across approach to MMTC data to evaluate MMT(EHMA).

The revised draft opinions support the dossier submitter's proposals agreed under TC C&L in its assessment for reprotoxicity for MMTC and MMT(EHMA). Regarding the

[1] Abbreviations in relation to harmonised classification and labelling (CLH):
CLP refers to EC Regulation No. 1272/2008; and DSD refers to Directive 67/548/EEC.

labelling for reprotoxicity RAC agreed to include the letter in the hazard statement and the footnote used in previous RAC opinions.

The weak effects in the micronucleus study were not regarded as sufficient to support the proposal for the classification as mutagenic.

Some members questioned whether and when RAC should a) spend time for review and b) deviate from TC C&L conclusions. The Chair concluded that the procedure for CLH of TC C&L agreed substances is the same as for any other CLH dossier submitted to ECHA. In general, RAC needs to assess the dossier submitter's proposal for CLH based on the comparison of the data against the CLH criteria. Although there is a general incentive to assess these substances in the most satisfactory way focussing on new information and using the information from the previous discussions, RAC is free to reassess the data as needed – especially when questions on the justification are brought up during a public consultation and in cases where deviation from TC C&L conclusions are well justified.

RAC adopted by consensus the revised draft opinions on the CLH proposals for MMTC and MMT(EHMA). The proposed classifications are presented in Table 1 of Part II of this document.

The Chair thanked the rapporteurs and the members for the work.

7.1.e Fenamiphos

The Chair welcomed a representative of EFSA who took part in the discussions as remote participants based on an early identification, as requested under Art. 95 of the REACH Regulation, of a possible conflict with a previous EFSA conclusion. The Chair invited the RAC rapporteurs to present the first draft opinion for the CLH proposal submitted by the Netherlands for discussion.

There is already an existing Annex VI entry for fenamiphos for which a revision is proposed. The dossier focuses on acute toxicity and eye irritation as preliminary agreed under TC C&L. However, the dossier submitter presented all other hazard classes for information. The human health hazard classes were not further discussed by RAC, because the results of the data are clear, they were presented at the last RAC meeting and no new information was available since the TC C&L discussions.

However, as requested by the Commission, RAC compared the environmental hazards of the substance with the criteria of the 2nd ATP. The presented data clearly supported the classification for acute and chronic aquatic toxicity but did not provide sufficient detail to determine the M-factors. Therefore RAC consulted the original key studies that were only briefly summarised in the CLH dossier. RAC came to the conclusion that, even though it is not possible to determine a precise effect threshold for chronic toxicity from the available studies, it is sufficient for classification purposes to consider that the threshold is above 0.12 µg/L and below 0.49 µg/L. This threshold provides for an M-factor of 100 for chronic aquatic toxicity.

RAC adopted by consensus the draft opinion on the CLH proposal for fenamiphos. The proposed classification is presented in Table 1 of Part II of this document.

The Chair thanked the rapporteurs and the members for the work on this CLH proposal.

7.1.f Pitch, coal tar, high temp. (CTPHT)

The Chair invited the RAC rapporteurs to present the revised draft opinion on the CLH proposal submitted by the Netherlands. The revised opinion supports the proposal agreed under TC C&L, in its assessment for carcinogenicity (Carc. 1A, CLP), and for mutagenicity (Muta. 1B, CLP). For reproductive toxicity the draft opinion outlined a borderline case between category 1B and 2. The discussion at the RAC-16 meeting expressed support for the original proposal (Repr. 1B, CLP). RAC provisionally agreed to this classification as presented in Table 2 of Part II of this document.

The environmental classification is based on the presence of PAHs in the UVCB substance CTPHT for classification of aquatic acute and aquatic chronic toxicity. The proposal by the Netherlands indicates that a specific M-factor cannot be applied due to the variable content of PAHs and should only be assigned on a case by case basis. However RAC agreed to set a harmonised M-factor based on typical PAH concentrations. RAC was also in favour of suggesting COM to include a note indicating that this M-factor could then be adapted and recalculated if more exact information about the concentrations of the constituents in the specific CTPHT substance is available to the companies when classifying the substances.

The Chair thanked the rapporteurs for their presentation and RAC provisionally agreed on harmonised classification of CTPHT as indicated in Table 2 of Part II at the end of this document.

7.1.g Penconazole

The Chair welcomed an observer accompanying the ECPA stakeholder observer and the dossier submitter representative (remote participant) to the meeting and invited the rapporteurs to present the revised draft opinion.

The rapporteurs presented the classification for all relevant endpoints and discussed the available study results.

The rapporteurs supported the classification proposed by the dossier submitter and suggested to consider an additional classification of penconazole as STOT RE 2 H373 (liver) and to discuss toxicity for reproduction. These endpoints were proposed during the public consultation.

During the discussion the toxicity of an impurity was raised. It was stated that there are no relevant data on them and their toxicity.

The discussion was continued after the rapporteurs presented a revised Background document to the opinion to RAC.

The additional proposal of STOT RE 2 H373 (liver) classification was initially supported by some RAC members while other RAC members considered that the evidence was not sufficiently supportive. A RAC observer summarised the studies indicating that in their view there are no liver effects to support hepatic changes.

RAC provisionally agreed to propose penconazole to be classified as indicated in the Table 2 of Part II of this document.

The Chair thanked the rapporteurs for their presentation and invited RAC members to provide comments on modified Annex 1 via CIRCABC newsgroups by the date indicated in section 6.2c of Part II of this document. Rapporteurs were requested to update the draft opinion and revise the BD before RAC-18.

7.1.i Aclonifen

The Chair welcomed an observer accompanying the ECPA stakeholder observer and the dossier submitter representative and invited the rapporteurs to present the revised draft opinion on the CLH proposal submitted by Germany.

The rapporteurs supported the current classification for aclonifen in the existing entry of Annex VI of the CLP Regulation. The rapporteurs suggested to RAC to agree with the proposal from Germany for the additional classification of Carc. 2 – H351, skin Sens. 1 – H317 and the addition of an M-factor of 100 for Aquatic Acute Toxicity 1. As to skin sensitisation, aclonifen was concluded to be a strong sensitiser (category 1A), for which a specific concentration limit of 0.1% would be appropriate.

The classification for carcinogenicity was also supported in the comments received during public consultation except from one industry association.

Based on environmental data the rapporteurs proposed an M-factor according to 2nd ATP for Aquatic Chronic Toxicity 1 of 10.

RAC adopted by consensus the revised draft opinion on the CLH proposal for aclonifen. The proposed classification is presented in Table 1 of Part II of this document.

The Chair thanked the rapporteurs and the members for the work.

7.1.j Sulcotrione

The Chair introduced an observer accompanying the ECPA stakeholder observer and the dossier submitter representative and invited rapporteurs to present the first draft opinion on the CLH dossier submitted by Germany.

The rapporteurs supported the classification Skin Sens. 1A proposed by the dossier submitter and recommended that the classification for lactation effects Lact; H362 which was proposed during the public consultation, should also be added. During the discussion RAC members indicated that more data were needed to distinguish between effects indicating reproductive toxicity and effects via lactation.

In addition the rapporteurs raised for discussion the issues of eye irritation and carcinogenicity.

The ECPA stakeholder observer offered to provide RAC with additional data on irritation and also would indicate if further information relating to the findings on renal toxicity in the different studies could be provided to assist in resolving whether a STOT RE classification should be considered. RAC accepted the offer and the Chair indicated ECPA that all information should be submitted through the RAC Secretariat.

For the environmental classification the dossier submitter proposed an M-factor of 1 (acute and chronic) which was also supported during the public consultation. The rapporteurs proposed to modify the M- factor (chronic) to 10 in order to adapt the environmental hazards of the substance with the criteria of the 2nd ATP (these criteria were not in force when the dossier was submitted).

RAC provisionally agreed to propose sulcotrione to be classified as indicated in the Table 2 of Part II of this document.

The Chair thanked the rapporteurs for their presentation and invited the rapporteurs to update the draft opinion in accordance with the comments from members, also considering as needed the information to be provided by the STO if relevant, and subsequently RAC members to provide comments on the revised draft opinion and its annexes for further discussion and possible adoption either before or at RAC-18.

7.1.k Perestane

The Chair invited the RAC rapporteur to present the first draft opinion on the CLH proposal submitted by the UK. The classification proposal for perestane concerns the removal of the current mutagenicity classification and the addition of a classification for specific target organ toxicity (single exposure). The misclassification of perestane for mutagenicity was due to a change in the definition of the risk phase 40 to 68 (at the 28th ATP). The addition of a classification for specific target organ toxicity (single exposure) was motivated by the amount of methanol present in perestane.

The draft opinion supports the dossier's proposal to remove for perestane the classification as mutagenic, and to add the classification for specific target organ toxicity (single exposure).

RAC adopted by consensus the revised draft opinion on the CLH proposal for perestane. The proposed classification is presented in Table 1 of Part II of this document.

The Chair thanked the rapporteur and the members for the work.

7.2 CLH Dossiers for first discussion

7.2.a Nitrobenzene

The Chair welcomed the dossier submitter representative from German CA (remote meeting participant) and the adviser to the rapporteurs and invited the rapporteurs to introduce the first draft opinion on the CLH proposal submitted by Germany.

Nitrobenzene could contain benzene as an impurity therefore the classification for nitrobenzene has been given twice: for nitrobenzene containing impurities of benzene less than 0.1 % (except water) and for nitrobenzene containing impurities of benzene between 0.1% and 0.3%.

The nitrobenzene containing impurities of benzene between 0.1% and 0.3% should be additionally classified as Carc. 1A and Muta. 1B.

The rapporteurs supported the classification proposed by the dossier submitter except the classification on repeated exposure. Based on key studies the rapporteur proposed to downgrade this classification. The rapporteurs proposed to strength the reprotox classification to Rep. 1B as well.

During the discussion, based on the results of the acute toxicity and mortality in skin irritation studies more strength for classification for acute dermal toxicity was suggested. The rapporteurs asked for the full study report to reconsider this proposal. There was also a recommendation to revise the conclusion on lactation effects. The rapporteurs proposed to revise the maternal toxicity part of the BD in line with the study of Mitsumori et al. 1994.

The classification as Repr. 1B for nitrobenzene containing <0.1% of impurities was discussed.

Further it was suggested that impurities should not be taken into account in the substance classification. It was confirmed that nitrobenzene has one entry in Annex VI of the CLP regulation, with no specification on concentration of benzene. The proposal from the MS to split the classification for nitrobenzene in two entries was new. This support the opinion that the substance should be classified in the form in which is placed on the market. However, it was also stated that the introduction to Annex VI CLP said that if the impurity contribute to the toxicity of the substance (is decisive for the toxicity) it should be mentioned in the proposal.

The Chair asked the Commission observers to clarify how the issues of impurity should be reflected in the classification in the future. The Commission representatives proposed to discuss this subject at the next CARACAL meeting or during the 3rd ATP meeting in October 2011 and inform RAC about the outcome. The Chair proposed to continue the RAC discussion on the split proposal while waiting for this clarification expected for the next RAC meeting.

The Chair thanked the rapporteurs for their presentation and invited RAC members to provide comments on the first draft opinion and its annexes by the date indicated in section 6.2d of Part II of this document.

7.2.b N-ethyl-2-pyrrolidone (NEP)

The Chair invited the RAC rapporteurs to present the first draft opinion on the CLH proposal submitted by France. The first draft opinion supports the proposal in its assessment for reproductive toxicity (Repr. 1B according to CLP, Repr. Cat. 2; R61 according to Directive 67/548/EEC). France proposed to use the hazard code H360D, but as effects on fertility had not been addressed in the dossier the rapporteurs were of the opinion that H360 would be the correct hazard statement. As there is no developmental study by inhalation available, it is proposed not to specify route of exposure in the hazard statement. There was an additional comment made by industry in the public consultation on possible inclusion of specific concentration limits which was not considered as necessary by the rapporteurs. It is also proposed to proceed with the procedure and not to postpone it with a view of awaiting data from a new 28d inhalation study (referred to by industry during the public consultation) that could possibly be relevant for the endpoint fertility. There were no comments raised by industry at the meeting.

The first discussion expressed support for the approach taken by the rapporteurs, but regarding the labelling, and particularly the inclusion of the letter “D” in the hazard code, some members asked the rapporteurs to consider the approach discussed in previous opinions and to include the footnote regarding the Reprotox labelling that has been used in similar cases.

The Chair thanked the rapporteurs for their presentation and invited RAC members to provide comments on the first draft opinion and its annexes by 27th September; after that a written procedure for the adoption will be launched.

7.2.c Ammoniumpentadecafluorooctanoate (APFO)

The Chair welcomed the representative of the dossier submitter from the Norwegian Competent Authority (MSCA) who took part in the discussions as a remote participant.

The Chair introduced an observer accompanying the CEFIC stakeholder observer and invited the RAC rapporteurs to present the data of the CLH proposal submitted by Norway for first discussion.

This substance classification was previously agreed under TC C&L. Rapporteurs presented their assessment for the different endpoints following the approach presented at RAC 16 (RAC-box). This approach aims to clarify in the background document:

1. Proposal of the dossier submitter
2. Comments submitted by concerned parties
3. Outcome of the RAC assessment

Rapporteurs stressed that their assessment can only be based on the information provided by parties within this CLH process and not to all information that may be publicly available. View of RAC members were specifically requested on acute toxicity (oral and inhalation), skin and eye irritation, repeated dose toxicity – dermal (only for DSD) and lactation.

The discussion focused on reproductive toxicity. In the key study (Lau et al. 2006) APFO effects take place very early. RAC discussed the benefit to clarify how the "early" resorptions were defined in the study. The fact that maternal toxicity is lower at gestation day (GD) 5 than at GD18 should also be reflected.

The CEFIC stakeholder observer commented that the maternal toxicity might be underestimated as the changes in liver weight were clearly substantial. Doses used in the study might not have been low enough to distinguish between developmental and maternal toxicity. The observer further noted that human data did not show evidence of birth defects. A study that was not indicated during the public consultation is ongoing on the population drinking water contaminated by PFOA.

The Chair thanked the rapporteurs for their presentation and invited RAC members to provide comments on the first draft BD. See also section 7.2c of Part II of this document.

7.2.d Perfluorooctanic acid (PFOA) and its ammonium salt

The Chair welcomed the representative of the dossier submitter from the Norwegian Competent Authority (MSCA) who took part in the discussions as remote participant.

The Chair introduced an observer accompanying the CEFIC stakeholder observer and invited the RAC rapporteurs to present the data of the CLH proposal submitted by Norway for first discussion.

The Chair invited the RAC rapporteurs to present the first draft Background Document (BD) on the CLH proposal submitted by Norway.

The Secretariat noted that identical classification was previously agreed under TC C&L also for several other salts. The dossier submitter clarified that the CLH dossier relates to PFOA and its ammonium salt (APFO). RAC discussed why the classification from APFO could be applied to PFOA: in buffer solutions, both

substances are identical. Therefore RAC provisionally agreed to apply to Perfluorooctanic acid (PFOA) the classification of APFO when adopted.

The Chair thanked the rapporteurs for his presentation. See also section 7.2d of Part II of this document.

7.2.e P-tert-butylphenol

The Chair invited the RAC rapporteurs to present the data of the CLH proposal submitted by Norway for first discussion.

The dossier focuses on the human health hazards specific target organ toxicity (respiratory tract irritation); skin irritation, serious eye damage as well as reproductive toxicity (fertility) as preliminary agreed under TC C&L.

It was clarified during the meeting that, RAC can not evaluate the environmental hazard classes according to the 2nd ATP, because no environmental classification was proposed for this substance in the dossier that went for public consultation and because there is also no current Annex VI entry. The dossier submitter should submit to ECHA a new CLH dossier to propose the environmental classification.

The Chair thanked the rapporteurs for their presentations and invited RAC members to provide comments on the first draft opinion and its annexes once it is available. See also section 7.2.e in Part II of this document.

7.3 Appointment of RAC (co-) rapporteurs for CLH dossiers

Room document RAC/17/2011/21 was introduced by the Chair who explained that (co-)rapporteurs are required for 14 intentions of CLH dossiers and for three dossiers already submitted to ECHA. RAC agreed to appoint as (co-)rapporteurs all members that had volunteered before and during RAC-17 for (co-)rapporteurship. Rapporteurs and co-rapporteurs are still required for five intentions. The RAC members are invited to come forward for the remaining positions.

RAC agreed that the current rapporteur will continue as rapporteur for the dossier of fenpyroximate as invited expert at the end of the member's mandate. RAC also agreed to change co-rapporteur for cycloxydim dossier following the RAC members' proposal for reallocating this dossier.

7.4 General CLH issues

a. State of play of the submitted CLH dossiers

As agreed in RAC-16 in June, the Chair informed RAC that the meeting document on the "State of play of the submitted CLH dossiers" will be provided only when it's prepared for CARACAL[2]. The next CARACAL meeting is in October 2011 and the document will be provided at RAC-18 meeting accordingly.

The Chair reminded members, that information on the status of the CLH dossiers is available in the regularly updated "tracking table" which was uploaded to the confidential CIRCABC site in the folder "General CLH issues".

[2] Competent Authorities for REACH and CLP

b. Review of the process for developing CLH opinions

The Secretariat informed RAC about the review of the process for the CLH opinion development following the workshop "On the way to CLH" and following the last RAC-16 plenary meeting. The main aspects identified for development are the accordance check, the background document as well as comments sent by stakeholder observers (STO) after public consultation.

Accordance check

On the aspect of the accordance check the Secretariat informed RAC that following the agreement to transform the working procedure into a framework at the last RAC-16 meeting, the Secretariat had now taken over the responsibility to verify the submitted CLH dossiers and to check that the information provided fulfils legal requirements.

During the discussions, members asked whose role it is to verify that the comparison between the study results and the CLP criteria are included into the submitted dossier. The Secretariat replied that its own role is to ensure that the legal requirements are met and that the rapporteurs are given the opportunity to comment on the dossier's scientific quality and to provide recommendations to the dossier submitter, should the information provided in the dossier not seem to allow RAC to take an opinion.

Members agreed to the presented approach to improve and to speed up the process for developing the accordance check reports.

In this context members stated that the information provided by the dossier submitter in the CLH report is often insufficient already now even though the information might be available as attachments to the dossier. Often the rapporteur had to obtain data from the original studies and needed to compare the results with the CLP criteria. These tasks were clearly part of the dossier submitter responsibility. The Secretariat emphasised RAC's possibility to conclude in the opinion, that the information provided by the dossier submitter is insufficient to classify the substance for the proposed hazard.

Members asked the Secretariat to contact dossier submitters of MSCA individually to improve dossiers and explain that for RAC to come to an independent opinion of the dossier it was essential that dossier submitters included in their weight of evidence approach good quality study summary reports (RSS). Specifically members asked the Secretariat to contact MSCAs which obviously did not extract the results of the hazard assessments of PPPs or BP from the DARs[3] and CARs[4] for the purpose of classification and labelling.

Some members proposed further to the Secretariat to support capacity building for MSCA to provide better quality dossiers, so that a majority of the submitted CLH dossiers may pass the accordance check.

Opinion development

The Secretariat presented results of the pilot project of the RAC-box approach and announced that for specific ongoing opinions pilot documents were prepared. One of the central requirements is that the background document was based on the original CLH report submitted for public consultation. Article 37(4) of CLP stipulates that

[3] Draft assessment report
[4] Competent authority report

RAC should 'adopt an opinion on any proposal submitted'. The 'submitted proposal' is the proposal which was published for public consultation. The publication of the proposal is carried out in order implement the ECHA obligation set out in Article 37(4) CLP to give the parties concerned the opportunity to comment. Therefore, the logic point of reference for the opinion referring back to the originally submitted proposal is the document which was subject to public consultation and not a version which was changed afterwards in the opinion forming process (the updated CLH dossier). The use of RAC-boxes would clarify the ownership of the justifications in the text. The document would support the Commission to assess the RAC opinion and to conclude whether the harmonisation of the classification and labelling of the substance concerned is appropriate. When assessing the appropriateness of harmonised classification and labelling, the Commission will also focus on the proper conduct of the regulatory process. Hence, it is essential that the RAC background document and/or opinion and RCOM clearly document the following:

- what was originally proposed by the dossier submitter;
- which information supported the proposal;
- which comments/additional information were received during public consultation;
- RAC view on the proposal and all comments.

As proposed at the workshop in February the Secretariat has ceased to request the dossier submitter to update the CLH report after the public consultation. The dossier submitter is requested to provide responses to the comments. In the context of such responses the dossier submitters should indicate whether the comment(s) led to a change of view.

The following approach for the modification of the current working procedure was proposed:

- the RAC-box concept should be used in future in combination with the original version of the CLH dossier for all dossiers for which RAC has not yet started work;
- for dossiers currently in the opinion-forming process RAC may decide case-by-case which approach to apply.

Several RAC members supported the improvement of the process and the approach in general, but doubted that a RAC workload reduction can be expected from the change. The Secretariat promised to support the RAC members in their work and stated that it could provide a proposal for parts of the RAC boxes should the rapporteurs wish so.

A Commission observer underlined the importance of fulfilment of the legal requirements and supported the approach.

Several RAC members considered that it was too early to adopt the new format yet, and that RAC first would like to try it out on a number of substances, to get familiar with the workload involved. Some RAC rapporteurs agreed to try out the first pilot projects on some substances to be adopted at the next RAC-18 meeting.

RAC members were requested to provide further comments. The Secretariat will prepare a proposal for a revised working procedure based on the proposal presented to RAC and the comments received from members.

In the context of the opinion development RAC members requested the Secretariat to clarify for the different type of dossiers (in particular for PPP and BP substances already included in Annex VI of the CLP, and for PPP and BP substances for which the proposal has not included the changes in the criteria according to the 2nd ATP to the CLP) which hazard classes need to be evaluated by RAC.

Stakeholder participation

From experiences of the first years of adopting CLH opinions the Secretariat presented a new approach and a first proposal of a working procedure (room document: RAC/17/2011/22) that will give STO the opportunity to comment on comments provided during the public consultation and on the draft opinion documents. RAC may address these comments, but is not obliged to do so. Only comments received during the public consultation will be routinely responded to by RAC.

Some STO observers stated that they will not have the capacity nor see their role to provide information to RAC on specific substances. As their status in the meeting is sector specific their role is to overview the overall process of the opinion development and not to defend the classification of a specific substance.

The Chair reminded STO of their role according to the "code of conduct for observers at ECHA meetings", to provide on request technical and scientific input based on the specific expertise and knowledge. The proposed working procedures are in line with the code of conduct.

Members supported the improved and clarified approach for stakeholder participation during the development of CLH opinions. Written comments can be provided to the Newsgroup established for this purpose. The Newsgroup will also be accessible for STO. STO were asked to provide their comments via the RAC functional mailbox.

8 Restrictions

8.1 Restriction Annex XV dossiers

Phthalates – outcome of the conformity check

The Chair welcomed the representative and other remote meeting participants from the Danish CA (dossier submitter).
The rapporteurs gave an overview of the revised Annex XV dossier proposing a restriction for the four phthalates DEHP, DBP, BBP and DIBP[5]. The revised proposal was resubmitted by the Danish authorities in August 2011 following the RAC agreement of non-conformity of the original dossier at its last meeting in June 2011.

According to RAC discussions the resubmitted restriction dossier has been improved in the sections considered insufficient in the last conformity report. Improvements were made in i) the description of the scope of the restriction proposal, ii) hazard information, iii) assessment of the effectiveness of the proposal (risk reduction capacity), practicality and monitorability and iv) background information on the scope and conditions of the restriction.

[5] (Bis(2-ethylhexyl) phthalate, EC No. 204-211-0 CAS No. 117-81-7; Benzyl butyl phthalate, EC No. 201-622-7, CAS No. 85-68-7; Dibutyl phthalate, EC No. 201-557-4, CAS No. 84-74-2; Diisobutyl phthalate, EC No 201-553-2, CAS No. 84-69-5)

The resubmitted restriction proposal aims to restrict the placing on the market of articles intended for use indoors and articles that may come into direct contact with the skin or mucous membranes containing the four phthalates in a concentration greater than 0.1% by weight of any plasticised material. Even though no new wording was proposed, examples presented clarified the intention of the restriction proposal. Following the experience of other restriction dossiers, the wording could also change during the Committee discussions and responsibility of the final wording of the restriction would lie with the Commission.

On the basis of the information provided, it will be possible for RAC to adopt an opinion; however for a solid justification further information will be necessary. Partly, this information may come from the public consultation. Additional descriptions or information may be provided by the dossier submitter who stated to have resources available for the improvement of the background document.

A stakeholder observer questioned the logic to restrict substances in certain uses, even though the substances had already been identified as SVHCs (substances of very high concern) under the authorisation process. The permission of use of SVHC is already subject to the authorisation process under REACH.

In conclusion, RAC agreed that the Annex XV dossier proposing a restriction for four phthalates is in conformity with the requirements of Annex XV for the RAC relevant parts, in accordance with Article 69(4) of the REACH Regulation. Following the procedure, the Secretariat will start the public consultation.

8.2 General restriction issues

a. Update on intended restriction dossiers

The Secretariat informed RAC that up to date two restrictions intentions have been notified to ECHA. Sweden intends to submit a restriction proposal on nonylphenol by August 2012. Denmark intends to submit a restriction proposal on hexavalent chromium (Cr^{VI}) to prevent skin allergy from contact with articles of leather. The registry of intentions is publicly available on the ECHA website[6].

b. Review of working procedures after experiences on first dossiers

Following the first experiences gained with the opinion development of the four finalised and one currently ongoing restriction proposals, the Secretariat informed about the planned revision of the Committee documents related to restrictions. RAC members were asked to contribute to this process by sending their improvement proposals to the CIRCABC Newsgroup to be established for this purpose or through a questionnaire distributed by the Secretariat by October 2011. See also section 8.2 of Part II of these meeting minutes.

9 Authorisation

9.1 Appointment of RAC rapporteurs for substances listed in Annex XIV

[6] ECHA website "Registry of intentions for Annex XV dossiers: http://echa.europa.eu/chem_data/reg_int_tables/reg_int_en.asp?substance_type=Restriction&substance_state=current

ECHA presented the room document (RAC/17/2011/23) listing volunteers for rapporteurship in different pools for substances included in Annex XIV.

RAC agreed to appoint in seven cases the volunteers to the pool as (co-)rapporteurs for the substances listed in Annex XIV.

The Chair indicated that the pools will be updated if new expressions for interests are received and the appointment is agreed by RAC. The potential rapporteurs will be informed as soon as an application for authorisation is submitted to ECHA, and rapporteurs will be selected according to the agreed procedure. In principle, members will remain in the pool until the end of their mandate, but may request the RAC Secretariat to be removed from a specific pool if needed.

9.2 Joint RAC&SEAC session

The session started with introduction by the ECHA Secretariat ("How Committees evaluate the Applications for Authorisation"). The presentation focused mainly on the issue of the cooperation between both Committees, it outlined key principles and suggested practical solutions to be followed when evaluating applications by Committees. After the presentation, the participants of the joint session were divided in four break-out groups to discuss the following topics:

1. The approach focuses on properties specified in Annex XIV, but what about the other risks?
2. In practice, alternatives are SEAC's business alone, do you agree?
3. DMELs cannot be used for demonstration of adequate control, but is useful in customising the SEA. What is your opinion?
4. SEAC should focus its attention on evaluating whether the costs of alternatives are correctly assessed. Do you agree?

The outcomes of the discussion in the groups were presented by the group's rapporteurs in the plenary session.

Additionally participants were asked also to provide comments on which issues would they consider that further discussion or development is needed and to provide ideas on how to avoid that uncertainties would always lead the Committees to a situation where no clear opinion in favour or against an authorisation can be delivered. The groups presented the following conclusions and proposals for further discussion

- Application template needs to define clearly what aspects relate to SEA/adequate control route.
- Need for legal clarification on what endpoints the Committees can consider. If it is not clear in the legal text can RAC/SEAC decide?
- What are the needs of the Commission?
- Processes where RAC/SEAC wants clarification from the applicant and/or, third party
- Possibilities to use competencies and knowledge of the Forum on technical processes and uses
- Is the information from registration dossiers accessible and reliable?
- Alternatives: what are system boundaries (final product, production process, no production alternatives)?; what economic perspective should be considered (applicant's *versus* society's)?

- Basis for an independent opinion beyond the information from an application and public consultation – may own assessment be included? How to deal with lack of knowledge/ information? How much can the Committees trust the information coming during the public consultation from third parties?

The Secretariat concluded that it would further elaborate on the issues in collaboration with the Commission and it would come back during the Committees' meetings in December 2011.

9.3 Follow-up of the joint RAC-SEAC session & 9.4 Follow-up of previous RAC discussions on opinions on authorisation applications

The Secretariat informed RAC that the objective of the project is to help RAC and SEAC members, and in particular future rapporteurs, to prepare for all tasks in evaluating applications for authorisation.
An internal ECHA task force has been created to prepare a proposal for 2012-13 but results strongly depend on input from RAC and SEAC. Any contribution is highly appreciated. Suggestions so far:

- Definitions and interpretations: e.g. feasibility, proportionality, available alternatives, precautionary principle
- Methodology: distinct the good from the bad; alternatives, environmental risk, variety of technical issues
- Approach: teams, database

RAC requested to the Commission to define clearly what the Commission expect from RAC and SEAC in the context of authorisation applications. Only after will be the time for discussion how to fulfil those expectations. The Commission has promised to come back to the issue at the next RAC meeting. RAC underlined, that the written opinion of the Commission will be highly appreciated and MSCAs should be also informed.

The proposal for having substance specific working groups would be considered in the further development of the capacity building project. RAC also suggested adding to the capacity building program training on the exposure assessment. The Secretariat will consider this proposal and the Chair clarified that in addition for particular dossiers the Committee can appoint invited experts with specific expertise in exposure assessment or any other scientific or technical aspect. The Chair also indicated that document RAC/17/2011/19 covering a set of proposals for streamlining of RAC procedures included a suggestion for creating an expert database for addressing the future RAC needs, including those related to the authorisation process, and requested RAC members to provide specific comments on this proposal.

Additionally the Workshop on Gathering Information for Risk Management Purposes (on 15-16 November 2011) was announced. The workshop is mainly addressed to MSCA staff and ECHA staff.

10 Guidance issues

10.a Feedback from guidance consultations

The Secretariat presented the main elements proposed for the update of the guidance on the application of the CLP criteria. This draft update includes guidance on the setting of SCLs for human health hazards and a revision of the environmental classification criteria introduced by the publication of the 2nd ATP[7]. The 2nd ATP entered into force on 19th April 2011.

Due to the high amount of comments received, the RAC consultation of this draft guidance update for the human health part is postponed, for the environmental part the consultation is foreseen as planned. Due to lack of consensus on the interpretation of "rapid removal" of metals from the water column ECHA will take out this issue from the current guidance consultation process. The Secretariat informed that a stakeholder workshop is planned for beginning of 2012 on this issue.

Following the experience gained by RAC to apply the CLP criteria, and to use the guidance on the Application of the CLP criteria, the Secretariat has launched the collection of feedback. The Chair invited RAC members to provide their feedback via the RAC CIRCABC Newsgroup by 29th November 2011 using the excel template.

10.b Report on other guidance activities

As agreed at RAC-16 in June, the Chair informed RAC that the meeting document "report on other guidance activities" will be provided only when it is prepared for CARACAL. Next CARACAL meeting is in October 2011 and the document is provided at RAC-18 meeting accordingly.

11 Any other business

New graduate scheme in the field of EU chemical policies at ECHA

RAC was informed about an awareness campaign on a new graduate scheme in the field of EU chemical policies which will be launched by ECHA in cooperation with the Commission in November 2011. As a first step, a registry will be created to gather all relevant post graduate qualification in this field. RAC members were invited to forward information to ECHA in this field.

12 Main conclusions and Action Points of RAC-17

The Secretariat presented the main conclusions and action points of the RAC-17 plenary meeting for final comments and agreement by the Committee. All suggestions from RAC were reflected accordingly[8] and RAC agreed to the document. The main conclusions and action points are attached as Part II of these meeting minutes.

o0o

[7] 2nd Adaptation to Technical Progress (ATP) to CLP Regulation (EC) No 286/2011 of the European Parliament and of the Council of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, OJ L 83, 30.03.2011, p. 1-53.

[8] Suggestions for inclusion in the Manual of Conclusions and Recommendations are included in the minutes rather than in the Main Conclusions and Action points.

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
(Adopted at the 17th meeting of RAC)
(13-16 September 2011)

Agenda point	
Conclusions / decisions / minority opinions	**Action requested after the meeting (by whom/by when)**
2. Adoption of the Agenda	
The revised Agenda (RAC/A/17/2011_rev.3) was adopted with some modifications.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-17 minutes.
3. Declarations of conflicts of interest to the Agenda	
13 members and three STO observers have declared a potential conflict of interest to different substance-related discussions on the Agenda.	-

5. Administrative issues and information items	
5. c Report from other ECHA bodies and activities	
The Committee was informed about the MB decision of requiring stakeholder organisations to be listed on the Commission's Register of Interest Representatives before being invited to Committee and Forum meetings.	All **stakeholder organisations** to be registered before the invitations for RAC-18 are sent out. **STO** to send to the RAC SECR the registration number of their organisation in the Commission's Register of Interest Representatives.
5. d Streamlining of RAC procedures	
The Chair reported from the MB meeting concerning the streamline of the workload of the Committees (ECHA-RAC/17/2011/19).	**SECR** to establish a Newsgroup on the RAC CIRCABC site for collecting comments. **Members** may provide comments on the documents via the RAC

	CIRCABC Newsgroup by 9 October. **SECR** to consider the comments, and to modify the document as needed, to elaborate concrete proposals to be presented to RAC and to inform the MB.
5. e Declaring Conflicts of Interest	
SECR introduced RAC with the new policy on handling conflicts of interest scheduled for the next Management Board (MB) meeting.	**SECR** to inform RAC (via the administrative issue document) about the outcome of discussions in the MB meeting.
5. f Participation of Croatia in the work of RAC-	
RAC agreed that Croatia may participate as an observer at the meeting. (ECHA-RAC/17/2011/20).	**SECR** to communicate the agreement of RAC to the MB for a decision to allow observers from Croatia to attend RAC meetings.
6. Requests under Article 77 (3)(c) - gallium arsenide	
The RAC rapporteurs summarised the outcome of the RAC preparatory meeting on 12 September. They presented the key issues arising from the public consultation and the first draft opinion and BD and provided responses to comments received. Some issues were raised for further consideration and discussed by RAC.	**Members** to provide any further comments or assistance to the rapporteurs in the CIRCABC newsgroup on the issues listed in the end of the rapporteurs' presentation (Slide 19-21 in the presentation entitled "Carcinogenicity of GaAs (rapporteurs) rev1) from 13 September, available on CIRCABC. **Rapporteurs** to prepare the revised draft opinion and provide to **SECR** by Monday 3 October.
7. CLH	
7.1 CLH dossiers for opinion adoption	
7.1 b. Di-n-hexyl phthalate	
RAC adopted by consensus the opinion and its annexes on the CLH proposal for Di-n-hexyl phthalate. RAC agreed to propose Di-n-hexyl phthalate to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on D-n-hexyl phthalate and its annexes to the RAC CIRCABC, and to forward them to COM and publish them on the ECHA web site after the

	meeting. **SECR** to check the S-phrases.
7.1 c. MMTC (trichloromethylstannane)	
RAC adopted by consensus the opinion and its annexes on the CLH proposal for MMTC. RAC agreed to propose MMTC to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on MMTC (trichloromethylstannane) and its annexes to the RAC CIRCABC, and to forward them to COM and publish them on the ECHA web site after the meeting. **SECR** to check the S-phrases.
7.1 d. MMT(EHMA)	
RAC adopted by consensus the opinion and its annexes on the CLH proposal for MMT (EHMA). RAC agreed to propose MMT(EHMA) to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on MMT (EHMA) and its annexes to the RAC CIRCABC, and to forward them to COM and publish them on the ECHA web site after the meeting. **SECR** to check the S-phrases.
7.1 e. Fenamiphos	
RAC adopted by consensus the opinion and its annexes on the CLH proposal. RAC agreed to propose fenamiphos to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion fenamiphos and its annexes to the RAC CIRCABC, and to forward them to COM and publish them on the ECHA web site after the meeting. **SECR** to check the S-phrases.
7.1 f. Pitch, coal tar, high temp. (CTPHT)	
RAC provisionally agreed to propose CTPHT to be classified as indicated in the table 2. below.	**Rapporteurs** to provide the final draft of the opinion and its Annexes to the **SECR**. **SECR** to distribute the revised draft opinion documents (BD and RCOM) to RAC when available

	for further discussion and possible adoption by written procedure.
7.1 g. Penconazole	
RAC provisionally agreed with the classification of penconazole regarding some hazard classes as indicated in the table 2. below.	**SECR** to establish a Newsgroup on the RAC CIRCABC site for collecting comments on discussions. **Members to** submit comments before 7 October. **Rapporteurs** to revise the opinion and the BD and provide them to SECR before the RAC-18 meeting. **SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption either by written procedure or at RAC-18.
7.1 h. Aclonifen	
RAC adopted by consensus the opinion and its annexes on the CLH proposal for aclonifen. RAC agreed to propose aclonifen to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on aclonifen and its annexes to the RAC CIRCABC, and to forward them to COM and publish them on the ECHA web site after the meeting.
7.1 i. Sulcotrione	
RAC provisionally agreed with the classification of sulcotrione regarding some hazard classes as indicated in the table 2. below.	**STO** to send additional data on irritation to the RAC functional mailbox. **STO** to indicate if further information related to the findings on renal toxicity in the various studies could be provided and if so to send it to the RAC functional mailbox. **Rapporteurs** to revise the draft opinion and its annexes and to provide them to SECR.

	SECR to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption either by written procedure or at RAC-18.
7.1 j. Perestane	
RAC adopted by consensus the opinion and its annexes on the CLH proposal for perestane. RAC agreed to propose perestane to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on perestane and its annexes to the RAC CIRCABC, and to forward them to COM and publish them on the ECHA web site after the meeting. **SECR** to check the S-phrases.

7.2 CLH dossiers for first discussion	
7.2 a. Nitrobenzene	
RAC discussed the first draft opinion.	**Members** to post their comments on the 1st draft opinion via the RAC CIRCABC Newsgroup by 28 September 2011. **Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) before 20 October 2011. **SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption at RAC-18.
7.2 b. N-ethyl-2-pyrrolidone (NEP)	
RAC discussed the first draft opinion.	**Members** to post their comments on the 1st draft opinion via the RAC CIRCABC Newsgroup by 27 September 2011. **Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM) before RAC-18.

	SECR to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption either by written procedure or at RAC-18.
7.2 c. Ammoniumpentadecafluorooctanoate (APFO)	
RAC discussed the first draft background document (BD).	**SECR** to establish a Newsgroup on the RAC CIRCABC site for collecting comments. **Members** to post their initial comments on the 1st draft BD via the RAC CIRCABC Newsgroup by 6 October 2011. **Rapporteurs** to finalise the first draft opinion taking RAC discussions and comments into account. **SECR** to distribute the 1st draft opinion documents to RAC when available for further discussion and possible adoption at RAC-18.
7.2 d. Perfluorooctanoic acid (PFOA)	
RAC provisionally agreed to apply to Perfluorooctanic acid (PFOA) the classification of APFO when adopted.	**Rapporteurs** to indicate this agreement in the PFOA draft opinion documents. Following the adoption of the APFO opinion by RAC: **SECR** to ensure that the opinion documents from APFO are integrated into the PFOA opinion documents following the RAC-box approach, and to consult with the rapporteur before launching the written adoption.
7.2 e. P-tert-butylphenol	
RAC discussed the first presentation of the data.	**Rapporteurs** to draft the first draft opinion. **SECR** to distribute the first draft opinion documents to RAC for further discussion and possible

	adoption either by written procedure or at RAC-19.

7.3 Appointment of RAC (co-) rapporteurs for CLH dossiers	
RAC agreed to appoint the volunteers as (co-) rapporteurs for the intended or submitted CLH proposals (listed in room document ***RAC/17/2011/21**_rev1*). RAC agreed that the current rapporteur will continue as rapporteur for the dossier of Fenpyroximate as invited expert at the end of the mandate.	**SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for CLH proposals after the meeting. **Members** are requested to come forward for the vacant positions. **SECR** to identify potential (co-) rapporteurs and encourage them to fill the vacant positions.
7.4 General CLH issues	
7.4 a. State of play of the submitted CLH dossiers	
	SECR to prepare the document "state of CLH dossiers" for RAC as soon as it is prepared for CARACAL before the next meeting.
7.4 b Review of the process for developing CLH opinions o **Accordance check** o **Opinion development**	
The Secretariat informed RAC that the modified procedure for the Accordance check is now established. RAC was informed about the planned further steps for the development of streamlining the opinion development. RAC discussed the participation of STO in the CLH opinion development process.	**SECR** to establish a Newsgroup on the RAC CIRCABC site for collecting comments on the opinion development and on the STO participation. **Members** may provide comments on document ***RAC/17/2011/22*** and on the streamlining of developing of RAC opinions via the RAC CIRCABC Newsgroup by 9 October. **SECR** to consider the comments when revising the working procedure.
	SECR is to present the revised working procedure for agreement

	at or after the RAC-18 meeting.
RAC requested clarification on which hazard classes should be covered regarding existing entries of active substances in PPP and BP, and the new criteria under the second ATP.	**SECR** to clarify with COM and to inform MS and RAPs on the hazard classes to be covered for the ongoing and future dossiers.
RAC has found it difficult to prepare opinions on certain pesticide/biocide proposals within the agreed timeframe; since key toxicological information had not been included in the CLH reports.	**SECR** to explain to the DS how a simple reference to information in the DAR/CAR was not helpful in this regard and to advise how reports could be improved in the future.
Continuation of the collaboration with MS who are DSs for CLH proposals in order to improve the CLH reports, in particular regarding the need to provide RSSs and a comparison of the weight of evidence with the criteria.	**SECR** to explain to the DS the legal requirements and RAC needs regarding the need for RSSs and a comparison of the weight of evidence with the criteria.
8. Restrictions	
8.1 Restriction Annex XV dossiers	
8.1 Phthalates	
RAC agreed on the conformity of the restriction proposal.	The **SECR** to publish the dossier for public consultation.
8.2 General restriction issues	
RAC was informed on two new intended restriction dossiers to be submitted by Member States.	
Review of working procedures after experiences on first dossiers	
RAC took note of a framework for the revision of the restriction process as regards the Committees' work presented by the Secretariat.	**SECR** to initiate newsgroups or distribute a questionnaire to RAC and SEAC and their stakeholder observers to identify ideas and issues that should be addressed in the revision process in October 2011. Following the issues identified, the **Secretariat** is to propose to SEAC and RAC by December 2011 how to proceed.

9 Authorisation	
9.1 Appointment of RAC rapporteurs for substances listed in Annex XIV	
RAC agreed to appoint the volunteers to the pool as (co-) rapporteurs for the substances listed in Annex XIV (room document ***RAC/17/2011/23***_rev.1).	**SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for substances listed in Annex XIV. **SECR** to inform RAC as soon as an application for authorisation is submitted to ECHA. **Members** may volunteer to be added to the pool of (co-) rapporteurs any time.
9.2 Joint RAC&SEAC session	
RAC discussed the documents and provided several suggestions.	**SECR** to open a newsgroup for collecting comments until 31 October on the capacity building programme.
9.3 and 9.4 Follow-up of the joint RAC-SEAC session and previous RAC discussions on authorisation applications	
RAC requested further clarifications from ECHA and COM on the depth of the Committees' evaluation/assessment of authorisation applications and its relationship with the opinion. The proposal for having substance specific working groups will be considered in the further development of the capacity building project.	**SECR** to further elaborate on the issues in collaboration with COM and to come back to RAC's and SEAC's meeting in December 2011. **SECR** to consider the comments and to reflect on the future capacity building needs for RAC and SEAC related to application for authorisations.

10. Guidance issues	
The SECR informed RAC about the ongoing request for feedback on the current CLP guidance document and about the content of the future consultation of the draft update of the same document.	**Members** may provide feed back using the comment template via the RAC CIRCABC Newsgroup by 29 November.
11. AOB	
The SECR informed RAC about the new graduate scheme in the field of EU chemical policies at ECHA (room document ***RAC/17/2011/24***).	**SECR** to initiate newsgroups on the graduate scheme. **Members** may provide course proposals or other comments on the document via the newsgroup.
GENERAL	

-	**SECR** to upload all presentations, room documents and the RAC-17 Main conclusions and action points (i.e. this doc) to RAC CIRCABC without delay after the meeting. **Members** to send to SECR elements to consider for the Manual of Conclusions and Recommendations. **SECR** to consider the proposals from the members for the Manual of Conclusions and Recommendations.

Table 1. List of adopted classifications by RAC

Classification & Labelling in accordance with the CLP Regulation

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	di-n-hexyl phthalate	201-559-5	84-75-3	Repr. 1B	H 360FD	GHS08 Dgr	H 360FD			

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	di-n-hexyl phthalate	201-559-5	84-75-3	Repr. Cat. 2; R61 Repr. Cat. 2; R60	T R: 60/61 S: S(1/2)-45-53		

Classification & Labelling in accordance with the CLP Regulation

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	Trichloromethylstannane (MMTC)	213-608-8	993-16-8	Repro. 2	H361d[9]	GHS08 Wng	H361d			

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Trichloromethylstannane (MMTC)	213-608-8	993-16-8	Repr. Cat. 3; R63	Xn R: 63 S: (2)-36/37		

[9] It is the view of RAC that hazard statement H361d is the most appropriate, given the available toxicological profile of MMTC, but RAC recognised that H361 could be applied if the available criteria are applied strictly

Classification & Labelling in accordance with the CLP Regulation

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate; MMT (EHMA)	260-828-5	57583-34-3	Repr. 2	H361d[10]	GHS08 Wng	H361d			

[10] It is the view of RAC that hazard statement H361d is the most appropriate, given the available toxicological profile of MMT(EHMA), but RAC recognised that H361 could be applied if the available criteria are applied strictly

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-methyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate; MMT (EHMA)	260-828-5	57583-34-3	Repr. Cat. 3; R63	Xn R: 63 S: (2)-36/37		

Classification & Labelling in accordance with the CLP Regulation

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	fenamiphos	244-848-1	22224-92-6	Acute Tox. 2 Acute Tox. 2 Acute Tox. 2 Eye irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	H300 H310 H330 H319 H400 H410	GHS06 GHS07 Dgr	H300 H310 H330 H319 H410		Acute M=100 Chronic M=100	

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	fenamiphos	244-848-1	22224-92-6	T+; R26/28 T; R24 Xi; R36 N; R50-53	T+, Xi, N R: 24-26/28-36-50/53 S: 1/2-23-26-28-35-36/37-45-60-61	C≥0.25% N;R50-53 0.025%≤C<0.25%N;R51-53 0.0025%≤C<0.025% R52-53	

Classification & Labelling in accordance with the CLP Regulation

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
612-120-00-6	Aclonifen (ISO) 2-chloro-6-nitro-3-phenoxyaniline	277-704-1	74070-46-5	Carc. 2 Skin. Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H351 H317 H400 H410	GHS08 GHS07 GHS09 Wng	H351 H317 H410		M = 100 (Acute) M = 10 (Chronic)	

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
612-120-00-6	Aclonifen (ISO) 2-chloro-6-nitro-3-phenoxyaniline	277-704-1	74070-46-5	Carc. Cat. 3; R40 R43 N; 50-53	Xn, N R: 40-43-50/53 S: (2-)36/37-60-61	C≥0.1% R43 C≥0.25% N; R50-53 0.025%≤C<0.25% N; R51-53 0.0025%≤C<0.025% R52-53	

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
	Reaction mass of: succinic acid, monopersuccinic acid, dipersuccinic acid, monomethyl ester of succinic acid, monomethyl ester of persuccinic acid, dimethyl succinate glutaric acid, monoperglutaric acid, diperglutaric acid, monomethyl ester of glutaric acid, monomethyl ester of perglutaric acid, dimethyl glutarate adipic acid, monoperadipic acid, diperadipic acid monomethyl ester of adipic acid,	432-790-1	N/A	Skin Corr. 1B Acute Tox. 4* Acute Tox. 4* Acute Tox. 4* STOT SE 2 (eye)	H314 H332 H312 H302 H371	GHS05 GHS07 GHS08 Dgr	H314 H332 H312 H302 H371	-	-	-

	monomethyl ester of peradipic acid, dimethyl adipate, hydrogen peroxide, methanol and water [Perestane]									

Classification and labelling in accordance with the criteria of Directive 67/548/EEC

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Reaction mass of: succinic acid, monopersuccinic acid, dipersuccinic acid, monomethyl ester of succinic acid, monomethyl ester of persuccinic acid, dimethyl succinate glutaric acid, monoperglutaric acid, diperglutaric acid, monomethyl ester of glutaric acid, monomethyl ester of perglutaric acid, dimethyl glutarate adipic acid, monoperadipic acid, diperadipic acid monomethyl ester of adipic acid, monomethyl ester of peradipic acid, dimethyl adipate, hydrogen peroxide, methanol and water	432-790-1	N/A	C; R34 Xn; R20/21/22 Xn; R68/20/21/22	C R: 20/21/22-68/20/21/22 S: 1/2-26-28-36/37/39-45	-	-

	[Perestane]						

Table 2. List of preliminary RAC agreement on proposals for classification

(Agreement reached for the following endpoints)

Classification & Labelling in accordance with the CLP Regulation

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
648-055-00-5	Pitch, coal tar, high temp. (CTPHT)	266-028-2	65996-93-2	Carc. 1A Muta. 1B Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H350 H340 H360FD H400 H410	GHS08 GHS09 Dgr	H350 H340 H360FD H410		 M=1000 M=1000	 COM to draft if needed.

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
648-055-00-5	Pitch, coal tar, high temp. (CTPHT)	266-028-2	65996-93-2	Carc. Cat. 1; R45 Muta. Cat. 2; R46 Repr. Cat. 2; R60/61 N; R50/53	T; N R45-46-60-61-50/53 S45-53-60-61		

Classification and labelling in accordance with the CLP Regulation (Regulation (EC) 1272/2008)

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard state-ment Code(s)	Pictogram, Signal Word Code(s)	Hazard state ment Code(s)	Suppl. Hazard statement Code(s)		
	Penconazole (1-[2-(2,4-dichloro-phenyl)pentyl]-1H-1,2,4-triazole)	266-275-6	66246-88-6	Acute Tox. 4 Aquatic Acute 1 Aquatic Chronic 1	H302 H400 H410	GHS07 GHS09 Wng	H302 H410		M-factor: 1 and 1	

Classification and labelling in accordance with the criteria of Directive 67/548/EEC

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Penconazole (1-[2-(2,4-dichloro-phenyl)pentyl]-1H-1,2,4-triazole)	266-275-6	66246-88-6	Xn; R22 N; R50/53	R22 R50/53 S: 60-61	N; R50/53, C ≥ 25% N; R51/53, 2.5% ≤ C < 25% R52/53, 0.25% ≤ C < 2.5%	

Classification & Labelling in accordance with the CLP Regulation

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
	Sulcotrione; 2-(2-chloro-4-mesylbenzoyl)cyclohexane-1,3-dione		99105-77-8	Skin Sens. 1A Aquatic Acute 1 Aquatic Chronic 1	H317 H400 H410	GHS07 GHS09 Wng	H317 H410		 M = 1 M=10	

Classification & Labelling in accordance with Directive 67/548/EEC:

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Sulcotrione; 2-(2-chloro-4-mesylbenzoyl)cyclohexane-1,3-dione		99105-77-8	 R43 N; R50/53	Xi, N R43-50/53	N; R50-53: C ≥ 25% N; R51-53: 2.5% ≤ C < 25% R52/53: 0.25% ≤ C < 2.5%	

oOo

Part III. List of Attendees of the RAC-17 meeting (13-16 September 2011)

Members		**ECHA staff**
ANDERSSON Alicja		ATLASON Palmi
BARANSKI Boguslaw		ANFÄLT Lisa
BARRON Thomasina		BARRUEL Philippe
BJØRGE Christine		CSAK Viktoria
BORGES Teresa		DE BRUIJN Jack
BRANISTEANU Radu		ERICSSON Gunilla
Di PROSPERO FANGHELLA Paola		FUHRMANN Anna
DUNAUSKIENE Lina		HOLLINS Steve
DUNGEY Stephen		KARJALAINEN Ari
GREIM Helmut		KLAUK Anja
GRUIZ Katalin		KNIGHT Derek
HAKKERT Betty		KOKKOLA Leila
HALKOVA Zhivka		LEBSANFT Jörg
JENSEN Frank		LEFEBVRE Alain
KADIKIS Normunds		LEFEVRE Remi
LARSEN Poul Bo		LUOTAMO Marita
LEINONEN Riitta		LUSCHÜTZKY Evita
LUND Bert-Ove		MAGGIORE Angelo
MULLOOLY Yvonne		MALM Jukka
OLTEANU Maria		MATTHES Jochen
PARIS Pietro		MOSSINK Jos
PASQUIER Elodie		NYGREN Jonas
PICHARD Annick		PELTOLA Jukka
PINA Benjamin		RODRIGUEZ IGLESIAS Pilar
POLAKOVICOVA Helena		ROGGEMAN Maarten
PRONK Marja		RÖCKE Timo
RUPPRICH Norbert		SAEZ RIBAS Monica
SCHLUETER Urs		SANDBERG Eva
SCHULTE Agnes		SCHÖNING Gabi
SMITH Andrew		SPJUTH Linda
STOLZENBERG Hans-Christian		TYNKKYNEN Sallamari
TADEO José L.		VAINIO Matti
Van der HAGEN Marianne		Van HAELST Anniek

DUSSART Aurélie (replacing Van MALDEREN Karen)		SOSNOWSKI Piotr
		TARAZONA Jose
Advisers to the RAC members		**Stakeholder observers**
ALESSANDRELLI Maria (adviser to Paola Di Prospero Fanghella)		ANNYS Erwin (Cefic)
CAÑAS Irene (adviser to José L. Tadeo) and adviser supporting rapporteurs on Pitch, coal tar		LAUBER Gertraud (EMCEF)
CURABA Mara (adviser to Aurélie Dussart, replacement of Karen van Malderen)		MEISTERS Marie-Louise (ECETOC)
EKOKOSKI Elina (adviser to Riitta Leinonen)		MUNARI Tomaso (EuCheMS)
HELLMER Lena (adviser to Alicja Andersson)		ROWE Rocky (ECPA)
LINDEMAN Birgitte (adviser to Marianne van der Hagen) and adviser supporting rapporteurs on Gallium Arsenide		MÜLLER Karsten (BusinessEurope), replacement to Volker Soballa
PECZKOWSKA Beata (adviser to Boguslaw Baranski) and adviser supporting rapporteurs on Nitrobenzene)		VEROUGSTRAETE Violaine (Eurometaux)
ROMOLI Debora (adviser to Pietro Paris)		
SOERENSEN Hammer Peter (adviser to Frank Larsen)		**Other observers**
SMITH Helen (adviser to Andrew Smith) and adviser supporting rapporteurs on Sulcotrione		BOMHARD Ernst(an observer acting as an expert to an observer representing Eurometaux for GaAs)
Invited Experts		BARNES Emma (an observer acting as an expert to an observer representing ECPA observer for penconazole)
Le CURIEUX-BELFOND Olivier (RAC rapporteur for CLH dossiers for Penconazole)		COHEN Samuel (an observer acting as an expert to an observer representing CEFIC for GaAs)
VILANOVA Eugenio (RAC rapporteur for CLH dossiers for P-tert-butylphenol and DnHP)		GELBKE Heinz-Peter (an observer acting as an expert to an observer representing Business Europe for GaAs)
		KENNEDY Gerald (an observer acting as an expert to an observer representing CEFIC for PFOA; APFO)
		SEMINO Giovanna (an observer acting as an expert to an observer representing ECPA for aclonifen, sulcotrione)
Representatives of the Commission		
BINTEIN Sylvain (DG ENV)		**Remote participants**

GIRAL-ROEBLING Anne (DG ENTR)		ANDERSSON Alicja (RAC member on 15-16.9.2011)
SCAZZOLA Roberto (DG ENTR)		AUTERI Domenica (EFSA following fenamiphos)
VLANDAS Penelope (DG ENV)		LOSERT Annemarie (RAC member)
ZIELINSKI Janusz (DG ENV)		CONWAY Louise (adviser to Yvonne Mullooly following CLH dossiers)
		DOBEL Shima (adviser to Frank Jensen following phthalates)
		HERBST Uta (a representative of the German CA following nitrobenzene)
		HERREMANS Joke (a representative of the Netherlands CA following fenamiphos and CTPHT)
		HERZLER Matthias (a representative of the German CA following nitrobenzene
		HUSA Stine (a representative of the Norwegian CA following APFO, PFOA)
		LARSEN Ann Kristin (a representative of the Norwegian CA following P-tert-butylphenol)
		Mc Mickan Sinead (adviser to Yvonne Mullooly following authorisation and restriction)
		NIEMANN Lars (a representative of the German CA following aclonifen, penconazole and sulcotrione)
		SMITH Colin (adviser to Yvonne Mullooly following CLH dossiers)
		TERENDIJ Carline (a representative of the French CA following MMTC and EHMA)

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-17 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-17 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-17 meeting

13 September 2011
RAC/A/17/2011_Final

Final Agenda

17th meeting of the Committee for Risk Assessment

13 – 16 September 2011

Helsinki, Finland

13 September: starts at 9:00
16 September: ends at 14:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/17/2011_Draft_Rev.3
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – RAC Manual of Conclusion and Recommendations

For discussion

Item 5 – Administrative issues and information items

a. Status report on the RAC-16 action points
b. Outcome of written procedures
c. Report from other ECHA bodies and activities

RAC/17/2011/18
ROOM DOCUMENT
For information

d. Streamlining of RAC procedures

ECHA-RAC/17/2011/19
For information

e. Declaring conflicts of interest (CoI)

For information

f. Participation of Croatia in the work of RAC

RAC/17/2011/20
For agreement

Item 6 – Requests under Article 77 (3)(c)

- Gallium arsenide

RAC/17/2011/25
ROOM DOCUMENT
For discussion and possible adoption

Item 7 – CLH

7.1 CLH Dossiers for opinion adoption ***(substances for which opinions are adopted by written procedure before the meeting will be removed from the revised agenda)***

a. PHMB (poly(iminoimidocarbonyl)iminohexamethylene hydrochloride)

adopted by written procedure

b. Di-n-hexyl phthalate

For adoption

c. MMTC (trichloride of methyltin)

For adoption

d. EHMA (methyltin tri(2-ethylhexyl-mercaptoacetate MMT)

For adoption

e. Fenamiphos

For adoption

f. Pitch, coal tar, high temp. (CTPHT)

For discussion and possible adoption

g. Penconazole

For discussion and possible adoption

h. Aclonifen

For discussion and possible adoption

i. Sulcotrione

For discussion and possible adoption

j. Perestane

For discussion and possible adoption

7.2 CLH Dossiers for first discussion (*if time allows*)

a. Nitrobenzene

For first discussion

b. N-ethyl-2-pyrrolidone (NEP)

For first discussion

c. Ammoniumpentadecafluorooctanoate (APFO)

For first discussion

d. Perfluorooctanic acid (PFOA) and its salts

For first discussion

e. P-tert-butylphenol

For first discussion

7.3 Appointment of RAC (co-) rapporteurs for CLH dossiers

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

RAC/17/2011/21
ROOM DOCUMENT
For agreement

7.4 General CLH issues

b. State of play of the submitted CLH dossiers

For information

c. Review of the process for developing CLH opinions

- Accordance check

For information

- Opinion development

RAC/17/2011/22
ROOM DOCUMENT
For discussion

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

- Phthalates – outcome of the conformity check

For agreement

8.2 General restriction issues (if relevant)

a. Update on intended restriction dossiers

For information

b. Review of working procedures after experiences on first dossiers

For discussion

Item 9 – Authorisation

9.1 Appointment of RAC rapporteurs for substances listed in Annex XIV

RAC/17/2011/23
ROOM DOCUMENT
For agreement

9.2 Joint RAC&SEAC session

Cooperation between RAC and SEAC during the opinion development

For discussion

9.3 Follow-up of the joint RAC-SEAC session

For discussion

9.4 Follow-up of previous RAC discussions on opinions on authorisation applications

For discussion

Item 10 – Guidance issues

a. Feedback from guidance consultations
b. Report on other guidance activities

For information

Item 11 – Any other business

- New graduate scheme in the field of EU chemical policies at ECHA

RAC/17/2011/24
ROOM DOCUMENT
For information

Item 12 – Main conclusions and Action Points of RAC-17

- Table with main conclusions and action points from RAC- 17

For adoption

o0o

ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-17 meeting.

RAC/A/17/2011	Final Draft Agenda
RAC/17/2011/18 room doc	Administrative issues and information items
RAC/17/2011/19	Streamlining of RAC procedures
RAC/17/2011/20	Participation of Croatia in the work of RAC
RAC/16/2011/21 room doc	Appointment of CLH rapporteurs intentions
RAC/17/2011/22 Room doc	General CLH issues – opinion development
RAC/17/2011/23 room doc	Appointment of RAC rapporteurs for substances listed in Annex XIV
RAC/17/2011/24 room doc	New graduate scheme in the field of EU chemical policies at ECHA
RAC/17/2011/25 room doc	Request under Article 77 (3)c – Gallium arsenide

o0o

ANNEX III

RAC-17 MEETING

AGENDA ITEM 3. DECLARATIONS OF CONFLICTS OF INTEREST TO THE AGENDA

The following participants declared conflicts of interest with the agenda items (according to Art 9 (2) of RAC RoPs)

Name of participant	Agenda item
RAC members	
Christine BJØRGE	PFOA/AFPO P-tert-butylphenol
Marianne van der HAGEN	PFOA/AFPO P-tert-butylphenol
Frank JENSEN	Phthalates
Poul Bo LARSEN	Phthalates
Elodie PASQUIER	Gallium Arsenide DnHP MMTC N-ethyl-2-pyrrolidone (NEP)
Annick PICHARD	MMTC DnHP EHMA N-ethyl-2-pyrrolidone (NEP)
Agnes SCHULTE	Nitrobenzene
Hans-Christian STOLZENBERG	Penconazole Nitrobenzene Aclonifen Sulcotrione
Marja Pronk	Pitch, coal tar; fenamiphos
Andrew Smith	Perestane
Stakeholders	
MUNARI Tomaso (EuCheMS) ECETOC, Marie-Louise MEISTERS	Pitch, coal tar PFOA

Businesseurope, Karsten Muller	N-ethyl-2-pyrrolidone (NEP) Nitrobenzene