RAC/M/19/2011

FINAL

20 February 2012

Minutes of the 19th meeting of the Committee for Risk Assessment (RAC-19) (29 November – 02 December 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. The Chair welcomed a RAC member who was appointed in September nominated by Cyprus and invited to briefly introduce herself. Seven advisers, one invited expert, seven stakeholder representatives (from Business Europe, CEFIC, ECETOC, ECPA, EuCheMS, ETUC and Eurometaux), six observers accompanying stakeholder observers (STO), one industry dossier submitter and four representatives from the Commission were welcomed.

For this meeting several participants took part in substance related discussions as remote participants. This included: two members, two SEAC members, one Forum representative, three RAC advisers, representatives of Member State Competent Authorities (MSCA) from Denmark, France, Germany and Norway, EFSA and Commission colleagues.

Apologies were received from three RAC members, two invited experts and four regular observers (CONCAWE, ECEAE and EMCEF and Eurogroup for animals). Two members were absent. The list of attendees is given in Part III of these minutes.

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 and that the minutes, to be published on the ECHA website, would include the list of participants.

2 Adoption of the Agenda

The final agenda (RAC/A/19/2011_rev.1) was adopted without modifications. The 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, as well as the observers, whether there were any conflicts of interest to be declared specific to the agenda items. Ten members declared potential conflicts of interest to the substance-related discussions due to their participation and/or the participation of their institutions in the preparation of the dossiers submitted by the MSCA. Two stakeholder observers also declared potential conflicts of interest to the substance-related discussions. The declarations are attached to these minutes as Annex III.

4 Adoption of the minutes of RAC-18

RAC adopted the draft minutes of the RAC-18 meeting after minor clarifications. The minutes are available on the ECHA web site.

5 Administrative issues and information items

5.1 Report on RAC-18 action points, written procedures and other ECHA activities

The Secretariat informed the Committee on administrative issues as set out in room document RAC/19/2011/34.

5.2 Annual declaration of interests

The Chair reported that based on the new ECHA Policy on Conflicts of Interests the template for the annual declaration of interests, which is Annex II to RAC's Rules of Procedure should be updated. The text developed by the Management Board was presented as room document RAC/19/2011/35. As the Rules of Procedure must be agreed by the Committee and then presented to the Management Board for the final decision the Secretariat will launch the corresponding written procedure for seeking RAC agreement after the RAC-19 meeting.

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

The Chair welcomed an observer accompanying the EUROMETAUX stakeholder observer.

The (co-) rapporteurs presented the revised draft opinion and gave a first response to the comments by members and observers on the revised draft opinion. Based on previous discussions the following issues had been re-examined: the weight of evidence for the proposed harmonised classification and labelling of gallium arsenide as carcinogenicity Cat. 1B; the route of exposure; and the physical form in which gallium arsenide can be reasonably expected to be used.

During the discussion the proposed classification for carcinogenicity of 1B was re-affirmed and it was agreed that the route of exposure should not be specified in the labelling because other possible routes cannot be entirely excluded. It was also agreed that gallium arsenide should be classified and labelled without referring to a specific physical form.

The rapporteurs presented a new revised draft opinion taking into account the comments received during the meeting. The opinion proposed a harmonised classification and labelling of gallium arsenide as carcinogenic Cat.1B – H350, which was adopted by consensus. The Secretariat was requested to carry out an editorial check of the opinion and its annexes and to consult with the (co-) rapporteurs before finalising the documents.

The Chair thanked the (co-) rapporteurs on behalf of RAC for their hard work.

The Chair also informed participants of a new mandate dated 30 November 2011 from the Executive Director of ECHA to RAC according to Article 77(3)(c) and which followed a further request from the Commission. The mandate asks RAC to: "*evaluate the information on toxicity to reproduction submitted during the public consultation on carcinogenicity in order to decide whether the previous opinion [of 25 May 2010] on the proposed classification for reprotoxicity should be revised and to draw up an opinion accordingly*".

The Chair invited the Commission to outline the rationale for the request to the Executive Director of ECHA that had resulted in the new mandate. The Commission informed that its request concerned whether the information on

reproductive toxicity of gallium arsenide submitted during the public consultation on carcinogenicity contains new elements that would potentially lead to a change in the proposed harmonised classification and labelling for reproductive toxicity.

The Secretariat informed that to assist RAC, the Secretariat had performed a brief analysis of the reprotoxicity-related information and this analysis was to be made available to RAC. The Secretariat emphasised that RAC should only focus on the submitted information and, if possible deliver an opinion in a timeframe that allows for the inclusion of gallium arsenide in the next ATP.

In the discussion, the EUROMETAUX stakeholder observer questioned the proposed scope of the new mandate. The stakeholder observer indicated that additional information might be available that had not been submitted during the previous public consultation. That consultation had been explicitly on carcinogenicity and the information submitted on reproductive toxicity came from companies that had not adhered to this limitation. The Chair reminded RAC and the stakeholder observers on the relevant procedural issues.

The Chair invited RAC members to consider rapporteurship for the new mandate. Two volunteers came forward and were duly appointed by RAC as (co-) rapporteurs.

7 CLH[1] dossiers

7.1. a Pitch, coal tar, high temperature (CTPHT)

RAC was informed that the opinion on the CLH dossier for CTPHT was adopted by consensus following a written procedure before the meeting.

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

As agreed during RAC-18, industry provided additional data on the application of specific concentration limits (SCL) for the substance for reproductive toxicity. The assessment provided by industry concluded that the application of the draft guidance recommendations for setting SCL for reproductive toxicity to the available data for NEP would confirm that the generic concentration limits were applicable and the rapporteurs confirmed that the classification should remain as agreed at RAC-18. RAC adopted the opinion by consensus.

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

7.1. c Nitrobenzene

The Chair welcomed the dossier submitter representative and the adviser to the rapporteur and invited the rapporteur to introduce the revised draft opinion on the CLH proposal submitted by Germany. The observer accompanying CEFIC expected to attend was excused by the stakeholder observer.

Acute toxicity, reproductive toxicity and specific target organ toxicity were discussed.

Concerning the acute toxicity the results of animal studies meet the criteria for classification in Category 4 (CLP). However, RAC concluded that the well established higher sensitivity of humans to methemoglobin formation was a valid argument for considering a more severe classification than that resulting from the strict application of the criteria to the data on less sensitive animal species.

[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.

Therefore, RAC considered that there is no evidence supporting a change in the current classification, and classification as Acute Tox. 3 was agreed.

0Specific target organ toxicity was evaluated by inhalation, oral and dermal exposure. The most sensitive cells to toxicity of nitrobenzene are erythrocytes. Nitrobenzene is currently classified as STOT RE 1 (CLP) and T; R48/23/24 (DSD). The dossier submitter proposed to confirm classification for CLP and add R48/25 for DSD. Animal studies support classification in STOT RE 2 but due to higher sensitivity of humans to methemoglobin formation and lack of evidence supporting the need to change the current classification, RAC agreed to maintain the current classification (with target organ blood) as well as to add R48/25.

For reproductive toxicity the dossier submitter proposed to confirm classification as Repr. 2 – H361f and add classification for lactational effects. Reproductive toxicity of nitrobenzene has been observed at very low doses. Following the discussion RAC members concluded that the observed damage to spermatogenic epithelium and reduced fertility is a specific effect of nitrobenzene and is independent from its ability to induce methemoglobin and related hematotoxic effects. RAC members therefore agreed with the rapporteur's proposal to classify Nitrobenzene as Repr. 1B – H360F. RAC already agreed at the previous meeting that classification for lactational effects was not warranted.

RAC agreed on the classification of nitrobenzene as indicated in Table 2 of Part II of this document.
The Chair thanked the rapporteur and RAC for their discussion and invited the rapporteur to modify the draft opinion based on the agreed classification, in order to launch an editorial commenting round and the adoption by written procedure.

7.1. d. e. f. g. h Octadecylamine; (Z)-octadec-9-enylamine; amines, hydrogenated tallow alkyl; amines, coco alkyl; amines, tallow alkyl

The Chair welcomed an observer accompanying the CEFIC stakeholder observer and the dossier submitter representatives to the meeting and invited the rapporteurs to present the revised draft opinion for the CLH proposals submitted by Germany.

As in the last meeting, the draft opinions of the five different alkyl amines were discussed together, as the CLH proposal follows a group approach, evaluating the substances together in a 'many-to-many read across' approach based on similarities in terms of physico-chemical properties, common functional groups and common metabolic breakdown products.

The discussion focused on the M-factor derivation for the chronic aquatic hazard, and the use of the surrogate approach was agreed because of the limited quality of the available chronic data. The discussions of other proposed hazard classes had been finalised and preliminarily agreed at RAC-18.

RAC adopted by consensus the revised draft opinions on the CLH proposals for octadecylamine; (Z)-octadec-9-enylamine; amines, hydrogenated tallow alkyl; amines, coco alkyl; and amines, tallow alkyl. 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. i Ammoniumpentadecafluorooctanoate (APFO)

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

The Chair welcomed an observer accompanying the CEFIC stakeholder observer.

The rapporteurs gave a detailed presentation on the evidence and conclusions referring to CMR hazards, followed by a discussion of the RAC members. In relation to reproductive toxicity, the observer accompanying CEFIC provided the view that there would be little evidence for any effects during pregnancy. However, several RAC members were of the opinion that there is clear-cut evidence for developmental effects, while maternal toxicity is low, justifying a classification into cat. 1B for reproductive toxicity.

As a conclusion from the discussions during this and the preceding RAC meeting, RAC finally agreed with the proposal from Norway to classify APFO as acutely toxic both for the oral and the inhalation route but in category 4, (H302, H332) rather than the suggested category 3, as toxic after repeated exposure cat. 1 (H372), carcinogenic Cat. 2 (H351), and as toxic to reproduction Cat. 1B (H360D). RAC also agreed to classify the substance for severe eye damage cat. 1 (H318) instead of the proposed category 2 and for lactational effects (H362), which had not been proposed by Norway.

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

It was agreed that the Secretariat would make an editorial check for aligning the background document with the adopted opinion in consultation with the rapporteurs, and would check the S-phrases related to the DSD classification.

The Chair thanked the rapporteurs and RAC for their discussions.

7.1. j Perfluorooctanoic acid (PFOA)

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

The Chair welcomed an observer accompanying the CEFIC stakeholder observer.

The rapporteur proposed a way how to handle the opinion on PFOA. RAC agreed that the same conclusions on the classification should be included in the opinion as for APFO, based on the justification that PFOA and APFO share the same chemical structure, i.e. the carboxylate anion is formed, warranting the same toxicological effects. In this connection, a comparable degree of bioavailability must be expected for both substances under biologically relevant conditions.

The draft opinion on PFOA was adopted by consensus. The Secretariat will prepare the background document for PFOA in consultation with the rapporteurs and undertake the same final steps as for APFO.

7.1.k Aluminium phosphide

The Chair invited the rapporteurs to present the second draft opinion updated on the basis of information submitted by RAC members and harmonised also with the opinion on trimagnesium diphosphide.

In addition to the originally proposed classification and already classified hazard classes, it was proposed to classify both aluminium phosphide and trimagnesium diphosphide also as acutely toxic by inhalation route.

A general observation for substances classified with EUH029 is recorded under point 7.3 of these minutes.

The draft opinion was adopted by consensus. 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.l Trimagnesium diphosphide

The Chair invited the rapporteurs to present the second draft opinion updated on the basis of information submitted by RAC members, and harmonised also with the opinion on aluminium phosphide.

In addition to the originally proposed classification and already classified categories, it was proposed to classify both aluminium phosphide and trimagnesium diphosphide also as acutely toxic by inhalation route.

A general observation for substances classified with EUH029 is recorded under point 7.3 of these minutes.

The draft opinion was adopted by consensus. 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.m p-tert-butylphenol

The Chair welcomed the representative of the dossier submitter from the Norwegian MSCA who took part in the discussions as a remote participant. The Chair invited the RAC rapporteurs to present the first draft opinion on the CLH proposal.

Currently there is for this substance no entry in Annex VI to the CLP Regulation. A harmonised classification and labelling was previously agreed under TC C&L. The proposal relates to the hazard classes skin irritation, eye damage, respiratory tract irritation and reproductive toxicity. First discussions were focused on the STOT SE 3 concerning the respiratory tract irritation.

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 7.1m of Part II of this document.

7.1. n 4-vinylcyclohexene (VCH)

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

Currently there is for this substance no entry in Annex VI to the CLP Regulation.

In the draft opinion the rapporteurs supported the classification proposed by France as Carc.1B based on ovary tumors observed in mice.

Mutagenicity and reproductive toxicity of VCH were considered as not conclusive due to the limited amount of information.

The Chair thanked the rapporteurs for their presentation and invited members to provide their comments as soon as possible and rapporteurs to update the draft opinion. Possible adoption was envisaged either through written procedure or at RAC-21.

7.1. o Cymoxanil

The Chair welcomed an observer accompanying the ECPA observer and the adviser of the rapporteurs and invited rapporteurs to introduce the first draft opinion on the CLH proposal submitted by Austria.

Cymoxanil is currently listed in Annex VI to the CLP Regulation with the classification: Acute tox 4*, H302 (Xn, R22), Skin Sens. 1, H317 (Xi, R43), Aquatic Acute 1, H400 M-factor 1, Aquatic Chronic 1 H410 (N R50/53). The

dossier submitter proposes to add classification as STOT RE 2 H373 (Xn, R48/22); Repr. Cat 2, H361 (Repr. Cat. 3; R63).

The rapporteurs presented their first draft opinion and initial conclusions, asking RAC members for their view on category allocation for STOT RE classification and proposed addititional classification for effects seen on sexual function and fertility in repeated dose studies.

RAC members requested better description of the study results for Skin Sens. 1A and more information on metabolites in degradability studies.

The RAC Chair reminded members they can provide further comments on the draft opinion via CIRCABC by 6 December 2011. The rapporteurs will revise the draft opinion and its annexes and the ECHA Secretariat will distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption via written procedure or at RAC-20.

7.1. p Proquinazid

The observer accompanying ECPA expected to attend was excused by the stakeholder observer.

The Chair invited the rapporteurs to introduce the dossier and the proposed classification and labelling. Three hazards classes or differentiations were proposed by the dossier submitter. RAC was invited to discuss the relevance of carcinogenicity data. The dossier submitter concluded that changes in livers of test animals are attributable to carcinogenicity. The rapporteur concluded that the changes in thyroid gland are due to repeated dose toxicity of Proquinazid and therefore proposed inclusion of STOT RE (thyroid, oral) in the RAC draft opinion. The relevance of the reported data on rats for human health was discussed and comments supported differences in sensitivities between the test species and humans being only of quantitative but not qualitative relevance. A RAC member referred to an IARC evaluation and volunteered to provide this information to RAC. Another RAC member requested the Secretariat to provide ECBI/22/98 document to RAC, since it may clarify the interpretation and relevance of rat thyroid gland tumours to humans. In relation to endocrine disruption the Commission representative pointed out that it would be too early to draw any conclusion on endocrine disruption as classification criterion as an EU-wide discussion is still on-going; the opinion should therefore be based on the observed effects and their relevance for humans.

The Chair invited the RAC members to provide comments by 21 December 2011. Based on the comments the draft opinion will be updated and possible adoption is envisaged either through written procedure or at RAC-20.

7.1. q Dioctyltin bis(2-Ethylhexylmercaptoacetate)

The Chair welcomed the industry dossier submitter and an Industry expert accompanying the CEFIC observer and invited the rapporteurs to introduce the dossier and the proposed classification and labelling.

The dossier submitter proposed a harmonised classification for Reproductive Toxicity Cat. 2, while the rapporteur argued that a classification for Reproductive Toxicity Cat. 1B would be more appropriate because of the available evidence. The dossier submitter argued that the lower reliability due to the read-across approach warranted Repr. 2.

In the first discussion, RAC commented that a group entry for Dioctyltin compounds could be appropriate. The expert representing the Industry dossier submitter explained that they could only submit a CLH proposal for the substance

they market. The RAC Chair clarified that RAC could only conclude on the proposal submitted and a group entry could only be proposed by Member States.

The RAC members were invited to provide further comments via CIRCABC by 20 December 2011. After the rapporteurs have revised the draft opinion and its annexes in accordance with the comments received, the Secretariat will distribute the revised draft opinion documents to RAC, for further discussion and possible adoption via written procedure or at RAC-20.

7.1. r Amidosulfuron

The Chair invited the rapporteurs to give a short presentation on the M factor to facilitate the preparation of the first draft opinion.

Amidosulfuron is an herbicidal active substance currently without entry in Annex VI to the CLP Regulation. The dossier has been prepared by Austria.

The rapporteurs see sufficient grounds for hazard class categories Acute 1 with M = 100 and Chronic 1 (as proposed by DS), but chronic M-factor requires further scrutiny (10 proposed by DS, issue also addressed by one comment in public consultation). The rapporteurs asked RAC if there are sufficient grounds to propose a chronic M-factor of 100, based on NOEC < 1 μg/l.

Given the unreliability of the studies for chronic endpoints, the RAC members recommended the application of the surrogate approach. Moreover RAC appreciated the effort of the rapporteur to check original study results which was very useful in this case.

The rapporteurs will prepare the first draft opinion soon after the meeting.

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

RAC agreed to appoint the volunteers as (co-)rapporteurs for the intended or submitted CLH proposals as listed in room document RAC/19/2011/36.

7.3 General CLH issues

As a general observation following the discussion on trimagnesium diphosphide and aluminium phosphide RAC agreed on the need to treat all substances classified with EUH029 (*contact with water liberates toxic gas*) in Annex VI to the CLP Regulation in a comparable way to trimagnesium diphosphide and aluminium phosphide with regard to classification for Acute Inhalation Toxicity. Upon further inspection, this is indeed the case with most of them.

8 Restrictions

8.1 Restriction Annex XV dossiers

8.1.a. Phthalates

The Chair welcomed the SEAC rapporteurs, the member of the Forum working group, two RAC members' advisers, and the representatives of the dossier submitter and dossier submitter expert from the DK Competent Authority (MSCA) who took part in the discussions as remote participant. The Chair invited the RAC rapporteurs to present the first draft opinion on the dossier.

After briefly presenting the outline of the first draft opinion and the first Forum advice, the rapporteurs focused their presentation on the main elements, key considerations and specific questions for RAC to consider.

Subsequently, the dossier submitter presented the aim of the restriction, issues being addressed in the preparations of the first Background document and the

different risk management options that were being discussed by the drafting group.

CEFIC questioned the extension of the scope to a general ban with a list of exemptions, its relation with the authorisation process and objected to the description of the reproductive properties of DINP in the dossier. According to the DS, the rationale for the restriction and for the exemptions was solely based on the potential for exposure. The rapporteurs clarified that the work on the wording of the scope is in progress and is being discussed by the drafting group.

The Commission clarified that although the final wording in the legal proposal is in the remits of the Commission, the opinion needs to be clear on what the Committee considers to be in the scope of the restriction and what not.

The Committee was informed that the adoption of the joint opinion from SCHER, SCENIHR and SCCS on the toxicity and assessment of chemical mixtures is in the final stage (SCHER had already adopted the opinion). The joint opinion is relevant to the validity of the dose additivity approach taken in the restriction dossier and for the selection of the calculation method. RAC rapporteurs and members were supportive to the dose additivity approach. The most appropriate method of calculation (hazard index method or the relative potency factor method) would still need further discussions.

Rapporteurs and members voiced criticism towards the conservatism of exposure calculations in the dossier, in particular with regards to conservative assumptions and the summing up of worst cases. Several members indicated that they consider biomonitoring data to be important supportive evidence. It was also pointed out that there is many such data in comparison with most substances, however there are issues with study design and relevance of the data to be considered.

Rapporteurs concluded that considering the open issues with regards to the exposure assessment, and awaiting the improvements to the dossier, it can at present not be judged whether or not the identified risks in the dossier are warranted or not.

The public consultation deadline for early comments is 16 December 2011. RAC members can provide comments on the first draft opinion by 15 December 2011. The rapporteurs requested RAC members to consider in their comments to address the specific questions presented during the meeting and in the draft opinion.

8.2 General restriction issues

8.2.a. Update on intended restriction dossiers

The Chair reminded that the ECHA Secretariat has launched a call for rapporteurs for 1,4-dichlorobenzene restriction dossier. The dossier is under preparation by ECHA and is expected to be ready in April 2012.

8.2.b. Update on the review of the restriction process including the project on improving the quality of incoming restriction reports

The ECHA secretariat introduced the agenda item with two complementary presentations.

In the first one: *Improving the quality of upcoming restriction reports* the Secretariat informed RAC on the results of the first step in collecting experiences and ideas for improving the quality of the restrictions reports. Planned follow-up actions were reported to the RAC in the second part of the presentation. The follow-up actions will be implemented in 2012.

The second presentation was on the "*Review of the restriction process after experiences on the first dossiers"*. The outcome of the consultation with RAC and SEAC was presented. According to the received feedback, there are many aspects which worked fine and those should be kept unchanged but there was also space for improvement and for streamlining the process due to the expected huge increase in the RAC workload. Some examples were presented. The discussion will be continued during the next SEAC meeting in break out groups. RAC members were invited to participate. The Secretariat will prepare a proposal for revising the working procedure to be discussed by both Committees in early 2012.

The Secretariat will open a Newsgroup in CIRBABC to collect the feedback of the RAC members.

9 Authorisation

9.1 Evaluation of applications by RAC and SEAC & Capacity building

9.1.a Common approach of RAC and SEAC in opinion development on Applications for Authorisation

The Secretariat presented the meeting document (RAC/19/2011/37), a draft developed by the Secretariat in consultation with the Commission. The document describes how to deal during the opinion development on authorisation applications efficiently with issues identified in earlier discussions. Issues are, for example, how to deal with missing or inadequate information, which endpoints are relevant in the opinion development in case of the adequate control route and which endpoints need to be taken into account when evaluating the analysis of alternatives. Main emphasis was given to the general Committees' task to evaluate the assessment – including the methods and the lines of reasoning – carried out in the authorisation application. The main RAC task is to give its opinion on the remaining risk if an authorisation would be granted in the socio economic assessment route. It was emphasised that RAC (and SEAC) have to be prepared to be able to handle over 50 applications in any one meeting and that each member may have half a dozen applications for reporting. Due to this workload RAC (and SEAC) need to have a very streamlined and efficient way of giving their opinions.

9.1.b Discussion

RAC members appreciated the clarifications provided by the Secretariat. It was clarified that any missing information or further information to bring an application into conformity must be provided by applicants. The Secretariat mentioned that in general there will always be a wish for more information. However, due to the time constraints and what can be considered reasonable will make it a necessity to limit such requests.

If information is insufficient to draw firm conclusions, RAC (and SEAC) has – besides asking for additional information – the possibility (i) to give a "negative" opinion stating that "the application does not give enough information for RAC to give an opinion", or (ii) to give an opinion with a recommendation for short review period.

RAC members expressed some concern if it will always be possible to rely on information provided by applicants or by third parties for evaluating submitted data. Some members mentioned that RAC might need to acquire missing information or to provide a partial risk assessment themselves when they propose other RMM or OC (risk management measures, operational conditions). On the other hand no suggestions were given how this could be undertaken with the

foreseen workload. Thus, it was recognised that it is the applicant that has to make the case of providing all information to RAC (and SEAC).

Some members were emphasising the RAC and SEAC cooperation in relation to the quantification of risk and how it is to be translated into health or environmental impact. The Secretariat answered that it is up to the applicants to demonstrate that the socio-economic benefits outweigh the remaining risks. The Committees' task will be to evaluate the applicants reasoning. This issue may also be further taken into the capacity building programme for further clarifications.

A STO mentioned their concern to properly control SVHCs only by assessing the intrinsic properties mentioned for each of the substances in Annex XIV. Their understanding was that all properties mentioned in Article 57 need to be assessed for a SVHC not only the properties for which a substance was placed on Annex XIV in the end. The STO mentioned that the MSCA might have used the most obvious endpoint in order to limit public resources in assessing other endpoints. In their opinion a substance may have further SVHC properties for example endocrine disrupting.

The Chair thanked the presenters and the RAC members for the discussions and asked RAC members to post their comments via the RAC CIRCABC newsgroup established for that purpose by the date indicated in table 9.1 of part II of this present document.

9.1.c Overview of the capacity building programme

The Secretariat presented the planned programme of capacity building to prepare RAC and SEAC on the authorisation process. First applications for authorisations are expected to be in the second half of 2012. The aim to deliver a large number of useful scientific opinions to the Commission within a tight legal deadline was emphasised. The capacity programme will support a RAC's (and SEAC's) common approach on sharing the vision on key concepts, addressing needs arising during the process preparation and familiarising with the organisation of the work and also to continue the capacity building when the first dossiers arrive.

RAC members welcomed the initiative, and expressed in the following discussions the need to thoroughly prepare themselves for this task. The Secretariat will organise discussions on specific substances included in Annex XIV for members who have interest for applications for authorisation at the next meeting as part of the capacity building programme.

Other issues mentioned by RAC members concerned cumulative effects of several authorisations for the same substance. A RAC member reminded however that RAC's task is to provide opinions on single authorisation applications. RAC's task is not to assess and monitor the cumulative risks of several authorisations.

The Chair thanked the presenter and the RAC members for the discussions and asked RAC members to post their comments on the presentation and the capacity building via the RAC CIRCABC newsgroup established for that purpose by the date indicated in table 9.1 of part II of this present document.

9.1.d Use of registration data, possibilities, limitations, quality issues with emphasis on exposure scenarios

The Secretariat presented an overview of CSRs submitted in order to support the registration dossier. Based on this information the Secretariat presented what kind of CSRs could be expected to support the authorisation application in the future. The quality of the submitted data was put into the context of first experience with CSRs prepared in the rush of the first REACH registration deadline. The submitted CSRs did not yet have any feedback review.

During the discussion of the roles of RAC, the Chair clarified the task of RAC when evaluating the CSR of an authorisation application. The first task for RAC is to review the quality and coherence of the presented hazard identification, the developed exposure scenarios and assessments and the resulting risk characterisation.

In the second task, in case RAC may detect some weaknesses, gaps or errors in the applicant's estimations, the Committee would need to evaluate the consequences of these issues on the overall applicant's assessment of the level of exposure and the level of remaining risk. Depending on the "route", RAC would need to conclude based on the above mentioned assessment and the uncertainties, if the Committee finally consider that the risk are adequately controlled, and if not if the remaining risks have been correctly calculated in the application.

A RAC member mentioned that a lot of arithmetic scaling may be expected to derive a NOEL for an exposure route.

A further issue was mentioned on how to evaluate possible minimisation and reduction models for substances, for which a safe use is not possible to achieve. The issue may also be further taken into the capacity building programme. The ETUC STO emphasised that an acceptable level of minimisation is a political decision that can not be answered by RAC. Furthermore, the same STO clarified that according to its views, even when DMEL values are not exceeded, this can under no circumstances be considered as "full protection", since a DMEL means a minimal effect level, instead of no effect level.

The confidentiality of the CSR and of the future authorisation applications was mentioned. The Chair clarified that RAC members may have access to confidential data and that confidential data can only be discussed in closed RAC plenary sessions.

The Chair thanked the presenter and the RAC members for the discussions.

9.1.e Demonstration of the use of dissemination portals for databases on chemicals

In this session, it was demonstrated how dissemination portals could be used by RAC members themselves to find data on substances. The presenter also gave indications about future plans of further improving the databases by providing information on the production volume and on the status for the substances in legislative contexts.

A STO congratulated the good improvement of the portals. They announced also their own establishment on an information portal on alternatives, best practices, and exposure scenarios.

The Chair thanked the presenter and the RAC members for the discussions.

9.2 Appointment of RAC rapporteurs for substances listed in Annex XIV

The room document (RAC/19/2011/38) listing volunteers for rapporteurship in different pools for substances included in Annex XIV was presented.

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

10 Guidance issues

10.1 Update on guidance activities including on the Guidance on the Application of the CLP Criteria

The Chair informed RAC that the next update will follow at RAC-20.

The Chair invited the RAC members (or their advisers) to register, by 2 December 2011, for a workshop on the concept of rapid removal of metals and metal compounds from the water column which will take place in ECHA on 8 February 2012.

11. Update on Stakeholder participation in the work of RAC (closed session)

The Secretariat presented the report on the participation of stakeholder organisations in the work of RAC. The Secretariat informed RAC that ECHA had registered in the list of stakeholder organisations fulfilling the eligibility criteria new sector specific STO with interest in RAC activities and that several STOs previously agreed by RAC have not appointed yet a contact person.

RAC agreed with the Secretariat proposals for inviting three new sector specific STOs and for sending reminders to six STOs to appoint contact person, indicating that in case of no answer they will be deleted from the list.

RAC agreed to include the minutes of the closed session in the general minutes of RAC-19.

12 Any other business

A RAC member provided information on a project his organisation and European co parties are starting. The aim of the project called E-Team is to evaluate Tier 1 exposure assessment models and to disseminate the project findings effectively. Several RAC members expressed interest. The Chair indicated that the results could be also relevant for the RAC discussions and asked the RAC member to provide information to RAC on the results when available.

A RAC member requested to receive more information about the status of their reimbursements of expenses from previous meetings. The Secretariat will ensure that the members and reimbursed observers would get additional information regarding their reimbursements.

13 Main conclusions and Action Points of RAC-19

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

oOo

2 December 2011

Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
(Adopted at the 19th meeting of RAC)
29 November-02 December 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/19/2011_rev. 1) was adopted.	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-19 minutes.
3. Declarations of conflicts of interest to the Agenda	
10 members and 2 STO observers have declared a potential conflict of interest to different substance-related discussions on the Agenda.	
4. Adoption of the minutes of the RAC-18	
The revised Minutes (RAC/M/18/2011) were adopted.	**SECR** to upload the adopted Minutes to the RAC CIRCABC and to the ECHA website.
5. Administrative issues and information items	
5.2 New format of the annual declaration of interest	**SECR** to launch written procedure after the RAC-19 meeting.
6. Requests under Article 77 (3)(c) - gallium arsenide	
RAC adopted by consensus the opinion and its annexes on harmonised classification of gallium arsenide regarding carcinogenicity. RAC agreed to propose gallium arsenide to be classified as carcinogen Cat. 1B H350	**SECR** to make editorial check and consult with the rapporteurs before uploading the adopted opinion on gallium arsenide and its annexes to the RAC CIRCABC and to forward them to COM and publish them on the ECHA website.
RAC was informed on a new mandate to evaluate the information on toxicity to reproduction submitted during public consultation. **RAC** appointed two RAC members as rapporteurs.	**Rapporteurs** to evaluate the information and to produce draft opinion to be discussed by RAC.

7. CLH	
7.1 CLH dossiers for opinion adoption	
7.1 b. N-ethyl-2-pyrrolidone (NEP)	
RAC adopted by consensus the opinion and its annexes on the CLH proposal on N-ethyl-2-pyrrolidone (NEP). RAC agreed to propose N-ethyl-2-pyrrolidone (NEP) 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 N-ethyl-2-pyrrolidone (NEP) and its annexes to the RAC CIRCABC and to forward them to COM and publish them on the ECHA website.
7.1 c. Nitrobenzene	
RAC agreed on the classification of nitrobenzene as indicated in the table 2 below.	**Rapporteur** to adjust the draft opinion and its annexes accordingly to the classification agreed by RAC and to provide them to SECR. **SECR** to distribute the revised draft opinion documents to RAC when available for editorial comments and organise the adoption by written procedure.
7.1.d Octadecylamine **7.1.e (Z)-octadec-9-enylamine** **7.1.f Amines, hydrogenated tallow alkyl** **7.1.g Amines, coco alkyl** **7.1.h Amines, Tallow alkyl**	
RAC adopted by consensus the opinions and its annexes on the CLH proposal on amines. RAC agreed to propose amines to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult with the rapporteurs before uploading the adopted opinions on amines and its annexes to the RAC CIRCABC and to forward them to COM and publish them on the ECHA website.
7.1 i. Ammoniumpentadecafluorooctanoate (APFO) **7.1 j. Perfluorooctanoic acid (PFOA)**	
RAC adopted by consensus the opinion and its annexes on the CLH proposal on ammoniumpentadecafluorooctanoate (APFO). RAC agreed to propose ammoniumpentadecafluorooctanoate (APFO) to be classified as indicated in the table 1. below. RAC adopted by consensus the opinion and its annexes on the CLH proposal on perfluorooctanoic acid (PFOA). RAC agreed to propose perfluorooctanoic acid (PFOA) to be classified as indicated in table 1 below.	**SECR** to finalise the background document for APFO, to check the S-phrases and to make an editorial check and consult with the rapporteurs before uploading the adopted opinion on APFO and its annexes to the RAC CIRCABC and to forward the documents to COM and publish them on the ECHA website. The **SECR** to prepare the background document for PFOA on the basis of the BD for APFO**,** to make an editorial check, consult with the rapporteurs before uploading the adopted opinion on PFOA and its annexes to the RAC CIRCABC and to forward the documents to COM and

	publish them on the ECHA website.
7.1.k Aluminium phosphide	
RAC adopted by consensus the opinion and its annexes on the CLH proposal on aluminium phosphide. RAC agreed to propose aluminium phosphide to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult if necessary with the rapporteurs before uploading the adopted opinion on aluminium phosphide and its annexes to the RAC CIRCABC and to forward them to COM and publish them on the ECHA website.
7.1.l Trimagnesium diphosphide	
RAC adopted by consensus the opinion and its annexes on the CLH proposal on trimagnesium diphosphide. RAC agreed to propose trimagnesium diphosphide to be classified as indicated in the table 1. below.	**SECR** to make an editorial check and consult if necessary with the rapporteurs before uploading the adopted opinion on trimagnesium diphosphide and its annexes to the RAC CIRCABC and to forward them to COM and publish them on the ECHA website.
7.1.m p-tert-butylphenol	
RAC discussed the first draft opinion.	**Members** to post their comments on the 1st draft opinion and annexes via the RAC CIRCABC Newsgroup by 19 December 2011. **SECR** to present the criteria and guidance for respiratory tract irritation in the CLP and the DSD, and to check the classification of similar substances to facilitate the discussions. **Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)). **SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption via written procedure or at RAC-20.
7.1.n 4-vinylcyclohexene (VCH)	
RAC discussed the first draft opinion.	**Members** to provide the latest comments to the rapporteurs ASAP. **Rapporteurs** to revise the draft opinion and its annexes. **SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption via written procedure or at RAC-21.
7.1.o Cymoxanil	

RAC discussed the first draft opinion.	**Members** to provide further comments via CIRCABC by 6 December. **Rapporteurs** to revise the draft opinion and its annexes. **SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption via written procedure or at RAC-20.
7.1.p Proquinazid	
RAC discussed the first draft opinion.	**Members** to provide further comments via CIRCABC by 21 December**.** **SECR** to upload to CIRCABC document ECB I/22/98. **Rapporteurs** to revise the draft opinion and its annexes. **SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption via written procedure or at RAC-20.
7.1.q Dioctyltin bis(2-Ethylhexyl mercaptoacetate)	
RAC discussed the first draft opinion.	**Members** to provide further comments via CIRCABC by 20 December**.** **SECR** to consult ECHA experts on read-across approach. **Rapporteurs** to revise the draft opinion and its annexes. **SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption via written procedure or at RAC-20.
7.1.r Amidosulfuron	
RAC preliminary discussed elements of the environmental classification	**Rapporteurs** to submit the first draft opinion to SECR. **SECR** to open news group in CIRCABC and launch RAC consultation on the first draft opinion.

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	**SECR** to upload in RAC CIRCABC the updated document to reflect RAC appointments for CLH proposals after the

proposals (listed in room document RAC/19/2011/36).	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 and procedural CLH issues	
7.4 a. State of play of the submitted CLH dossiers	
	SECR to incorporate in the minutes of this meeting the general observation on the need to treat all substances classified with the risk phrase R29 (*contact with water liberates toxic gas*) in Annex VI to the CLP Regulation in a comparable way to trimagnesium diphosphide and aluminium phosphide in regard to classification for Acute Inhalation Toxicity.

8. Restrictions	
8.1 Restriction Annex XV dossiers	
8.1.a Phthalates – first draft opinion	
RAC rapporteurs presented the first draft opinion.	**SECR** to contact EFSA to check the availability of recent data on phthalates in food. **Members** to provide comments on the first draft opinion especially focused on the issues raised by the rapporteurs in the presentation during the RAC-19 meeting by 15 December 2011. **Rapporteurs** to prepare the second draft opinion.
8.2 General restriction issues	
8.2 a Update on intended restriction dossiers	
RAC was informed on one new intended restriction dossiers (1,4-dichlorobenzene) to be prepared by ECHA. The call for rapporteurs is open till 19 December 2011.	**Members** to express their interest in rapporteurship.
8.2.b Update on review of the restriction process including the project on improving the quality of incoming restriction reports	
RAC was informed on the progress in the project on improvement of the restriction dossiers and the	**SECR** to open Newsgroup in CIRCABC to send comments on the quality project.

comments received from RAC and SEAC.	**Members** to volunteer to contribute to the review of the restriction process. **SECR** to consider comments from the members and to organise the revision of the working procedure.

9 Authorisation	
9.1 Evaluation of applications by RAC and SEAC & Capacity building	
Document RAC/19/2011/37 was presented to RAC	**SECR** to open a newsgroup for RAC member comments on the room document (RAC/19/2011/37) common approach of RAC and SEAC in opinion development on applications on authorisation and additional RAC specific elements. **Members** to provide comments by 15 January 2012. **SECR** to amend room document based on comments received with the view of getting agreement at the March meeting.
Overview of the capacity building programme was presented to RAC	**SECR** to open a newsgroup for RAC member comments on the capacity building program on preparing RAC for the process of developing opinions on authorisation. **Members** to provide comments by 15 January 2012. **SECR** to consider the comments received when implementing the capacity building programme.
RAC was introduced on the use of the registration data and the dissemination portals for databases on chemicals	**SECR** to organise the discussion on specific substances included in Annex XIV for members who have interest for applications for authorisation at the next meeting as part of the capacity building programme.
9.2 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/19/2011/38).	**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.

10. Guidance issues	
10.1 Update on guidance activities including on guidance on the application of the CLP criteria	
SECR informed RAC about the ongoing request for feedback on guidance documents.	**Members** may provide feed back using the comment template via the RAC CIRCABC Newsgroup by 2nd January 2012.
SECR informed RAC about the Guidance workshop on interpretation of "rapid removal" of metals in the water column.	**Members** may apply for participation via answering the email to the guidance functional mailbox (Cc to the RAC functional mailbox) by the 2nd December.
11. Update on stakeholder participation in the work of RAC (Closed session)	
RAC agreed on the proposal in the room document RAC/19/2011/39 RAC agreed to report the closed session in the public minutes.	**SECR** to contact the STOs that have not appointed the contact person and to delete them from the list in case no respond and invite 3 new sector specific STOs.
12. AOB	
Question on reimbursement practice was raised.	**SECR** to clarify the reimbursement practice to RAC.
GENERAL	
	SECR to upload all presentations, room documents and the RAC-19 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[1]

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)		
-	N-ethyl-2-pyrrolidone (NEP)	220-250-6	2687-91-4	**Repr. IB**	**H360D[2]**	**GHS08**	**H360**	-		

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
-	N-ethyl-2-pyrrolidone (NEP)	220-250-6	2687-91-4	**Repr. Cat. 2; R61**	**T** **R: 61** **S: 45-53**		

[1] Hazard classes, category and hazard statement codes are written in **bold** if agreed during the meeting.

[2] It is the view of RAC that hazard statement H360D is the most appropriate, given the available toxicological profile of NEP, but RAC recognised that H360 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)		
	Octadecylamine	204-695-3	124-30-1	**Skin Irrit. 2** **Eye Dam. 1** **Asp. Tox. 1** **STOT RE2 (GI-tract, liver, immune system)** **Aquatic Acute 1** **Aquatic Chronic 1**	**H315; H318** **H304; H373;** **H 400** **H 410**	**GHS05** **GHS07** **GHS08** **GHS09** **Dgr**	**H315** **H318** **H304** **H373;** **H 410**		**M (acute) = 10** **M (chronic) = 10**	None

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Octadecylamine	204-695-3	124-30-1	**Xi; R38-41** **Xn; R48/22-65** **N; R50/53**	**Xn; N;** **R: 38-41-48/22-65-50/53** **S: (2-)26-36/37/39-60-61-62**	**N; R50-53: C ≥ 2.5 %** **N; R51-53: 0.25 % ≤ C < 2.5 %** **R52-53: 0.025 %≤C<0.25 %**	None

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)		
	(Z)-octadec-9-enylamine	204-015-5	112-90-3	**Acute Tox. 4** **Skin Corr. 1B** **Asp Tox. 1** **STOT SE 3** **STOT RE 2 (GI-tract, liver, immune system)** **Aquatic Acute 1** **Aquatic Chronic 1**	**H302** **H314** **H304** **H335** **H373** **H 400** **H 410**	 **GHS05** **GHS07** **GHS08** **GHS09** **Dgr**	**H302** **H314** **H304** **H335** **H373** **H410**		**M(acute) = 10** **M (chronic)= 10**	None

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	(Z)-octadec-9-enylamine	204-015-5	112-90-3	**Xn; R22-48/22-65** **C; R34** **N; R50/53**	**C, N, R:22-34-48/22-65 50/53** **S: (1/2-)23-26-36/37/39-45-60-61-62**	**C; R34: C ≥ 10%** **Xi; R36/37/38: 5% ≤ C < 10%** **N; R50-53: C ≥ 2.5 %** **N; R51-53: 0.25 % ≤ C < 2.5 %** **R52-53: 0.025 % ≤ C < 0.25 %**	None

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)		
	Amines, hydrogenated tallow alkyl	262-976-6	61788-45-2	**Skin Irrit. 2 Eye Dam. 1 Asp Tox. 1 STOT RE 2 (GI-tract, liver, immune system) Aquatic Acute 1 Aquatic Chronic1**	**H315 H318 H304 H373 H 400 H 410**	**GHS05 GHS08 GHS09 Dgr**	**H315 H318 H304 H373 H410**		**M(acute) = 10 M(chronic)= 10**	None

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Amines, hydrogenated tallow alkyl	262-976-6	61788-45-2	**Xi, R38-41 Xn; R48/22-65 N; R50/53**	**Xn; N R: 38-41-48/22-65-50/53 S: (2-)26-36/37/39-60-61-62**	**N; R50-53: C ≥ 2.5 % N; R51-53: 0.25%≤C<2.5 % R52-53: 0.025 %≤C<0.25 %**	None

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)		
	Amines, coco alkyl	262-977-1	61788-46-3	**Acute Tox. 4** **Skin Corr. 1B** **Asp. Tox. 1** **STOT SE3** **STOT RE 2 (GI-tract, liver, immune system)** **Aquatic Acute 1** **Aquatic Chronic 1**	**H302** **H314** **H304** **H335** **H373** **H 400** **H 410**	 **GHS05** **GHS07** **GHS08** **GHS09** **Dgr**	**H302** **H314** **H304** **H335** **H373** **H410**		 **M(acute)=10** **M(chronic) = 10**	None

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Amines, coco alkyl	262-977-1	61788-46-3	**Xn; R22-48/22-65** **C; R35** **N; R50/53**	**C; N** **R: 22-35-48/22-65-50/53** **S: (1/2)23-26-36/37/39-45-60-61-62**	**C; R35: C ≥ 10%** **C; R34: 5% ≤ C < 10%** **Xi; R36/37/38: 1% ≤ C < 5%** **N; R50-53: C ≥ 2.5%** **N; R51-53: 0.25% ≤ C < 2.5%** **R52-53: 0.025% ≤ C < 0.25%**	None

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)		
	Amines, tallow alkyl	263-125-1	61790-33-8	**Acute Tox. 4 Skin Corr. 1B Asp. Tox. 1 STOT RE 2 (GI-tract, liver, immune system) Aquatic Acute 1 Aquatic Chronic 1**	**H302 H314 H304 H373 H400 H410**	**GHS05 GHS07 GHS08 GHS09 Dgr**	**H302 H314 H304 H373 H410**		**M(acute) =10 M(chronic)= 10**	None

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Amines, tallow alkyl	263-125-1	61790-33-8	**Xn; R22-48/22-65 C; R35 N; 50/53**	**Xn, C, N R 22-35-48/22-65-50/53 S: (1/2-)26-36/37/39-45-60-61-62**	**N; R50-53: C ≥ 2.5 % N; R51-53: 0.25 % ≤ C < 2.5 % R52-53: 0.025 % ≤ C < 0.25 %C ≥ 2.5%: N, R50-53**	None

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 statement Code(s)	Suppl. Hazard statement Code(s)		
	Ammoniumpentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	**Carc. 2, Repr. 1B Lact STOT RE 1 (liver) Acute Tox. 4 Acute Tox. 4 Eye dam. 1**	**H351 H360D H362 H372 H332 H302 H318**	**GHS07 GHS08 Danger**	**H351 H360D H372 H332 H302 H318**		**-**	**None**

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
	Ammoniumpentade	223-320-4	3825-26-1	**Carc. Cat 3; R40**	**T, Xn**	**-**	**-**

	cafluorooctanoate (APFO)			**Repr. Cat. 2: R61: R64 T; R48/23 Xn; R48/21/22, R20/22, Xi; 41**	**R: 40-61-48/23-48/21/22-20/22-41** **S: 26-36/37-39-45-46-53-63**		

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 statement Code(s)**	**Suppl. Hazard statement Code(s)**		
	Perfluorooctanoic acid (PFOA)	206-397-9	335-67-1	**Carc. 2, Repr. 1B Lact STOT RE 1 (liver) Acute Tox. 4**	**H351 H360D H362 H372 H332 H302**	**GHS07 GHS08 Danger**	**H351 H360D H372 H332**		**-**	**-**

				Acute Tox. 4 **Eye dam. 1**	**H318**		**H302** **H318**			

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**
	Perfluorooctanoic acid (PFOA)	206-397-9	335-67-1	**Carc. Cat 3; R40** **Repr. Cat. 2: R61: R64** **T; R48/23** **Xn; R48/21/22, R20/22,** **Xi; 41**	**T, Xn** **R: 40-61-48/23-48/21/22-20/22-41** **S: 26-36/37-39-45-46-53-63**	**-**	**None**

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)		
015-004-00-8	Aluminium phosphide	244-088-0	20859-73-8	**Water-react. 1 Acute Tox. 2 Acute Tox. 3 Acute Tox. 1 Aquatic Acute 1**	**H260 H300 H311 H330 H400**	**Dgr. GHS02 GHS06 GHS09**	**H260 H300 H311 H330 H400**	**EUH029 EUH032**	**M = 100**	None

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
015-004-00-8	Aluminium phosphide	244-088-0	20859-73-8	**F; R15/29 T+; R26/28 Xn; R21 R32 N; R50**	**F; T+ ; N R:15/29-26/28-21-50 S:(1/2)-3/9/14/49-8-22-30-36/37-43-45-60-61**	**N; R50: C ≥ 0.25 %**	None

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 statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
015-005-00-3	magnesium phosphide; trimagnesium diphosphide	235-023-7	12057-74-8	**Water-react. 1** **Acute Tox. 2** **Acute Tox. 3** **Acute Tox. 1** **Aquatic Acute 1**	**H260** **H300** **H311** **H330** **H400**	**GHS02** **GHS06** **GHS09** **Dgr**	**H260** **H300** **H311** **H330** **H400**	**EUH029** **EUH032**	**M=100**	**None**

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
015-005-00-3	magnesium phosphide; trimagnesium diphosphide	235-023-7	12057-74-8	**F; R15/29** **T+; R26** **T+; R28** **Xn; R21** **R32** **N; R50**	**F; R15/29** **T+; R26** **T+; R28** **Xn; R21** **R32** **N; R50** **S:(1/2)-3/9/14/49-8-22-30-36/37-43-45-60-61**	**N; R50: C≥0.25 %**	**None**

Table 2. List of preliminary RAC agreement on proposals for classification[4]

Classification & Labelling in accordance with the CLP Regulation for Nitrobenzene:

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)		
609-003-00-7	Nitrobenzene	202-716-0	98-95-3	**Carc. 2.** **Repr. 1B** **Acute Tox. 3** **Acute Tox. 3** **Acute Tox. 3** **STOT RE 1 (blood)** **Aquatic Chronic Cat. 3**	**H351** **H360F** **H301** **H331** **H311** **H372** **H412**	**GHS06** **GHS08** **Dgr**	**H351** **H360F** **H301** **H331** **H311** **H373** **H412**			None

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes

[4] Hazard classes, category and hazard statement codes are written in **bold** if agreed during the meeting.

609-003-00-7	Nitrobenzene	202-716-0	98-95-3	**Carc. Cat. 3; R40 Repr. Cat. 2; R60 T; R23/24/25 T; R48/23/24/25 R52/53**	**T, R:23/24/25-48/23/24/25-40-60-52/53 S: 2-36/37-45-46-53**		None

Part III. List of Attendees of the RAC-18 meeting (26-28 October 2011)

Members		**ECHA staff**
BARANSKI Boguslaw		ATLASON Palmi
BARRON Thomasina		BARRUEL Philippe
BJØRGE Christine		CSÁK Viktória
BORGES Teresa		ERICSSON Gunilla
BRANISTEANU Radu		FUHRMANN Anna
Di PROSPERO FANGHELLA Paola		HOLLINS Steve
DUNAUSKIENE Lina		HONKANEN Jani
DUNGEY Stephen		KARJALAINEN Ari
GREIM Helmut		KLAUK Anja
GRUIZ Katalin		KOKKOLA Leila
HALKOVA Zhivka		LEBSANFT Joerg
JENSEN Frank		LUOTAMO Marita
KADIKIS Normunds		LUSCHÜTZKY Evita
LEINONEN Riitta		MAGGIORE Angelo
LUND Bert-Ove		MALM Jukka
MULLOOLY Yvonne		MATTHES Jochen
NUNES Céu		MOSSINK Jos
OLTEANU Maria		NYGREN Jonas
PARIS Pietro		PELTOLA Jukka
PASQUIER Elodie		RODRIGUEZ IGLESIAS Pilar
PICHARD Annick		ROECKE Timo
PINA Benjamin		ROGGEMAN Maarten
POLAKOVICOVA Helena		SAEZ RIBAS Monica
PRONK Marja		SCHÖNING Gabi
RUCKI Marian		SOSNOWSKI Piotr
RUPPRICH Norbert		TARAZONA Jose
SCHLUETER Urs		VAINIO Matti
SCHULTE Agnes		Van HAELST Anniek
SMITH Andrew		
SOERENSEN Peter		
STOLZENBERG Hans-Christian		**Stakeholder observers**
TADEO José Luis		ANNYS Erwin (Cefic)
TROISI Gera		MEISTERS Marie-Louise (ECETOC)

Van der HAGEN Marianne		MUNARI Tomaso (EuCheMS)
CURABA Mara (replacement to van Malderen)		ROWE Rocky (ECPA)
		SOBALLA Volker (BusinessEurope)
Advisers to the RAC members		SANTOS Tatiana (ETUC)
CANAS Irene (adviser to Tadeo J.L) and adviser supporting rapporteurs on Cymoxanil		VEROUGSTRAETE Violaine (Eurometaux)
EKOKOSKI Elina (adviser to Riitta Leinonen)		**Remote participants**
LINDEMAN Birgitte (adviser to Marianne van der Hagen) and adviser supporting rapporteurs on Gallium Arsenide		ANDERSSON Alicja (RAC member)
PECZKOWSKA Beata (adviser to Boguslaw Baranski) and adviser supporting rapporteurs on Nitrobenzene and Trimagnesum diphosphide)		HAKKERT Betty (RAC member)
ROMOLI Debora (adviser to Pietro Paris)		Van MALDEREN Karen (RAC member)
Smith Helen (adviser to Andrew Smith)		BRIGNON Jean-Marc (SEAC rapporteur for phthalates)
VEGA Milagros (adviser to Céu Nunes and adviser supporting rapporteurs on the 5 Amines)		THIELE Karen (SEAC rapporteur for phthalates)
		Attias Leonello (Forum representative for phthalates)
Invited Experts		LARSEN Poul Bo (RAC advisor for phthalates and GaAS)
VILANOVA Eugenio		Schuur Gerlienke (RAC advisor for phthalates)
		McMickan Sinead (RAC advisor for restriction/autorisation)
Representatives of the Commission		Lindeman Birgitte (RAC advisor)
BINTEIN Sylvain (DG ENV)		Hofer Tim (RAC advisor for 4-vinylcyclohexene (VCH)
GIRAL Anne (DG ENTR)		MARQUES Daniele Court (EFSA)
SCAZZOLA Roberto (DG ENTR)		ISTACE Frederique (EFSA)
ZIELINSKI Janusz (DG ENV)		MORTE Juan Parra (EFSA)
		TIRAMANI Manuela (EFSA)
Other observers		SHARP Rachel (EFSA)
VARNAI Veda (Croatian observer)		HERRANZ Montes Javier (EFSA)

ANDREW David (an observer acting as an expert to an observer representing ECPA for cymoxanil_proquinazid) /		SZENTES Csaba (EFSA)
COSTLOW Richard D.(an observer acting as an expert to an observer representing CEFIC for Dioctyltin		BOBERG Julie (a representative of the Danish CA following phthalates)
GELBKE Heinz-Peter (an observer acting as an expert to an observer representing Business Europe for GaAs)		HUSA Stine (a representative of the Norwegian CA following APFO and PFOA)
GEURTS Marc (an observer acting as an expert to an observer representing CEFIC for the 5 Amines)		LARSEN Ann Kristin (a representative of the Norwegian CA following APFO ,PFOA and p-tert-butylphenol)
KENNEDY Gerald (an observer acting as an expert to an observer representing CEFIC for PFOA; APFO)		STARK Christiane (a representative of the German CA following nitrobenzene, and 5 amines)
POOLE Alan (an observer acting as an expert to an observer representing CEFIC for nitrobenzene)		HERBST Uta (a representative of the German CA following nitrobenzene, and 5 amines)
GAOUA-CHAPELLE Wassila (dioctyltin bis) (dossier submitter, IND)		Averbeck Jan/BAuA (a representative of the German CA following 5 amines, nitrobenzene, aluminium phosphide, trimagnesium diphosphide)
		Niederstrasser Bernd (a representative of the German CA following Amines
		Niot Vanessa (a representative of the French CA following VCH)
		Vlandas Penelope (COM)
		Gil Sebastian (COM)
		Bintein Sylvain (COM)
		Pirselova Katarina (COM)
		Rozwadowski Jacek (COM)
		Bertato Valentina (COM)
		Scazzola Roberto (COM)
		Lipkova Adriana (ECHA)

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-19 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-19 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-19 meeting

29 November 2011
RAC/A/19/2011_final

Final Agenda

19th meeting of the Committee for Risk Assessment

29 November – 2 December 2011

Helsinki, Finland

29 November: starts at 9:00
2 December: ends at 13:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/19/2011 rev.1
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the minutes of the RAC-18

RAC/M/18/2011
For adoption

Item 5 – Administrative issues and information items

5.1 Report on RAC-18 action points, written procedures and other ECHA bodies

RAC/19/2011/34
Room document
For information

5.2 Update of the form on annual declaration of interests (Annex 2 to the RAC Rules of Procedure)

RAC/19/2011/35
Room document
For information

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

6.1 Gallium arsenide

For discussion and possible adoption

Item 7 – CLH

7.1 CLH Dossiers

a. Pitch, coal tar, high temp. (CTPHT) - *adopted via written procedure, no further discussion*

b N-ethyl-2-pyrrolidone (NEP)

c Nitrobenzene

d Octadecylamine

e (Z)-octadec-9-enylamine

f Amines, hydrogenated tallow alkyl

g Amines, coco alkyl

h Amines, tallow alkyl

i Ammoniumpentadecafluorooctanoate (APFO)

j Perfluorooctanic acid (PFOA)

k Aluminium phosphide

l Trimagnesium diphosphide

For discussion and possible adoption

m p-tert-butylphenol

n 4-vinylcyclohexene (VCH)

o Cymoxanil

p Proquinazid

q Dioctyltin bis(2-Ethyhexyl mercaptoacetate)

r Amidosulfuron

For discussion

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

RAC/19/2011/36
Room document
For agreement

7.3 General and procedural CLH issues

a. State of play of the submitted CLH dossiers

For information

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

a. Phthalates – first draft opinion

For discussion

8.2 General restriction issues

a. Update on intended restriction dossiers

For information

b. Update on the review of the restriction process including the project on improving the quality of incoming restriction reports

For discussion

Item 9 – Authorisation

9.1 Evaluation of applications by RAC and SEAC & Capacity building

a. Common approach of RAC and SEAC in opinion development on Applications for Authorisation
b. Discussion
c. Overview of the capacity building programme
d. Use of registration data, possibilities, limitations, quality issues with emphasis on exposure scenarios
e. Demonstration of the use of dissemination portals for databases on chemicals

RAC/19/2011/37
Room document
For discussion

9.2 Appointment of RAC rapporteurs for substances listed in Annex XIV (if relevant)

RAC/19/2011/38
Room document
For agreement

Item 10 – Guidance issues

10.1 Update on guidance activities including on guidance on the application of the CLP criteria

For information

Item 11 – Update on stakeholder participation in the work of RAC (Closed session)

RAC/19/2011/39
Room document
For agreement

Item 12 – Any other business

12.1 Information on the BauA project on the evaluation of exposure models.

RAC/19/2011/40
Room document
For information

Item 13– Main conclusions and Action Points of RAC-19

Table with main conclusions and action points from RAC- 19

For adoption

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ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-19 meeting.

RAC/A/19/2011 rev.1	Final Draft Agenda
RAC/M/18/2011	Adoption of the minutes of the RAC-18
RAC/19/2011/34	Administrative issues and information items
RAC/19/2011/35	Administrative issues and information items
RAC/19/2011/36	Appointment of CLH rapporteurs intentions
RAC/19/2011/37	Evaluation of applications by RAC and SEAC & Capacity building
RAC/19/2011/38	Appointment of rapporteurs for authorisation dossiers
RAC/19/2011/39	Update on stakeholder participation in the work of RAC
RAC/19/2011/40	Any other business: Information on the BauA project on the evaluation of exposure models

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ANNEX III

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
Stephen DUNGEY	Proquinazid
Marianne van der HAGEN	PFOA/AFPO
Frank JENSEN	Phthalates
Peter Hammer SØRENSEN	Phthalates
Elodie PASQUIER	Gallium Arsenide N-ethyl-2-pyrrolidone (NEP) 4-vinylcyclohexene (VCH)
Annick PICHARD	Gallium Arsenide N-ethyl-2-pyrrolidone (NEP)
Agnes SCHULTE	Nitrobenzene Amines (Group 5)
Andrew SMITH	Proquinazid
Hans-Christian STOLZENBERG	Nitrobenzene Amines (Group 5) Aluminium phosphide Trimagnesium diphosphide
Stakeholders	
ECETOC, Marie-Louise MEISTERS	APFO and PFOA Cymoxanil Proquinazid
Tomaso MUNARI	Pitch, coal tar, high temp (CTPHT)