RAC/M/18/2011

FINAL

2 December 2011

Minutes of the 18th meeting of the Committee for Risk Assessment (RAC-18) (26-28 October 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 one new RAC member, nominated by Cyprus (not present at the meeting). The Chair welcomed a RAC member who was appointed in June, nominated by Denmark and invited to briefly introduce himself. Eight advisers, two invited experts, six stakeholder representatives (from Business Europe, CEFIC, ECETOC, ECPA, EuCheMS, and Eurometaux), six observers accompanying stakeholder observers (STO), and three representatives from the Commission were welcomed.

For this meeting some participants took part in substance related discussions as remote participants. This included: one member, one invited expert and representatives of Member State Competent Authorities (MSCA) from Germany and Norway.

Apologies were received from four RAC members and three regular observers (CONCAWE, ECEAE and ETUC). One member was 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.

2 Adoption of the Agenda

The draft agenda (RAC/A/18/2011_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 whether there were any conflicts of interest to be declared specific to the agenda items. Seven 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 Member States Competent Authorities. 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-17

RAC adopted the revised draft minutes of the RAC-17 after minor clarifications. The minutes are available on the ECHA web site.

5 Administrative issues and information items

The Secretariat informed the Committee on administrative issues (room document RAC/18/2011/28). In relation to the part of the document reporting about other ECHA bodies and activities, the Secretariat pointed to the satisfaction survey that would be launched soon. The RAC members were invited to respond to the questions set out in the pertinent questionnaire comprising a handful of questions.
In relation to the new policy on the handling of conflicts of interest, the Secretariat reported that this policy would be implemented for all ECHA bodies equally and also for the ECHA staff. The Secretariat pointed out that the implementation of the new policy might also entail changes to the Rules of Procedure of the Committees; RAC will be informed on further steps in due course.

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

The Chair introduced an observer accompanying the EUROMETAUX stakeholder observer.

The (co-)rapporteurs presented the second draft opinion and in their presentation responded to the comments that had been made by members and stakeholders on this draft and other issues that had arisen at the previous meeting of RAC.

A discussion then followed in which it was highlighted that the new information arsing from the public consultation in relation to carcinogenicity had required a new assessment of the overall weight of evidence. The new data suggested a lower bioavailability of GaAs when compared to the classified Carc. Cat. 1A arsenic compounds. At the same time, the data provided stronger evidence regarding the assessment of the animal studies and the additional supportive evidence. The new weight of evidence confirms the need for classification as carcinogen Cat. 1; and the discussion focussed on the appropriateness of the subcategories 1A or 1B.

The form of gallium arsenide to be classified (crystalline or amorphous (dust)) was also extensively considered. The Chair clarified that the form that is put on the market and in which it can be expected to be used should be classified so if both forms are present the classification should apply to both. It was also considered that insufficient evidence was available to RAC to consider that the two forms may require different harmonised classifications.
Following these discussions, there was provisional agreement that the most appropriate harmonised classification for carcinogenicity should be category 1B. The (co-) rapporteurs were to prepare a revised version of the opinion with a view to adopt it at RAC-19.

The Chair thanked the rapporteur and RAC for their discussion and invited the rapporteur to modify the draft opinion for further discussion.

7 CLH[1] dossiers

7.1a N-ethyl-2-pyrrolidone (NEP)

The Chair introduced an observer accompanying the Cefic stakeholder observer and invited the RAC rapporteurs to present the second draft opinion on the CLH proposal submitted by France. The only remaining issue was the application of the letter D to the hazard code H360. Following comments received during the written procedure from RAC members, the rapporteurs concluded that RAC supports the proposal of the dossier submitter for H360D. RAC provisionally agreed to the draft opinion; the note used earlier will be added by the Secretariat.

An industry observer proposed to consider establishing specific concentration limits (SCL) for the substance, in alignment to the SCL set for the similar substance N-methyl-2-pyrrolidone. The Commission observers clarified that the generic concentration limits would apply if no SCL are included in the harmonised classification. It was agreed that industry would provide additional data before RAC-19. The rapporteurs will consider the data and include it in the revised draft opinion if needed.

The Chair thanked the rapporteur and RAC for their discussion.

7.1.b Ammoniumpentadecafluorooctanoate (APFO)

The Chair welcomed an observer accompanying the Cefic stakeholder observer and representatives 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.

The Chair informed RAC that based on the discussions at RAC-17, a shorter consultation period than foreseen in the RAC working procedure (18 instead of 28 days) had been applied for allowing a discussion at this meeting. He invited the RAC rapporteur to present the first draft opinion on the CLH proposal.

The rapporteurs summarised the steps of the opinion development that had been completed so far. They proposed to discuss all relevant endpoints except carcinogenicity and reprotoxicity; the discussion of the latter should be done at RAC-19. RAC agreed to first discuss the ambiguous classifications ("borderline cases") with the aim to clarify the assignment to a particular hazard category.

RAC provisionally agreed with the classification of APFO regarding some hazard classes as indicated in Table 2 of Part II of this document.

In relation to skin irritation the rapporteur indicated that a pertinent conclusion cannot be established due to insufficient information. The Chair informed RAC that skin irritation had not been proposed by the dossier submitter, and, therefore, there is no need for covering this hazard class in the RAC opinion.

The Chair thanked the rapporteur and RAC for their discussion and invited the rapporteurs to modify the draft opinion for further discussion.

[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.

7.1.c Perfluorooctanic acid (PFOA) and its ammonium salt

In accordance with the adopted minutes for RAC-17, any classifications / rationale agreed for APFO is considered applicable to PFOA. This will also be reflected in the relevant draft opinion and classification tables.

7.1.d Sulcotrione

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

RAC agreed to classify sulcotrione as skin sensitiser (category 1A; H317), and to include SCL of 0.1% with this classification under the DSD in order to harmonise the concentration limits to be used under the DSD and CLP. RAC agreed that the criteria for skin or eye irritation were not supported by the evidence.

In relation to repeated dose toxicity, RAC discussed the findings relevant for classification as STOT RE according to the CLP Regulation and agreed to classify sulcotrione as STOT RE 2 (H373) based on evidence for kidney toxicity.

RAC agreed to classify sulcotrione for developmental toxicity (category 2; H361d) and agreed that classification for adverse effects on or via lactation were not supported.

The environmental classification had been provisionally agreed at the previous meeting (RAC-17).

RAC adopted by consensus the revised draft opinion on the CLH proposal for sulcotrione. 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.e Nitrobenzene

The Chair welcomed an observer accompanying the Cefic stakeholder observer, the dossier submitter representative and the adviser to the rapporteur and invited rapporteurs to introduce the revised draft opinion on the CLH proposal submitted by Germany.

Currently there is an entry in Annex VI to the CLP Regulation for nitrobenzene.

The rapporteur presented the proposal for classification for nitrobenzene containing less than 0.1% of impurities. The Commission representative confirmed that RAC is requested to consider in the opinion the proposal for the harmonised classification of nitrobenzene in its pure state and do not need to consider the classification related to the presence of benzene as impurity.

RAC provisionally agreed to classify nitrobenzene as Carcinogen cat 2. and that classification for lactation effects was not warranted.

Regarding reprotoxicity, the rapporteur indicated that a classification as Repr. 1B could be more appropriate than Cat 2. This view was supported by several RAC members. RAC suggested exploring potential differences with the previous classification at TC C&L and include them in the opinion before deciding on this endpoint.

The rapporteur provided the evidence to classify nitrobenzene as STOT RE 2 (blood).

A stakeholder observer offered to provide additional data on methemoglobin-forming and spermatotoxicity of nitrobenzene. The data will be considered by the rapporteur who would reflect on different sensitivity to methemoglobin formation in rats and humans. Furthermore, also for this endpoint potential differences with the previous TC C&L classification will be explored and included in the opinion.

Acute oral toxicity, acute inhalation toxicity and acute dermal toxicity were discussed. RAC agreed to come back to the acute toxicity when the issue of different sensitivity of humans and rats to methemoglobin formation was more clear.

RAC provisionally agreed on the environmental classification of nitrobenzene. Additionally a RAC member provided to the rapporteur further information on previous environmental classification which would be included in the opinion and BD.

RAC provisionally agreed with the classification of nitrobenzene regarding some hazard classes as indicated in Table 2 of Part II of this document.
The Chair thanked the rapporteurs and RAC for their discussion and invited the rapporteurs to modify the draft opinion for further discussion.

7.1.f Penconazole

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

RAC provisionally agreed not to classify penconazole as STOT RE 2.

RAC discussed on how to conclude on classification for reproductive toxicity and whether the information provided by the dossier submitter was sufficient for concluding on classification for reproductive toxicity. RAC decided to postpone the final conclusion on this hazard class until EFSA's view and justification to propose a possible classification for reproductive toxicity (EFSA Conclusion in 2008) are clarified.

The adoption of the draft opinion, including the conclusion on reproductive toxicity, was therefore postponed either for the next meeting or by written procedure.

RAC provisionally agreed on the harmonised classification of penconazole as indicated in Table 2 of Part II of this document.

The Chair thanked the rapporteurs and RAC for their discussion.

7.1.g Ethylbenzene

The Chair introduced an observer accompanying the Cefic stakeholder observer and the dossier submitter representative and invited the rapporteur to present the revised draft opinion on the CLH dossier on ethylbenzene submitted by Germany.

The proposed classification for ethylbenzene referred to ototoxicity and aspiration toxicity and is based on inhalation exposure in animals as well as physical properties. No relevant human data is available concerning repeated dose toxicity or ototoxicity.

Irreversible ototoxicity with loss of outer hair cells in organ of Corti (located in cochlea) was found in rats after repeated inhalation exposure to ethylbenzene vapour for 13 weeks. The LOAEC was established to be 200 ppm (0.9 mg/l) (Gagnaire et al.,

2007). Classification as STOT RE 2 (hearing organs) was agreed.

Ethylbenzene was identified as an aspiration hazard and should be classified as Asp. Tox.1; H304 (May be fatal if swallowed and enters airways) because it is a hydrocarbon with a kinematic viscosity of 0.63 mm^2/s determined at 40°C.

Although not strictly necessary when applying the criteria under DSD, classification as R48/20 was suggested to be added and supported by RAC, to be in line with the classification for toluene, also an ototoxic substance.

RAC supported the proposed classification as indicated in Table 2 of Part II of this document.

The Chair thanked the rapporteur and RAC for the discussion and invited the rapporteurs to provide the revised draft opinion and its annexes for adoption by RAC by written procedure.

7.1.h, i, j, k, l Octadecylamine, (Z)-octadec-9-enylamine, amines, hydrogenated tallow alkyl, coco alkyl, 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 first draft opinion for the CLH proposals submitted by Germany.

The dossiers are interlinked as they are partially based on read–across approach due to similarities in physico-chemical properties, having common functional groups and common metabolic breakdown products. Therefore, the opinions were discussed together.

Currently there are no entries in Annex VI to the CLP Regulation for these substances. However, the substances were discussed in the TC C&L according to the DSD without reaching final conclusion on all hazard classes. The Secretariat informed RAC about relevant information in the existing registration dossiers.

Discussions concerning the human health part focused on acute toxicity, skin corrosion and irritation, respiratory irritation and aspiration, and repeated dose toxicity.

The environmental discussions focused on bioconcentration and setting the M-factors. The only point that remained open for further discussion was the proposal and justification for the chronic M-factor.

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

The Chair thanked the rapporteurs and RAC for their discussions.

7.2 CLH dossiers for first discussion

7.2.a Aluminium phosphide

The Chair welcomed the dossier submitter representative and invited the RAC rapporteurs to present the main points of the draft opinion for first discussion.

The substance is used as a biocide.

The dossier focuses on the human health hazards Acute Toxicity 2 (oral; confirmation of current entry) and Acute Toxicity 3 (dermal; additional classification). The substance has already harmonised classification in Annex VI to the CLP Regulation

as acutely toxic (oral), water reactive, hazardous to the environment and as releasing toxic gas upon contact with water and acid.

During the public consultation, all comments were in favour of the dossier submitter's proposal concerning the additional classification for Acute Dermal Toxicity. According to the rapporteurs, the classification as Acute Dermal Toxicity is justified.

During public consultation, the classification as Acute Inhalation Toxicity Cat. 1 was proposed, given that the substance releases the toxic gas phosphine. The rapporteurs would like to discuss with RAC this proposal but they were of the view that classification as Acute Inhalation Toxicity Cat. 2 was better justified by the available data. They also felt RAC should discuss whether classification as EUH032 is sufficient for this potential hazard.

A RAC member offered to provide additional information concerning hydrolysis kinetics and workplace exposure which can help to assess real use pattern exposure conditions to the substance potentially relevant for the hazard identification.

The rapporteurs will continue their work on the draft opinion. Following the discussion they will clearly state which endpoints were not assessed in the draft opinion.

The Chair thanked the rapporteurs for their presentations and invited RAC members to provide comments on the first draft opinion. The Chair reminded that the commenting period was open till 7th November 2011.

7.2.b Trimagnesium diphosphide

The Chair mentioned the close relationship with the aluminium phosphide dossier, welcomed the dossier submitter representative and invited the RAC rapporteurs to present the main points of the draft opinion for first discussion.

The rapporteur stressed the importance of the information on use of the substance.

The dossier focuses on the human health hazards Oral Acute Toxicity (confirmation of current entry) and Dermal Acute Toxicity (additional classification). In principle the rapporteurs agreed with the proposal but with some comments.

Although classification for Acute toxicity – inhalation was neither proposed by the dossier submitter not brought up during public consultation, the rapporteurs felt that it should be discussed based on the similarities between aluminium phosphide and trimagnesium diphosphide in releasing phosphine.

RAC members underlined the importance of the classification related to the inhalation route if the substance is in powder form. Similar to the aluminium phosphide dossier a RAC member offered to provide additional information concerning hydrolysis kinetics and workplace exposure which can be of help for the hazard assessment.

The Chair offered any support of the Secretariat if there would be need for additional cooperation between rapporteurs of aluminium phosphide and trimagnesium diphosphide.

The Chair thanked the rapporteurs for their presentations and invited RAC members to provide comments on the first draft opinion. The Chair reminded that the commenting period was open till 14th November 2011.

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 as listed in room document ***RAC/18/2011/29***.

7.4 General CLH issues

RAC requested the Secretariat to clarify in the Guidance that information on the physical form of the substance and the form in which the substance is used should be included in the dossier when relevant for C&L purposes in relation to Article 5.1 of the CLP Regulation.

a. State of play of the submitted CLH dossiers

The Chair informed RAC that the document prepared for CARACAL had been distributed as meeting document RAC/18/2011/26.

b. Review of the process for developing CLH opinions

The Chair informed RAC that the revision of the process was on-going and that a room document with the Secretariat response to the comments received from RAC members had been distributed shortly before the meeting.

8 Restrictions

8.1 Restriction Annex XV dossiers

a. Phthalates

RAC was informed by the rapporteur via oral report about the current status. The rapporteur informed RAC that the scope of restriction was the main topic addressed at the first rapporteurs' dialog as this was one of the issues during the conformity check. In relation to the enforceability of the proposed restrictions, the FORUM anticipates issues with enforceability of the proposed new entry to Annex XVII (no reference to analytical methods, wording too complex and not clear enough).

It was reported that the dossier submitter intends to provide more clear wording of the scope of the restriction proposal. The dossier submitter intends to submit the first version of the background document in January 2012, which should then be presented to RAC at the RAC-20 meeting.

8.2 General restriction issues

b. Review of working procedures after experiences on first dossiers

The Chair reminded the RAC members that the deadline for comments in the CIRCABC Newsgroup on working procedures is 31 October 2011 and invited RAC members to share their experience.

8.3 Appointment of RAC (co-) rapporteurs for restriction dossiers

RAC appointed two members as (co-)rapporteurs for chromium VI compounds dossier as proposed in document *RAC/18/2011/30.*

9 Authorisation

9.1 Appointment of RAC rapporteurs for substances listed in Annex XIV

The room document (RAC/18/2011/31) listing volunteers for rapporteurship in different pools for substances included in Annex XIV was presented.

RAC agreed to appoint the new volunteer to the pool as (co-)rapporteur for the substances listed in Annex XIV.

Following the routine from the last meetings, the Chair indicated that the pools would be updated if new expression of interests are received and the appointment is agreed by RAC. The rapporteurs in the pool 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 General authorisation issues

The Chair informed RAC that following the last joint RAC-SEAC session at RAC-17 the clarification and planning of further preparation on the authorisation process is on-going. More information on the progress will be provided in the following plenary meetings.

Concerning the RAC preparation, RAC members expressed, in particular, the need to establish the most appropriate approach to discuss and agree on any missing reference values for risk assessment of Annex XIV substances for which applications are reasonably expected to be submitted**,** in order to be able to finalise RAC opinions on authorisation applications within the tight deadlines set for the authorisation application procedure. The Chair clarified that, as requested by RAC, the need for substance-specific preparations will be reflected in the on-going plans for the capacity building.

10 Guidance issues

10.a Feedback from guidance consultations

The Chair informed RAC that the document prepared for CARACAL was available as room document *RAC/18/2011/27*, including relevant information pertaining to guidance issues.

10.b Report on other guidance activities

The Chair reminded the RAC members to provide their feedback on issues for review of the *Guidance on the application of the CLP criteria* by end November 2011 by means of the excel template provided to the RAC members in September 2011.

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

The Chair 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. Given that the document was not ready for discussion at the meeting,

RAC agreed that the Secretariat will distribute the document for RAC agreement either by written procedure or at RAC-19.

RAC agreed to include the minutes of the closed session in the general minutes of RAC-18.

11 Any other business

No issues were raised.

12 Main conclusions and Action Points of RAC-18

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.

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Part II. Conclusions and action points

MAIN CONCLUSIONS & ACTION POINTS
(Adopted at the 18th meeting of RAC)
(26-28 October 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/18/2011_rev.1) was adopted	**SECR** to upload the adopted Agenda to the RAC CIRCABC and to the ECHA website as part of the RAC-18 minutes.
3. Declarations of conflicts of interest to the Agenda	
Seven members and two 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 17	
The minutes of RAC 17 was adopted after consideration of RAC member's comments.	**SECR** to upload the adopted minutes to the RAC CIRCABC and to the ECHA website.

6. Requests under Article 77 (3)(c) - gallium arsenide	
RAC provisionally agreed the classification of gallium arsenide for carcinogenicity as Carc. 1B.	**Rapporteurs** to revise the draft opinion based on the discussion during RAC-18 and provide it to the **SECR** well in advance of the next meeting with a view to adopting the opinion during RAC-19.
7. CLH	
7.1 CLH dossiers for opinion adoption	
7.1 a. N-ethyl-2-pyrrolidone (NEP)	
RAC provisionally agreed with the classification of N-ethyl-2-	**IND** to provide the assessment for SCL.

pyrrolidone (NEP). RAC agreed to propose N-ethyl-2-pyrrolidone (NEP) as indicated in the table 2. below. The addition of the SCL will be discussed at RAC-19.	**Rapporteurs** to consider the IND assessment and to include SCL in a revised draft opinion if needed 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-19.
7.1 b. Ammoniumpentadecafluorooctanoate (APFO) **7.1 c. Perfluorooctanoic acid (PFOA)**	
RAC provisionally agreed with the classification of ammoniumpentadecafluorooctanoate (APFO) regarding some hazard classes as indicated in the table 2. below. Carcinogenicity and reprotoxicity will be discussed on RAC-19.	**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-19.
7.1 d. Sulcotrione	
RAC adopted by consensus the opinion and its annexes on the CLH proposal for sulcotrione RAC agreed to propose sulcotrione to be classified as indicated in table 1 below.	**Rapporteurs** to check consistency between the opinion, BD and RCOM and to provide them to SECR. **SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on sulcotrione 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 e. Nitrobenzene	
RAC provisionally agreed with the classification of nitrobenzene regarding some hazard classes as indicated in the table 2. below. RAC member has provided to the rapporteur additional information on previous environmental classification.	**Rapporteur** to introduce provided information on previous environmental classification to the opinion and BD. **STO** to provide data on methemoglobin-forming and spermatotoxicity. **Rapporteurs** to consider the TC C&L discussion and 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.
7.1 f. Penconazole	
RAC provisionally agreed with the classification of penconazole as indicated in table 2 below. RAC provisionally agreed not to propose classification as STOT RE 2. RAC discussed on how to conclude on classification for reproductive toxicity and decided to postpone final conclusion on this hazard class until EFSA's view is clarified.	**SECR** to contact EFSA and request scientific justification for their view on reproductive toxicity classification of penconazole and provide it to the Rapporteurs. **Rapporteurs** to evaluate the information provided by EFSA on classification for reproductive toxicity and its possible consideration by RAC in the opinion. **Rapporteurs** to make sure that the opinion and the BD are consistent. **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-19.
7.1 g. Ethylbenzene	
RAC agreed to propose ethylbenzene to be classified as indicated in the table 2. below.	**SECR** to make an editorial check of the BD and RCOM. **Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)). **SECR** to distribute revised draft opinion documents to RAC when available for possible adoption by written procedure.
7.1.h Octadecylamine **7.1.i Z)-octadec-9-enylamine** **7.1.j Amines, hydrogenated tallow alkyl** **7.1.k Amines, coco alkyl** **7.1.l Amines, Tallow alkyl**	
RAC provisionally agreed with the classification of the substance's hazard classes as indicated in the table 2. below.	**SECR** to check S-phrases, the use of R37 and to include the SCL where relevant. **SECR** to make an editorial check in consultation with the **Rapporteurs**. **SECR** to distribute revised draft opinion documents to RAC for editorial comments and possible adoption either by written procedure or at RAC-19.

7.2 CLH dossiers for first discussion	
7.2.a Aluminium phosphide	
RAC discussed the first presentation of the data.	**Members** to post their comments on the 1st draft opinion and annexes via the RAC CIRCABC Newsgroup by 7 November 2011. **RAC member** to provide information on hydrolysis kinetics and workplace exposure. **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 at RAC-19.
7.2.b Trimagnesium diphosphide	
RAC discussed the first presentation of the data.	**Members** to post their comments on the 1st draft opinion and annexes via the RAC CIRCABC Newsgroup by 14 November 2011. **RAC member** to provide information on hydrolysis kinetics and workplace exposure. **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 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/18/2011/29**_rev1*).	**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	
RAC requested SECR to clarify in the Guidance that information	**SECR** to consider the RAC proposal during the revision of the Guidance.

on the physical form of the substance and the form in which the substance is used should be included in the dossier when relevant for C&L purposes (Article 5.1 of the CLP Regulation).	
8. Restrictions	
8.1 Restriction Annex XV dossiers	
8.1.a Update on Phthalates dossier	
RAC was informed by the rapporteur via oral report about current progress.	
8.3 Appointment of RAC (co-)rapporteurs for restriction dossiers	
RAC appointed two members as (co-)rapporteurs for chromium VI compounds dossier as proposed in document ***RAC/18/2011/30***.	**SECR** to inform RAC as soon as the dossier is submitted to ECHA.
9 Authorisation	
9.1 Appointment of RAC rapporteurs for substances listed in Annex XIV	
RAC agreed to appoint the volunteer to the pool as (co-) rapporteurs for the substances listed in Annex XIV (room document ***RAC/18/2011/31***_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.

11. Update on stakeholder participation in the work of RAC (closed session)	
The Chair informed the STOs about the discussion of the closed session.	**RAC** agreed to include the minutes of the closed session in the general minutes of RAC-18. **SECR** to distribute the document with the possible new sector specific STOs for RAC agreement by written procedure or at RAC-19.

Table 1. List of adopted classifications by RAC[1]

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 (ISO); 2-(2-chloro-4-mesylbenzoyl)cyclohexane-1,3-dione	N/A	99105-77-8	**Skin Sens 1A** **STOT RE 2 (kidney)** **Repr. 2** **Aquatic Acute 1** **Aquatic Chronic 1**	**H317** **H373** **H361d** **H400** **H410**	GHS07 GHS09 Wng	**H317** **H373** **H361d** **H410**		**Acute M=1** **Chronic 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 (ISO); 2-(2-chloro-4-mesylbenzoyl)cyclohexane-1,3-dione	N/A	99105-77-8	**R43** **Xn: R48/22** **Repr. Cat. 3; R63** **N; R50/53**	**Xi; N** **R43-48/22-63-50/53** **S(2-)22-36-37-60-61**	**N; R50/53: C ≥ 25%** **N; R51/53: 2.5% ≤ C < 25%** **R52/53: 0.25%** **R43: C ≥ 0.1%**	

[1] Hazard classes, category and hazard statement codes are written in **bold** if agreed during the meeting. Those not written in bold are already harmonised in Annex VI to the CLP Regulation.

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

(Agreement reached for the following endpoints[2])

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	220-250-6	2687-91-4	**Repr. IB**	**H360D[3]**	**GHS08**	**H360**	**-**		

Classification and labelling in accordance with Directive 67/548/EEC

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

[2] Hazard classes, category and hazard statement codes are written in **bold** if agreed during the meeting. Those not written in bold are already harmonised in Annex VI to the CLP Regulation.

[3] 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

-	N-ethyl-2-pyrrolidone	220-250-6	2687-91-4	**Repr. Cat. 2; R61**	**T** **R: 61** **S: (1/2)-36/37-45-53**		

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)		
	Ammoniumpentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	**STOT RE 1 (liver)** **Acute Tox. 4** **Acute Tox. 4** **Eye dam. 1**	**H372** **H332** **H302** **H318**	GHS07 GHS08 **Danger**	**H372** **H332** **H302** **H318**		-	-

Classification and labelling in accordance with Directive 67/548/EEC

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
	Ammoniumpentadecafluorooctanoate (APFO)	223-320-4	3825-26-1	**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: 53-45	-	-

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.** **Aquatic Chronic Cat. 3**	H351 H412	GHS06G HS08 Dgr	H351 H412			

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
609-003-00-7	Nitrobenzene	202-716-0	98-95-3	**Carc. Cat. 3; R40** **R52/53**	T, R: 40--52/53 S: 2-36/37-45-46-53		

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 stateme nt 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		**Acute M= 1 Chronic M=1**	

Classification and labelling in accordance with 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**	**R: 22-50/53** S: 2-46-60-61	**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)		
601-023-00-4	Ethylbenzene	202-849-4	100-41-4	Flam. Liq. 2 Acute Tox. 4 * **Asp.Tox. 1** **STOT RE 2 (hearing organs)**	H225 H332 **H304** **H373**	GHS02 GHS07 GHS08 Dgr.	**H225** **H332** **H304** **H373**			

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

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
601-023-00-4	Ethylbenzene	202-849-4	100-41-4	F; R11 Xn; R20-**R48/20-65**	F; Xn R: 11-20-48/20-65 S: (2-)16-24/25-29-62	-	

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. 1B, 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			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, Xn,, N ;R 38-41-48/22-65-50-53**	Xi,Xn; N ;R 38-41-48/22-65-50/53 S 60-61	C ≥ 2.5%: N, R50-53 0.25% ≤ C < 2.5%: N, R51-53 0.025% ≤ C < 0.25%: R52-53	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 RE 2 (GI-tract, liver, immune system);** **STOT SE 3** **Aquatic Acute 1** **Aquatic Chronic 1**	H302 H314 H304 H373 H335 H 400 H 410	 GHS05 GHS07 GHS08 GHS09 Dgr	H302 H314 H304 H373 H335 H410			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, C, N R 22-34-48/22-65-50-53**	Xn, C, N R 22-34-48/22-65 50/53 S60-61	Cn ≥ 2.5%: N, R50-53 0.25% ≤ Cn < 2.5%: N, R51-53 0.025% ≤ Cn < 0.25%: R52-53 R37 and GCL	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. 1B;** **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 GHS07 GHS08 GHS09 Dgr	H315; H318; H304; H373 H410			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, Xn; N ; R 38-41-48/22-65-50-53**	Xi, Xn; ;R 38-41-48/22-65-50/53 S 60-61	C ≥ 2.5%: N, R50-53 0.25% ≤ C < 2.5%: N, R51-53 0.025% ≤ C < 0.25%: R52-53	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 RE 2 (GI-tract, liver, immune system);** **STOT SE 3** **Aquatic Acute 1** **Aquatic Chronic 1**	H302 H314 H304 H373 H335 H 400 H 410	 GHS05 GHS07 GHS08 GHS09 Dgr	H302 H314 H304 H373 H335 H410			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, N; C, R 22-35-48/22-65-50-53**	Xn, C, R 22-35-48/22-65-50/53 S60-61	C ≥ 2.5%: N, R50-53 0.25% ≤ C < 2.5%:N, R51-53 0.025% ≤ C < 0.25%: R52-53 R37 and GCL	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			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, C,N ;R 22-35-48/22-65-50-53**	Xn, C, N ;R 22-35-48/22-65-50/53 S 60-61	C ≥ 2.5%: N, R50-53 0.25% ≤ C < 2.5%: N, R51-53 0.025% ≤ C < 0.25%: R52-53	None

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

Members
ANDERSSON Alicja
BARANSKI Boguslaw
BARRON Thomasina
BJØRGE Christine
BORGES Teresa
Di PROSPERO FANGHELLA Paola
DUNAUSKIENE Lina
DUNGEY Stephen
GREIM Helmut
GRUIZ Katalin
HAKKERT Betty
HALKOVA Zhivka
KADIKIS Normunds
LEINONEN Riitta
LUND Bert-Ove
MULLOOLY Yvonne
NUNES Céu
OLTEANU Maria
PARIS Pietro
PASQUIER Elodie
PICHARD Annick
PINA Benjamin
POLAKOVICOVA Helena
PRONK Marja
RUCKI Marian
RUPPRICH Norbert
SCHLUETER Urs
SCHULTE Agnes
SMITH Andrew
SOERENSEN Peter
STOLZENBERG Hans-Christian
CANAS Irene (replacement for TADEO José L.)

ECHA staff
ATLASON Palmi
CSÁK Viktória
ERICSSON Gunilla
FUHRMANN Anna
HOLLINS Steve
HONKANEN Jani
KARJALAINEN Ari
KLAUK Anja
KOKKOLA Leila
LUOTAMO Marita
LUSCHÜTZKY Evita
MAGGIORE Angelo
MATTHES Jochen
NYGREN Jonas
PELTOLA Jukka
RODRIGUEZ IGLESIAS Pilar
ROGGEMAN Maarten
SAEZ RIBAS Monica
SCHÖNING Gabi
SOSNOWSKI Piotr
TARAZONA Jose
TYNKKYNEN Sallamari
Van HAELST Anniek
Stakeholder observers
JANOSI Amaya (replacing Erwin Annys (Cefic)
MEISTERS Marie-Louise (ECETOC)
MUNARI Tomaso (EuCheMS)
ROWE Rocky (ECPA)
MÜLLER Karsten (BusinessEurope), replacement to Volker Soballa
VEROUGSTRAETE Violaine (Eurometaux)
Other observers

TSITSIMPIKOU Christine		BARNES Emma (an observer acting as an expert to an observer representing ECPA observer for penconazole)
Van der HAGEN Marianne		GELBKE Heinz-Peter (an observer acting as an expert to an observer representing Business Europe for GaAs and CEFIC for Ethylbenzene and NEP)
Van MALDEREN Karen		HOUTHOFF Erik (an observer acting as an expert to an observer representing CEFIC for the 5 Amines)
		KENNEDY Gerald (an observer acting as an expert to an observer representing CEFIC for PFOA; APFO)
Advisers to the RAC members		POOLE Alan (an observer acting as an expert to an observer representing CEFIC for nitrobenzene)
ALESSANDRELLI Maria (adviser to Paola Di Prospero Fanghella)		Shipp Elizabeth (an observer acting as an expert to an observer representing ECPA for sulcotrione)
EKOKOSKI Elina (adviser to Riitta Leinonen)		
ESPOSITO Dania (adviser to Pietro Paris)		**Remote participants**
KORATI Safia (adviser to Karen van Malderen)		José Luis Tadeo (RAC member)
LINDEMAN Birgitte (adviser to Marianne van der Hagen) and adviser supporting rapporteurs on Gallium Arsenide		HERBST Uta (a representative of the German CA following nitrobenzene, Amines, ethylbenzene)
McGarry Helen (adviser to Andrew Smith) and adviser supporting rapporteurs on Sulcotrione		HERZLER Matthias (a representative of the German CA following Amines, ethylbenzene
PECZKOWSKA Beata (adviser to Boguslaw Baranski) and adviser supporting rapporteurs on Nitrobenzene)		LARSEN Ann Kristin (a representative of the Norwegian CA following APFO and PFOA)
VEGA Milagros (adviser to Céu Nunes and adviser supporting rapporteurs on the 5 Amines)		NIEMANN Lars (a representative of the German CA following penconazole and sulcotrione)
		STARK Christiane (a representative of the German CA following sulcotrione, nitrobenzene, ethylbenzene, penconazole, aluminium phosphide,)
		FRIESEN Anton (a representative of the German CA following sulcotrione, nitrobenzene, amines, ethylbenzene, penconazole, aluminium phosphide, trimagnesium diphosphide,)
Invited Experts		THIELE Karen (SEAC rapporteur for phthalates)
Le CURIEUX-BELFOND Olivier (RAC rapporteur for CLH dossiers for		BRIGNON Jean-Marc (SEAC rapporteur

Penconazole)		for phthalates)
POSPISCHIL Erich (RAC rapporteur for CLH dossiers for Ethylbenzene)		Niederstrasser Bernd (a representative of the German CA following Amines)
		Staude Claudia (a representative of the German CA following amines)
<u>Representatives of the Commission</u>		LARSEN Poul Bo (RAC invited expert for GaAS)
BINTEIN Sylvain (DG ENV)		SCHWAEGLER Mark (a representative of the German CA following Amines)
SCAZZOLA Roberto (DG ENTR)		EHRLICH Gunnar (a representative of the German CA following Amines)
ZIELINSKI Janusz (DG ENV)		LIEBMANN Susanne (a representative of the German CA following aluminium phosphide, trimagnesium diphosphide,)
		GALL Andrea (a representative of the German CA following aluminium phosphide and trimagnesium diphosphide)
		INSTANES Christine (a representative of the Norvegian CA following APFO and PFOA)
		OLSEN Ann Karin (a representative of the Norwegian CA following APFO and PFOA)

Part IV. LIST OF ANNEXES

ANNEX I Final Agenda of the RAC-18 meeting

ANNEX II List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-18 meeting

ANNEX III Declarations of conflicts of interest to the Agenda of the RAC-18 meeting

ANNEX I

26 October 2011
RAC/A/18/2011- Final

Final Agenda

18th meeting of the Committee for Risk Assessment

26 – 28 October 2011

Helsinki, Finland

26 October: starts at 9:00
28 October: ends at 14:00

Item 1 – Welcome & Apologies

Item 2 – Adoption of the Agenda

RAC/A/18/2011_Rev.1
For adoption

Item 3 – Declarations of conflicts of interest to the Agenda

Item 4 – Adoption of the minutes of the RAC-17

RAC/M/17/2011
For adoption

Item 5 – Administrative issues and information items

5.1 Status report on the RAC-17 action points

5.2 Outcome of written procedures

5.3 Report from other ECHA bodies and activities

- Report on MB policy of handling of conflict of interest

RAC/18/2011/28
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 for discussion and possible adoption

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

b. Ammoniumpentadecafluorooctanoate (APFO)

c. Perfluorooctanic acid (PFOA) and its salts

d. Sulcotrione

e. Nitrobenzene

f. Penconazole

g. Ethylbenzene

h. Octadecylamine

i. (Z)-octadec-9-enylamine

j. Amines, hydrogenated tallow alkyl

k. Amines, coco alkyl

l. Amines, Tallow alkyl

7.2 CLH dossiers for first discussion

m. Aluminium phosphide

n. Trimagnesium diphosphide

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

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

RAC/18/2011/29
room document
For agreement

7.4 General CLH issues

a. State of play of the submitted CLH dossiers

RAC/18/2011/26
For information

b. Review of the process for developing CLH opinions

RAC/18/2011/33
room document
For information

Item 8 – Restrictions

8.1 Restriction Annex XV dossiers

a. Update on the Phthalates dossier

For information

8.2 General restriction issues (if relevant)

a. Update on intended restriction dossiers

For information

8.3 Appointment of RAC (co-) rapporteurs for restrictions dossiers

RAC/18/2011/30
room document
For agreement

Item 9 – Authorisation

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

RAC/18/2011/31
room document
For agreement

9.2 General authorisation issues (if relevant)

Item 10 – Guidance issues

10.1 Feedback from guidance consultations

10.2 Report on other guidance activities

RAC/18/2011/27
For information

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

RAC/18/2011/32
room document
For agreement

Item 12 – Any other business

Item 13 – Main conclusions and Action Points of RAC-18

Table with main conclusions and action points from RAC- 18

For adoption

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ANNEX II

Documents submitted to the members of the Committee for Risk Assessment for the RAC-18 meeting.

RAC/A/18/2011 Rev.1	Final Draft Agenda
RAC/M/17/2011	Adoption of the minutes of the RAC-17
RAC/18/2011/28	Administrative issues and information items
RAC/18/2011/29 room document	Appointment of CLH rapporteurs intentions
RAC/18/2011/26	General CLH issues - State of play of the submitted CLH dossiers
RAC/18/2011/33 room document	General CLH issues – opinion development
RAC/18/2011/30 room document	Appointment of rapporteurs for restrictions dossiers
RAC/18/2011/31 room document	Appointment of rapporteurs for authorisation dossiers
RAC/18/2011/27	Guidance issues

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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) in RAC-18

Name of participant	Agenda item
RAC members	
Christine BJØRGE	PFOA/AFPO
Marianne van der HAGEN	PFOA/AFPO
Peter Hammer SØRENSEN	Phthalates
Elodie PASQUIER	Gallium Arsenide N-ethyl-2-pyrrolidone (NEP)
Annick PICHARD	Gallium Arsenide N-ethyl-2-pyrrolidone (NEP)
Agnes SCHULTE	Nitrobenzene Ethylbenzene Amines (Group 5)
Hans-Christian STOLZENBERG	Penconazole Nitrobenzene Sulcotrione Amines (Group 5)
Stakeholders	
ECETOC, Marie-Louise MEISTERS	APFO and PFOA
Businesseurope, Karsten Muller	N-ethyl-2-pyrrolidone (NEP) Nitrobenzene Ethylbenzene