**RAC/M/16/2011**

FINAL

6 September 2011

# Minutes of the 16th meeting of the Committee for Risk Assessment (RAC-16) (7-10 June 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 four new members, the newly appointed members were welcomed and invited to briefly introduce themselves. Eight advisers, two invited experts, ten stakeholder representatives (from BusinessEurope, CEFIC, ECETOC, ECPA, ETUC, EuCheMS, Eurogroup for Animals and Eurometaux), nine observers accompanying stakeholder observers (STO), one representative of dossier submitters and four representatives from the Commission were welcomed.

For this meeting some participants took part in substance related discussions as remote participants. This included: three advisers, five SEAC rapporteurs and representatives of Member State Competent Authorities (MSCA) from Norway and Germany.

Apologies were received from two RAC members and three regular observers (CONCAWE, ECEAE and HEAL). 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 revised agenda (RAC/A/16/2011_rev.4) was adopted with some modifications. The final agenda and the list of all meeting documents are attached to these minutes as Annexes I and II, respectively.

### 3 Declarations of conflicts of interest to the Agenda

The Chair asked the members and their advisers whether there were any conflicts of interest to be declared specific to the agenda items. Seven members and one stakeholder observer declared potential conflicts of interest to the substance-related discussions.

### 4 Administrative issues and information items

Administrative issues and information items (a-c) were covered by a room document (RAC/16/2011/13). Members were informed of the possibility to provide comments under the relevant agenda item or under any other business at the end of the meeting.

### 5 Request under Article 77(3)(c)

### 5a Gallium arsenide

The rapporteurs gave a preliminary overview of the information that had been provided in the recent public consultation (11 March – 27 April 2011) on the carcinogenicity of gallium arsenide. On the basis of the information provided, the following timetable was proposed for preparing a RAC opinion in response to the RAC mandate from the Executive Director of ECHA according to Article 77(3)(c) following a request to ECHA from the Commission:

- Preparatory meeting for RAC-17 (Sep 2011)
- Discussion on a first draft opinion RAC-17 (Sep 2011)
- Second draft opinion RAC-18 (Oct 2011)
- Adoption of the final RAC opinion RAC-19 (Nov 2011).

A brief discussion took place in which RAC members considered the scientific issues arising from the information received during the public consultation. There was a common view on the need to carefully consider any new and relevant information in the context of the criteria for classification for carcinogenicity and in particular, information relating to the metabolites of gallium arsenide.

The proposed timetable was agreed. A STO observer asked if STOs will be invited to participate in the preparatory meeting. The Chair confirmed that the preparatory meeting will be open and that the participation of interested STOs will be welcomed, with the usual caveat that close sessions may be required for handling confidential information or by other reasons as specified in the RAC procedures.

The Chair explained that despite the targeted public consultation, some comments had been submitted that were concerned with the proposed classification for reprotoxicity that had been previously adopted by RAC on 25 May 2010. RAC confirmed that its opinion on reprotoxicity was based on a proper assessment by RAC of the available data and that the industry claims indicating misquoting of the NTP report were not correct. RAC confirmed that its opinion was fully in line with the data as reported in the NTP report tables. To respond to these specific comments, RAC agreed to use the following standard response in the RCOM document: *RAC confirms that its conclusion regarding the classification of gallium arsenide for reproductive toxicity in its opinion of 25 May 2010 was based upon a proper evaluation of the data*.

## 6 CLH[1] Dossiers

### 6.1a White spirit dossiers (CAS No. 8052-41-3, 64742-82-1, 64742-88-7; EC No. 232-489-3, 265-185-4, 265-191-7)

The Chair introduced an observer accompanying the CEFIC stakeholder observer and invited the rapporteurs to present the revised opinion on the CLH proposal submitted by Denmark. RAC noted that following previous discussions at RAC, Denmark as dossier submitter has withdrawn the classification proposal for white spirit type 2 and 3 (CAS No. 64741-92-0, 64742-48-9; EC No. 265-095-5, 265-150-3).

As already mentioned RAC considered in its opinion development the available data on substance ID provided for white spirits type 0, type 1 and Stoddard solvent in the

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

registration dossiers. It was found that part of the registrants had applied a new naming system while the rest had applied the old one as presented by the dossier submitter and included in the CLP Annexes. Although the new naming system has a number of consequences for some types of white spirits (as mentioned above), the data from the registration dossiers have shown that the composition of the types of white spirits covered by the dossier (i.e. Stoddard solvent, white spirit type 0 and 1) is in general in agreement with the classification proposal. Based on the evaluations of IPCS and SCOEL, rather than a full assessment of all the individual studies, RAC summarizes both evaluations and states, that Stoddard solvent, white spirit type 0 and white spirit type 1 can produce a number of serious health effects in the central nervous system progressing to chronic toxic encephalopathy after prolonged exposure in humans.

It should be noted that at a late stage in the forming of this opinion, Hydrocarbon Solvent Producers' Association (HSPA) provided some information regarding white spirit substances registered under REACH using a new naming proposal for hydrocarbons. The HSPA document identifies seven substances registered under the new proposed naming strategy for hydrocarbons (which include over 40 substances) which in their view largely correspond to white spirits identified with the conventional EC numbers. Four of these substances are said to correspond to either white spirit type 0, white spirit type 1 or Stoddard solvent. These substances were automatically allocated provisional EC numbers during the registration process and are currently undergoing a compliance check in order to confirm their substance identity by ECHA.

As the outcome of the ECHA evaluation will not be available before the deadline for the RAC opinion, RAC cannot address the issue in its opinion. RAC considers that further reflection is necessary on how to apply the new identification developed for REACH for those UVCB substances which are on the market with similar composition to the current entries in Annex VI covered by this opinion.

RAC adopted by consensus the revised draft opinion on the CLH proposal for three white spirit dossiers *(Stoddard solvent, white spirit type 0 and White spirit type 1)*. 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.

### 6.1b PHMB

The Chair introduced an observer accompanying the regular CEFIC observer and invited the rapporteurs to present the revised opinion. The Chair also informed that a set of industry documents related to the classification for acute toxicity had been distributed to RAC and considered by the rapporteurs. RAC agreed with the rapporteurs that the submitted information did not affect the previously agreed classification although some additional explanations in the justification may be needed.

The harmonised classification for PHMB was provisionally agreed by RAC at the RAC-14 meeting, except for carcinogenicity and skin sensitisation with regard to a possible subcategory (in line with the new criteria implemented with the 2$^{nd}$ ATP).

According to the rapporteurs, PHMB was shown to be a moderate to strong sensitizer in guinea pigs. Human data showed that repeated exposure to PHMB, from 2%, caused a significant level of sensitisation, although the percentage of positive responders was relatively low (less than 1%). Classification as skin sensitising category 1B (according to 2nd ATP, CLP) was agreed by RAC.

Carcinogenicity was then discussed. The three key carcinogenicity studies were presented also considering the comments received during and after the last RAC discussion (RAC-14); one oral study in the rats and one oral and one dermal study in mice. In the mice oral study, vascular tumours were observed in the liver of male and female mice, of which some were also seen after dermal administration although above MTD. The identical tumours observed at and below MTD in mice and their dose-related incidences supported the conclusion that the tumours were related to PHMB treatment, according to the rapporteurs. There was also evidence of site of contact carcinogenic effects. Therefore, the rapporteurs considered the proposal for classification as a carcinogen in category 2; H351 (Carc. Cat. 3; R40) as appropriate.

The stakeholder observer disagreed with this interpretation and claimed that MTD was clearly exceeded as shown by high tumour related mortalities.

The stakeholder observer questioned why two additional "negative" cancer studies, although not GLP, were not considered in the background document.

Following this discussion the rapporteurs presented a revised draft opinion including further clarification on the MTD issue and on the two additional carcinogenicity studies, which could not be regarded as completely negative. These two studies were concluded not to be acceptable. RAC provisionally agreed to classify PHMB as presented in Table 2 of Part II of this document. The final draft opinion will be provided to RAC for an editorial commenting round and for possible adoption by written procedure before RAC-17.

### 6.1c **Chloroform**

The Chair introduced an observer accompanying the CEFIC stakeholder observer and invited the rapporteurs to present the revised opinion on the CLH proposal submitted by France. Weight of evidence analyses both for and against classification as a mutagen were available to RAC for discussion in order to decide on its view regarding mutagenicity.

The original proposal by France, was to classify chloroform for mutagenicity (Muta. 2, CLP). Indeed, phosgene, a metabolite of chloroform is shown to bind to DNA. However, based on generally negative results in *in vitro* studies, negative DNA binding experiments for chloroform itself as well as non coherent results from *in vivo* studies regarding chromosome aberration and micronuclei, RAC concluded that the body of evidence does not support the classification of chloroform as a mutagen according to CLP and DSD criteria. Data on mutagenicity of chloroform were complex in terms of interpretation (a large number of studies showing an overall lack of coherence in the data set, due to a combination of negative and seemingly positive results with several inconsistencies); therefore, some RAC members proposed that these interpretational issues should be included into the Manual of Conclusion and Recommendations (MoCR) as example for further similar cases.

Although narcotic effects are well recognised, specific data related to this effect were not presented in the CLH dossier. Therefore RAC did not support to classify chloroform for STOT SE 3 H336.

The current harmonised classification for chloroform concerns carcinogenicity, acute toxicity, repeated dose toxicity and skin irritation. The technical Committee for Classification and Labelling (TC C&L) under the previous legislation confirmed the existing harmonised classification and agreed for further harmonised classification as toxic for reproduction, for renal and severe nasal effects after repeated exposure, for eye irritation, as well as it may cause drowsiness or dizziness (CLP only). The classification for mutagenicity was not finalised by TC C&L.

RAC adopted by majority the revised draft opinion on the CLH proposal for chloroform. One RAC member disagreed with the RAC opinion on germ cell mutagenicity and expressed a minority position considering that the available information is sufficient for classifying chloroform as Muta Cat 2 H341. The minority position was motivated by both a deviating interpretation of the data and of the criteria for classification in the germ cell mutagenicity hazard class. The agreed classification is presented in Table 1 of Part II of this document.

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

### 6.1d **Reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene**

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

The harmonised classification and labelling for this substance was agreed at the Technical Committee for Classification and Labelling (TC C&L) under the previous legislation. Germany proposed, in addition to the classification agreed by TC C&L, to add R19/EUH019, but it was concluded by RAC that EUH019 (May form explosive peroxides; CLP) / R19 (DSD) is not appropriate. The Note D takes sufficiently care of the concern of dangerous polymerisation.

Following a discussion of specific S-phrases, RAC agreed from now on that the Secretariat should identify and include in the draft opinions the proposed labelling under the DSD based on the labelling requirements. The Secretariat took note of the suggested key issue for inclusion in the updated MoCR.

RAC adopted by consensus the revised draft opinion on the CLH proposal for Reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene. 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.

### 6.1e **Aluminium-magnesium-zinc-carbonate-hydroxide**[2]

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

[2] RAC determined that the use of “hydrate” was not appropriate after the substance name.

Aluminium-magnesium-zinc-carbonate-hydroxide already has a harmonised classification as hazardous for the aquatic environment. The original proposal from The Netherlands was to remove this classification.

The substance is a poorly soluble inorganic metal substance. Therefore, the metals strategy presented in Guidance on the Application of Regulation (EC) No 1272/2008 was used. The Eurometaux stakeholder observer favorably commented on the use of the metals strategy based on the guidance.

In the case of this substance there is no evidence that the substance would be rapidly lost from the environment or would rapidly partition from the water column. There is no information on bioaccumulation. In addition, there are no data generated using the Transformation/Dissolution Protocol on the rate and extent to which metal ions can be generated from the compound. Where such data are unavailable, the safety net classification should be applied. The reason for the safety net is that the known classifiable toxicity of the metal ions (here the classification is based on Zn) is considered to produce sufficient concern. Therefore, based on the available information, RAC recommended to keep the classification as hazardous to the aquatic environment but in a different category.

RAC adopted by consensus the revised draft opinion on the CLH proposal for Aluminium-magnesium-zinc-carbonate-hydroxide. The proposed classification is presented in Table 1 of Part II of this document.

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

### 6.1f Vinyl acetate

The Chair welcomed the representative of the dossier submitter from the German Competent Authority (MSCA) who took part in the discussions as remote participant. The Chair invited the RAC rapporteurs to present the revised draft opinion.

The harmonised classification and labelling for this substance was agreed at the Technical Committee for Classification and Labelling (TC C&L) under the previous legislation. It was considered that the additional proposal from the dossier submitter to have two entries for Vinyl acetate, one for the stabilised form and one for the non-stabilised form (proposed to be additionally classified with EUH019/R19) was not appropriate. RAC concluded that the Note D in the current Annex VI entry for vinyl acetate takes sufficiently care of the concern of dangerous polymerisation and that only one entry should be included in Annex VI for vinyl acetate. Applying EUH019 / R19 together with Note D would create inconsistencies in Annex VI. RAC members proposed this issue to be included into the Manual of Conclusion and Recommendations (MoCR) as example. RAC members also proposed to include Vinyl acetate in the MoCR as an example of classification for local carcinogenicity.

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

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

### 6.1g Flufenoxuron

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

All comments had been addressed in the revised draft opinion. RAC took note of the written comment on the lack of a corresponding hazard statement in CLP for R33 when it should be used together with R64. This hazard statement does not have an equivalent under the CLP.

The ECPA stakeholder observer supported the conclusions of the opinion.

RAC members suggested that the interpretation of haematological effects as not sufficient to reach criteria for STOT RE, should be considered for inclusion in the updated MoCR.

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

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

## 6.2 CLH Dossiers for first discussion

### 6.2a Penconazole

RAC discussion on the first draft opinion was postponed to the next RAC meeting (RAC-17).

### 6.2b Nitrobenzene

RAC discussion on the first draft opinion was postponed to the next RAC meeting (RAC-17).

### 6.2c Di-n-hexyl phthalate (DnHP)

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

Currently there is for this substance no entry in Annex VI of the CLP Regulation. The classification proposal provided relates to the reproductive toxicity of the substance. Support of the proposal was expressed during public consultation specifically on the justifications on developmental toxicity and on fertility provided by the dossier submitter (DS). Specific Concentration Limits (SCLs) were not proposed. The

rapporteurs emphasised that they may need to be entered into the opinion at a later stage, if applicable, once the draft guidance update on this issue is finalised.

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

### 6.2d Pitch, coal tar, high temp. (CTPHT)

The Chair invited the RAC rapporteurs to present the first draft opinion on the CLH proposal submitted by the Netherlands. The first draft opinion supports the proposal agreed under TC C&L, in its assessment for carcinogenicity (Carc. 1A, CLP), and for mutagenicity (Muta. 1B, CLP). For reproductive toxicity the draft opinion outlined a borderline case between category 1B and 2. The first discussion expressed support for the original proposal (Repr. 1B, CLP).

The environmental classification is based on the presence of PAHs in the UVCB substance CTPHT for classification of aquatic acute and aquatic chronic. The proposal by the Netherlands indicates that a specific M-factor cannot be applied due to the variable content of PAHs and should only be assigned on a case by case basis.

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

### 6.2e MMTC (trichloride of monomethyltin) and MMT(EHMA) (monomethyltin tri(2-ethylhexyl-mercaptoacetate MMT)

The Chair invited the RAC rapporteurs to present the first draft opinion on the CLH proposal submitted by France. The first draft opinion supports the dossier's proposal agreed under TC C&L in its assessment for reprotoxicity and mutagenicity for MMTC, but questions the justification of the classification proposed for these hazard classes for MMT(EHMA).

A study on hydrolysis of MMT(EHMA) to MMTC at very low pH, as presented in the dossier, does not provide an indication about the hydrolysis rate in a medium similar to the human stomach before or after food uptake. The data on environmental hydrolysis that was originally presented in the dossier before the public consultation was considered relevant in this respect. RAC requested therefore that the dossier submitter should be contacted for further clarification on hydrolysis of MMT to MMTC. The relevance of the information on hydrolysis for classification of MMT(EHMA) will be discussed in the next version of the draft opinion.

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

### 6.2f Fenamiphos

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

The dossier focuses on acute toxicity and eye irritation as preliminary agreed under TC C&L. As there is already an existing Annex VI entry for fenamiphos, the dossier submitter presented all other hazard classes for information only. In order to adapt the environmental hazards of the substance with the criteria of the second ATP, the preparation of the draft opinion will require more specific information on key studies.

The Chair thanked the (co-)rapporteurs for their presentations and invited RAC members to provide comments on the first draft opinion and its annexes once it is available. See also section 6.2f of Part II of this document.

### 6.2g Anticoagulant rodenticides

The Chair invited the RAC rapporteurs to present the preliminary outcome of the accordance checks of the group of eight anticoagulants, used as rodenticides, submitted by eight different CAs, namely the Danish, Irish, Spanish, Italian, Dutch, Finish, Swedish, and Norwegian. The (co-)rapporteurs alerted the RAC members on the following issues they encountered while preparing the accordance check report.

Warfarin is an anticoagulant rodenticide which is an established human teratogen classified as Repr. Cat. 1; R61 (DSD) (Repr. 1A, H360D (CLP)). All the anticoagulant substances have been discussed in the TC C&L in 2006-2007 and by the Specialised Experts, who unanimously agreed in September 2006, that all the eight anticoagulant rodenticides should collectively be regarded as human teratogens and classified a Repr. Cat. 1; R61 (DSD) (Repr. 1A, H360D (CLP)).
The main scientific question on this group of substances concerns the read-across to the human teratogen, warfarin. SCLs could be proposed according to the available evidence even if the draft CLP guidance is not yet finally agreed.
Furthermore it will be important to stream line the accordance checks of these dossiers to be consistent, in order to get good quality CLH reports which can facilitate the public consultation and RAC discussions on the issue of read-across for this group of substances. It is important to also agree on a similar time line for re-submissions, when needed, and on the time point for starting the public consultation for the dossiers. The (co-)rapporteurs pointed out that the dossiers failed the preliminary accordance check due to that e.g. the comparison with CLP criteria could be missing or was generally not sufficiently robust for the RAC to make an opinion, key studies may not be identified or not fully described, etc.

The Chair thanked the (co-)rapporteurs for their presentations and proposed to organise a meeting of the rapporteurs, ECHA staff experts involved in these accordance checks and the dossier submitters in order to establish efficient working relations and information exchange. It was agreed to organise the meeting and that the Secretariat will provide the required support. See also section 6.2g of Part II of this document.

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

Room document RAC/16/2011/14 was introduced by the Chair who explained that (co-)rapporteurs are required for 25 intentions of CLH dossiers. For all submitted CLH dossiers (co-)rapporteurs have been already appointed in previous meetings and via written procedures. RAC agreed to appoint as (co-)rapporteurs 11 members that had volunteered during RAC-16 for (co-)rapporteurship on 19 substances. One RAC

member announced that she would resign as RAC member in the near future because of a work position change. She informed that she had to step back from two dossiers appointed as (co-)rapporteur but could continue as (co-)rapporteur for several ongoing dossiers if agreed by RAC. RAC agreed that if the member resigns before the adoption of those opinions, she will be appointed as RAC invited expert acting as (co-)rapporteur for those ongoing dossiers. RAC members were also invited to come forward for the remaining three positions.

### 6.4 General CLH issues

#### a. State of play of the submitted CLH dossiers

RAC was informed by the Secretariat on the state of play of the submitted CLH dossiers via the room document (RAC/16/2011/10). Members were invited to contact the Secretariat if they needed further clarification.

The Chair explained that the provided document is a copy of the same document submitted to the CARACAL[3] meeting in order to reduce the Secretariat workload. Similar information is provided in the CLH tracking table regularly uploaded to the RAC CIRCA IG before the meeting. The "stay of play" document is also useful as it provides a better overview of the timings and because it enhances transparency as it is available to the regular STOs. RAC members agreed to use the documents prepared for CARACAL in the future instead of documents specifically prepared for the RAC meetings.
This practice would be applied in the future for this agenda point.

Concerning the fluorinated substances (PFOA/APFO and FTOH) an adviser to a RAC member from the dossier submitting (DS) competent authority informed RAC that the best way forward to handle these CLH dossiers was to start the discussion on a harmonised classification for PFOA/APFO, because the classification was already agreed in the former TC C&L group for these substances. After RAC agreement on those substances it would be helpful to then continue with the discussion of the CLH dossier for FTOH, since the proposed classification of FTOH is based on the classification of PFOA/APFO.

#### b. Outcome of the workshop on the classification and labelling of active substances in PPP taken place in April 2011

The Chair presented the outcome of the Workshop on Classification of Plant Protection Products (PPP), hosted by the German Federal Institute for Risk Assessment (BfR), which took place in Berlin on 12 – 13 April 2011. The workshop was organised in view of the PPP Regulation[4] that specifies strict criteria for the approval of active substances. The workshop focussed on streamlining of the processes within the legal framework of the PPP Regulation and the CLP Regulation and on practicalities concerning the preparation of dossiers. The Chair explained that the results of the workshop will be published in a workshop report. In addition, the

[3] Competent Authorities for REACH and CLP
[4] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market; OJ L 309, 24.11.2009, p. 1–50.

organising committee (COM, EFSA and ECHA and several MS experts) will also prepare a general recommendation paper on the cooperation procedure.

One member pointed out the difficulties to possibly streamline the respective documents of the CLH- and PPP-procedure, which data to extract from the Draft Assessment Report (DAR) and how to incorporate CLH data in the DAR.

One member asked whether there would be a possibility for RAC members to comment on the outline paper of the Workshop before publication.

The stakeholder organisation ECPA questioned how streamlining the processes would work out in practice for industry.

The Chair answered that all presentations of the workshop are uploaded on the RAC CIRCA IG. RAC Members will be given the opportunity to provide comments on both the workshop report and the outline paper via a dedicated Newsgroup in RAC CIRCA IG. Stakeholder's involvement in the process will be according to current practice following ECHA's stakeholders involvement procedures. The Chair also mentioned that ECHA (RAC and the Secretariat) would need to consider also the applicability of the recommendation for active substances in biocidal products.

### c. Framework for the accordance check

The Secretariat presented the RAC framework for accordance check of CLH dossiers (document RAC/16/2011/11).

RAC agreed to replace the current working procedure for accordance check of CLH dossiers by the RAC framework for accordance check of CLH dossiers.

RAC also agreed to maintain the previous working procedure for the ongoing dossiers. The Secretariat will inform RAC and apply the revised process following the agreed framework for accordance check of CLH dossiers as soon as possible.

### d. Review of the process for developing CLH opinions

As a follow-up of the outcome of the Workshop 'On the way to CLH' the Secretariat presented via an example a draft approach for restructuring the background document and RAC opinion on CLH proposals. The Secretariat explained that the idea behind keeping the text of the published CLH proposal as the basis for the background document is to avoid double writing, but nevertheless to take all comments into account, to follow the established procedures and to correctly apply the legal criteria.

A Commission observer underlined the importance of fulfilment of the legal requirements and supported the proposal to use the published CLH report as the basis for the background document, instead of a version revised by the DS after the public consultation.

Several RAC members supported the approach in general, but remarked that the details need to be worked out as well.

The Chair mentioned that the timing and the proposal are to be agreed by RAC. If agreed this would imply revision of the RAC working procedures as well.

RAC members stressed the importance of the accordance check in the proposed approach. During the accordance check, also within the agreed framework for accordance check, the completeness of the dossier and the availability of crucial data that justify the CLH proposal should be carefully checked.

The Chair summarised that the approach will be elaborated further by the Secretariat and that the results will be presented further at the forthcoming RAC meeting(s).

## 7 Restrictions

### 7.1 Restriction Annex XV dossiers

### 7.1a Phenylmercury compounds – fourth draft opinion

The Chair welcomed a representative and other remote meeting participants from the Norwegian CA (dossier submitter).

The rapporteurs presented the modifications in the 4th version of the draft RAC opinion, clarifying that all members' comments received during the RAC commenting round in May had been taken into account. Furthermore the rapporteurs thanked both the dossier submitter and the Secretariat for the good collaboration during the opinion development process.

The rapporteurs further explained key issues of the documents (organomercury alternatives; transitional period before the restriction start applying; enforcement; PBT section; calculations of emissions from manufacturing). The dossier submitter clarified why it would not have been more appropriate to restrict the specific use as catalyst – because for example the use is difficult to prove for imports into the EU.

RAC agreed not to focus on certain information on exposure (occupational, consumer) in the opinion due to remaining uncertainties. RAC also agreed to describe the uncertainties regarding the measured data on emissions from manufacturing, but not to include additional quantitative estimations of these emissions or of emissions from exported volumes coming back to the EU via long range transport.

RAC discussed how to express in the opinion their concern about potential use of other organomercury compounds as alternatives. The Secretariat provided some legal and procedural advice, explaining that it is not possible to include further substances in the scope of this restriction. The Secretariat also reminded that RAC should provide its opinion on the proposed restriction and that the issue of unsuitable alternatives would be appropriate to highlight in the justification of the opinion. RAC considered that mentioning the issue in the justification was not sufficient in this particular case, and agreed to add a statement to the opinion outlining that if the five substances subject to potential restriction were to be replaced by other organomercury compounds the restriction could become ineffective. RAC recommends considering necessary measures for verifying and controlling that other organomercury compounds are not used as alternative to the restricted substances. The COM observers confirmed that this approach was in line with their requirements for using the RAC opinion in their decision making process.

RAC adopted by consensus the draft opinion on this restriction proposal and took note of its supportive documentation. It was further agreed that the rapporteurs will ensure that the common supportive documentation (BD and RCOM) to the adopted RAC

opinion is in line with the adopted RAC opinion for this substance before the publication on the ECHA website.

The Chair thanked the rapporteurs and RAC members for their work and the representatives of the dossier submitter for their contributions.

### 7.1b Mercury in measuring devices

The rapporteurs presented the modifications in the 4th version of the RAC opinion and the responses to the RAC members' comments on it. Furthermore the rapporteurs thanked both the dossier submitter and the Secretariat for the good collaboration during the opinion development process.

RAC noted that only few comments had arrived on the 4th draft opinion. One comment related to the proposed derogation for historical devices. RAC agreed to take this comment on board and supported the dossier submitter proposal for replacing the derogation for measuring devices more than 50 years old on 3 October 2007 by a derogation for measuring devices which are to be displayed in exhibitions for cultural and historical purposes.

RAC took note of the rapporteurs' reply to the second Forum advice.

RAC adopted by consensus the opinion on the restriction proposal for mercury in measuring devices and took note of its supportive documentation. It was further agreed that the rapporteurs will ensure that the common supportive documentation (BD and RCOM) to the adopted RAC opinion is in line with the final RAC opinion before its publication on the ECHA website.

The Chair thanked the rapporteurs and the members for the work and the representatives of the dossier submitter for their contributions.

### 7.1c Phthalates – outcome of the conformity check

The rapporteurs gave a brief overview of the Annex XV dossier proposing a restriction for the four phthalates DEHP, DBP, BBP and DIBP5. The proposal was submitted by the Danish authorities in April 2011 and it aims to restrict the placing on the market of articles intended for use indoors and articles that may come into direct contact with the skin or mucous membranes containing the four phthalates in a concentration greater than 0.1% by weight of any plasticised material. The rapporteurs highlighted that the experience of the four previous restriction dossiers (DMFu, Lead, Hg, Phenyl-Hg) had been taken on board during the conformity check. They explained that even though the report was generally extensive, elaborated and well structured, yet the overall conclusion of the conformity check was that the dossier was found by rapporteurs not in conformity. The rapporteurs clarified that the dossier was found non-conforming in particular due to deficiencies in i) the description of the scope of the restriction proposal, ii) hazard information, iii) assessment of the effectiveness of the proposal (risk reduction capacity), practicality and monitorability and iv) background information on the scope and conditions of the restriction. These reasons for non-conformity are written out in the conformity check report.

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

In addition to the aforementioned report, the rapporteurs had prepared recommendations during the conformity check process. Those recommendations do not directly relate to the conformity, but are suggestions on how to significantly improve the report.

During the discussion, some members questioned whether the lacking summary information on other endpoints than the targeted one and the choice of substance(s) for a restriction proposal should be reasons for non-conformity. Some members expressed their support for better elaboration by the dossier submitter of the hazard description, the (combined) exposure due to phthalates and the resulting effect and scope of the restriction proposal. A stakeholder observer warned that potential risks posed by the alternatives may be of concern. One member highlighted that the restriction proposal is very specific due to the number of substances, articles covered and the novel type of assessment and said it may become a precedent for similar proposals to come. Some members voiced the need for communication with the dossier submitter during the conformity check. The Chair suggested this to be considered during the revision of the restriction procedures; in collaboration with the SEAC Chair the invitation of the dossier submitters to the conformity check discussions will also be considered.

In conclusion, RAC took a decision that the Annex XV dossier proposing a restriction for four phthalates is not in conformity with the requirements of Annex XV for the RAC relevant parts, in accordance with Article 69(4) of the REACH Regulation.

### 7.2 General restriction issues

A Commission representative presented a number of preliminary comments, based on the available RAC and draft SEAC opinions and some elements, which would be of valuable help to Commission services in the decision making process (room document RAC/16/2011/17).

## 8 Authorisation

## 8.1 Formulation of RAC opinions on authorisation applications

### 8.1a Format of the opinion

The Secretariat presented the comments received on the format of an opinion and the consequent changes in the explanatory note and the format. The Secretariat indicated that the template for the format of the opinion may need to be adapted when the real applications would be received. No additional suggestions were made on the note or the format during the discussion. However, several issues were raised by RAC members on how to carry out the assessment. It was noted that these issues need to be addressed in the future meetings of RAC but that they do not in themselves affect the way the opinion is documented. It was also agreed that the format would be tried out once the first applications arrive and will be used in a flexible manner.

The Chair concluded to organise the agreement by written procedure after the discussion and possible agreement on the format on the opinion in the SEAC meeting on 14-16 June.

### 8.1b Risk assessment of non-threshold substances

The Chair gave a short introduction about non-threshold substances and the need to discuss these issues at RAC.

A RAC member presented some views and proposals for the risk characterisation and risk evaluation for non-threshold carcinogens in the upcoming authorisation process.

The discussion focussed on possible ways to approach the risk assessment and the risk characterisation of non-threshold carcinogens for evaluating appropriate risk management options, and on how can RAC provide useful information for SEAC's assessment of impact. Several possibilities were discussed.

A RAC member presented some views and proposals on the possible assessment approaches for non-threshold substances regarding environmental effects.

The discussion focussed on the difficulties of illustrating the risk for PBTs and other non-threshold substances and how RAC can provide useful information for SEAC's assessment of impact.

Both discussions confirmed the need for exploring the different options and highlighted the need for cooperation among RAC and SEAC and for informing applicants on essential elements that should be included in their applications in order to allow a proper assessment of the information by both Committees.

The Chair thanked the two RAC members for presenting the basis of the discussion.

### 8.2 Appointment of RAC rapporteurs for substances listed in Annex XIV

ECHA presented the room document (RAC/16/2011/15_rev.2) listing volunteers for rapporteurship in different pools for substances included in Annex XIV.

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

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

### 8.3 Preparation of structure of RAC opinions on authorisation applications (Closed session)

In this closed session the RAC members discussed aspects related to the assessment of authorisation applications on the basis of data submitted to ECHA during the registration process on substances subject to authorisation. The establishment of RAC working groups was suggested for each of the substances listed in Annex XIV. In the working groups RAC members could become familiar with the information relating to the potential use of these substances and alternatives, RMMs and approaches to developing opinions on these substances. This suggestion was generally supported by

the Chair and RAC. The establishment of working groups on this topic will be further discussed in the following meetings.

## 9 Guidance issues

### 9.a Update on the guidance on the application of the CLP criteria

The Secretariat presented the main elements proposed for the update of the guidance on the application of the CLP criteria. This draft update includes guidance on the setting of SCLs for human health hazards and a revision of the environmental classification criteria introduced by the publication of the 2nd ATP[6]. The 2nd ATP entered into force on 19 April 2011. The RAC consultation of this draft guidance update is planned from mid August to mid September for the environmental issues and from September to October for the health parts. The publication of the final guidance is foreseen for the end of 2011 depending on feedback and issues arising.

### 9.b Report on other guidance activities

RAC was informed by the Secretariat on other guidance activities via the room document (RAC/16/2011/12). Members were invited to contact the Secretariat if they needed further clarification.

## 10 Any other business

### a. Role of RAC STOs (Closed session)

In this closed session RAC was informed on some direct contacts from STOs to RAC members. The Chair reiterated that all contacts should be done through the RAC Secretariat and that members are suggested to inform the RAC Secretariat if they are contacted directly by STOs or third parties regarding their role as RAC members.

### b. Cooperation with other Scientific Committees and Panels

The Chair presented two requests from other Scientific Committees and Panels.

The first request from DG SANCO SCENIHR concerns a proposal for presenting the Weight of Evidence using a framework developed by the Committee.

The second request, enlarged under the umbrella of the Meetings of Chairs and Secretariats, concerns an initial EFSA project on how to express uncertainty.

RAC rapporteurs may consider using some dossiers as pilot projects for checking if these approaches could benefit and facilitate the RAC discussions.

RAC members, interested to contribute to the request, are invited to contact the Chair.

### c. Timely submission of documents for the meeting

[6] 2nd Adaptation to Technical Progress (ATP) to CLP Regulation (EC) No 286/2011 of the European Parliament and of the Council of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, OJ L 83, 30.03.2011, p. 1-53.

RAC members commented that substance related documents were available only very shortly before the RAC-meetings. The short time may have consequences for a good preparation and for a high quality of the opinions. Following the discussion on this topic, the Chair indicated that documents need to be submitted well before the meeting.

## 11 Main conclusions and Action Points of RAC-16

The Secretariat presented the main conclusions and action points of the RAC-16 plenary meeting for final comments and agreement by the Committee. All suggestions were reflected accordingly[7] 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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[7] Suggestions for inclusion in the Manual of Conclusions and Recommendations are included in the minutes rather than in the Main Conclusions and Action points.

**Part II. Conclusions and action points**

**MAIN CONCLUSIONS & ACTION POINTS**
**(Adopted at the 16th meeting of RAC)**
**(7-10 June 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/16/2011_rev.4) was adopted with some modifications. | **SECR** to upload the adopted Agenda to the RAC CIRCA IG and to the ECHA website as part of the RAC-16 minutes. |
| **3. Declarations of conflicts of interest to the Agenda** | |
| Seven members and one STO observer have declared a potential conflict of interest to different substance-related discussions on the Agenda. | - |
| **5. Requests under Article 77 (3)(c)** | |
| • **Gallium arsenide** | |
| The RAC rapporteurs gave a preliminary view on the information that has been provided in the recent public consultation concerned with carcinogenicity. RAC agreed to the timeframe proposed by the rapporteurs as follows:<br>▪ Informal half day meeting before RAC-17 (Sep 2011)<br>▪ First draft opinion RAC-17<br>▪ Second draft opinion RAC-18 (Oct 2011)<br>▪ Adoption of the RAC opinion RAC-19 (Nov 2011) | **SECR** to invite the **Rapporteurs** to prepare the first draft opinion and together to draw up the agenda for the informal half day meeting. |
| RAC was informed that despite the targeted public consultation, some comments on the | For the response to comments document, **Rapporteurs** to use the agreed wording for |

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| adopted classification on reprotoxicity were submitted. RAC agreed to use the following standard response in the RCOM for the comments received on reprotoxicity: RAC confirms that its conclusion regarding the classification of gallium arsenide for reproductive toxicity in its opinion of 25 May 2010 was based upon a proper evaluation of the data. | comments relating to reproductive toxicity, which were not the subject of the public consultation. |

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| **6. CLH** | |
| **6.1. CLH dossiers** | |
| **6.1a. White spirit dossiers** | |
| RAC adopted <u>by consensus</u> the opinion and its annexes on the CLH proposal for 3 **white spirit dossiers (stoddard solvent, type 0, type 1)**. RAC agreed to propose **white spirit dossiers** to be classified as indicated in the table 1. below. | **Rapporteurs** to check and confirm the latest version of opinion and its annexes to SECR.<br><br>**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on **white spirit dossiers (stoddard solvent, type 0, type 1)** and its annexes to the RAC CIRCA IG, and to forward them to COM and publish them on the ECHA web site after the meeting. |
| **6.1b. PHMB** | |
| RAC provisionally agreed to propose PHMB to be classified as indicated in the table 2. below. | **Rapporteur** to provide the final draft of the opinion to the **SECR**.<br><br>**SECR** to launch an editorial commenting round and the adoption by written procedure after the meeting depending on the comments received. |

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| **6.1c. Chloroform** | |
| RAC adopted by [majority/consensus] of all members having the right to vote the opinion and its annexes on the CLH proposal for chloroform. RAC agreed to propose chloroform to be classified as indicated in the table 1. below. | **Rapporteurs** to confirm the latest version of opinion and its Annexes to **SECR**.<br><br>**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on chloroform and its annexes to the RAC CIRCA IG, and to forward them to COM and publish them on the ECHA web site after the meeting. |
| **6.1d. Reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene** | |
| RAC adopted by consensus the opinion and its annexes on the CLH proposal for reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene. RAC agreed to propose reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene 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 reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene and its annexes to the RAC CIRCA IG, and to forward them to COM and publish them on the ECHA web site after the meeting. |
| **6.1e. Aluminium-magnesium-zinc-carbonate-hydroxide** | |
| RAC adopted by consensus the opinion and its annexes on the CLH proposal for Aluminium--magnesium-zinc-carbonate-hydroxide. RAC agreed to propose Aluminium--magnesium-zinc-carbonate-hydroxide to be classified as indicated in the table 1. below. | **Rapporteurs** to confirm the latest version of opinion and its Annexes to **SECR**.<br><br>**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on Aluminium-magnesium-zinc-carbonate-hydroxide and its annexes to the RAC CIRCA IG, and to forward them to COM and publish them on the ECHA web site after the meeting. |
| **6.1f. Vinyl acetate** | |
| RAC adopted by consensus the opinion and its annexes on the CLH proposal for vinyl acetate. RAC agreed to propose vinyl acetate to be classified as indicated in the | **Rapporteurs** to confirm the latest version of opinion and its Annexes to SECR. |

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| table 1. below. | **SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on vinyl acetate and its annexes to the RAC CIRCA IG, and to forward them to COM and publish them on the ECHA web site after the meeting. |
| **6.1g. Flufenoxuron** | |
| RAC adopted by consensus the opinion and its annexes on the CLH proposal for flufenoxuron. RAC agreed to propose flufenoxuron to be classified as indicated in the table 1 below. | **Rapporteurs** to confirm the latest version of opinion and its Annexes to SECR.<br><br>**SECR** to make an editorial check and consult if necessary with the rapporteur before uploading the adopted opinion on flufenoxuron and its annexes to the RAC CIRCA IG, and to forward them to COM and publish them on the ECHA web site after the meeting. |
| **6.2a. Penconazole** | |
| RAC discussion on the first draft opinion was postponed to the next RAC meeting (RAC-17). | |

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| **6.2c. Di-n-hexyl phthalate (DnHP)** | |
| RAC discussed the first draft opinion. | **Members** to post their comments on the 1st draft opinion via the RAC CIRCA IG Newsgroup by 29 June 2011.<br><br>**Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) before 20 August.<br><br>**SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption before or at RAC-17. |

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| **6.2d. Pitch, coal tar, high temp. (CTPHT)** | |
| RAC discussed the first draft opinion.<br>It was revised accordingly and uploaded to the RAC CIRCA IG | **STO** to check if the late comments distributed at the RAC-16 meeting contain new data compared to the data provided by the same organisation during public consultation.<br><br>**Members** to post their comments on the revised draft opinion via the RAC CIRCA IG Newsgroup by 28 June 2011.<br><br>**Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) before 20 August.<br><br>**SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption before or at RAC-17. |
| **6.2e. MMTC (trichloride of methyltin) and EHMA (methyltin tri(2-ethylhexyl-mercaptoacetate MMT)** | |
| RAC discussed the first draft opinion. | **SECR** to contact the DS to provide further clarification on hydrolysis of MMT (EHMA).<br><br>**Members** to post their comments on the 1st draft opinion via the RAC CIRCA IG Newsgroup by 28 June 2011.<br><br>**Rapporteurs** to revise the draft opinion documents (revised draft opinion and its annexes (BD and RCOM)) before RAC-17.<br><br>**SECR** to distribute the revised draft opinion documents to RAC when available for further discussion and possible adoption before or at RAC-17. |
| **6.2f. Fenamiphos** | |
| RAC discussed the first presentation of the data. | **Rapporteurs** to draft the first draft opinion taking the 2nd ATP |

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| | for environmental classification and RAC discussions into account.<br><br>**SECR** to distribute the first draft opinion documents to RAC when available for further discussion and possible adoption before or at RAC-17. |
| **6.2g. Anticoagulant rodenticides (brodifacoum; bromadiolone; chlorophacinone; coumatetralyl; difenacoum; difethialone; flocoumafen and warfarin) – outcome of accordance checks and follow-up** | |
| RAC discussed the accordance check reports for this group of substances. | **SECR** to finalise the draft accordance check reports.<br><br>**SECR** to organise a meeting of the **Rapporteurs,** the **SECR** and the **MSCA Dossier Submitters** (initially planed for 7th July 2011) and to prepare the next steps and timelines of the dossiers. |
| **6.3 Appointment of (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/16/2011/14_rev1). | **SECR** to upload in RAC CIRCA IG the updated document to reflect RAC appointments for CLH proposals after the meeting.<br><br>**Members** are requested to come forward for the vacant positions.<br><br>**SECR** to identify potential (co-) rapporteurs and encourage them to fill the vacant positions. |
| **6.4 General CLH issues** | |
| **6.4.a. State of play of the submitted CLH dossiers** | |
| RAC agreed to be informed on the state of play of each CLH dossier with the document prepared for CARACAL instead of a specific RAC document.<br><br>RAC requested the SECR to identify and include in the draft opinions the proposed labelling under the DSD based on the labelling requirements. | SECR to upload the confidential excel tracking table on a more frequent basis (monthly) to the RAC CIRCA IG confidential section. |

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| **6.4.b Outcome of the workshop on the classification and labelling of active substances in PPP taken place in April 2011** | |
| RAC was informed on the outcome of the workshop and the planned next steps. | SECR to upload in CIRCA IG the report of the workshop, scheduled to be distributed in July 2011. |
| **6.4.c Modification of the current procedure for the accordance check** | |
| RAC agreed to replace the current working procedure for accordance check of CLH dossiers by the RAC framework for accordance check of CLH dossiers (RAC/16/2011/11) | **SECR** to initiate the revised process following the agreed RAC framework for accordance check of CLH dossiers as soon as possible. |
| **6.4.d Review of the process for developing CLH opinions** | |
| RAC discussed the proposed approach, presented via an example. | **SECR** to elaborate the approach further, based on the RAC comments and present the results at the forthcoming RAC-meetings |
| **7. Restrictions** | |
| **7.1 Restriction Annex XV dossiers** | |
| **7.1.a Phenylmercury compounds** | |
| RAC adopted by consensus the opinion on the restriction proposal on five Phenylmercury compounds and took note on its supportive documentation (BD and RCOM). | **Rapporteurs** to ensure that the supportive documentation (BD and RCOM) is in line with the adopted RAC opinion by 20 June 2011.<br><br>**SECR** to upload the adopted opinion and its supportive documentation to the RAC CIRCA IG, to forward them to COM and publish them on the ECHA web site after the meeting. |
| **7.1.b Mercury in measuring devices** | |
| RAC adopted by consensus the opinion on the restriction proposal for mercury in | **Rapporteurs** to ensure that the supportive documentation (BD |

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| measuring devices and took note on its supportive documentation (BD and RCOM). | and RCOM) is in line with the adopted RAC opinion by 16 June 2011.<br><br>**SECR** to upload the adopted opinion and its supportive documentation to the RAC CIRCA IG, to forward them to COM and publish them on the ECHA web site after the meeting. |
| **7.1.c Phthalates- outcome conformity check** | |
| RAC decided that the Annex XV dossier proposing a restriction for four phthalates is not in conformity with the requirements of Annex XV for the relevant parts for RAC, in accordance with Article 69(4) of the REACH Regulation. The dossier was found not in conformity in particular due to shortcomings in the proposal for the restriction, in the information on hazard and risk and in the justification for restriction at community level. | **SECR** to communicate to the dossier submitter the RAC outcome of the conformity check of the dossier on four phthalates, together with the SEAC one by 15 June 2011. |
| **7.2 General restriction issues** | |
| COM presented a document on their feedback after the adoption of the first RAC opinions on restrictions. | |
| **8 Authorisation** | |
| **8.1 RAC Formulation of RAC opinions on authorisation applications** | |
| **8.1.a. Format of an opinion**<br>RAC discussed the documents and provided several suggestions. | **SECR** to consider the comments and to organise the agreement by written procedure after the SEAC discussion.<br><br>**SECR** to open a newsgroup for collecting comments until 1 August 2011 on the capacity building programme. |
| **8.1.b. Risk assessment of non-threshold substances** | **SECR** to consider the comments and to reflect on the future needs |

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| RAC discussed the issues related to non-threshold substances, based on the presentations given on non-threshold CMR as well as on PBT substances. | for RAC and SEAC related to application for authorisations. |
| **8.2 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/16/2011/15_rev.2). | **SECR** to upload in RAC CIRCA IG the updated document to reflect RAC appointments for substances listed in Annex XIV.<br><br>**SECR** to inform RAC as soon as an application for authorisation is submitted to ECHA.<br><br>**Members** may volunteer to be added to the pool of (co-) rapporteurs any time. |
| **GENERAL** | |
| - | **SECR** to upload all presentations, room documents and the RAC-16 Main conclusions and action points (i.e. this doc) to RAC CIRCA IG without delay after the meeting.<br><br>**SECR** to consider the proposals from the members for the Manual of Conclusions and Recommendations. |

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## Table 1. List of adopted classifications by RAC

### Classification & Labelling in accordance with the CLP Regulation

| Index No | International Chemical Identification | EC No | CAS No | Classification | | Labelling | | | Specific Conc. Limits, M-factors | Notes |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Hazard Class and Category Code(s) | Hazard statement Code(s) | Pictoram, Signal Word Code(s) | Hazard statement Code(s) | Suppl. Hazard statement Code(s) | | |
| 649-345-00-4 | **Stoddard solvent;**[1)]<br>**Low boiling point naphtha — unspecified;**<br>[A colourless, refined petroleum distillate that is free from rancid or objectionable odors and that boils in a range of approximately 300 oF to 400 oF.] | 232-489-3 | 8052-41-3 | Carc. 1B<br>Muta. 1B<br>STOT RE 1 (central nervous system)<br>Asp. Tox. 1 | H350<br>H340<br>H372<br>H304 | GHS08<br>Dgr | H350<br>H340<br>H372<br>H304 | | | P |
| 649-330-00-2 | **Naphtha (petroleum), hydrodesulphurized heavy;** [2)]<br>**Low boiling point hydrogen treated naphtha;**<br>[A complex combination of hydrocarbons obtained from a catalytic hydrode-sulfurization process. It consists of hydrocarbons having carbon numbers predominantly in the range of C7 through C12 and boiling in the range of approximately 90 oC to 230 oC (194 oF to 446 oF).] | 265-185-4 | 64742-82-1 | Carc. 1B<br>Muta. 1B<br>STOT RE 1 (central nervous system)<br>Asp. Tox. 1 | H350<br>H340<br>H372<br>H304 | GHS08<br>Dgr | H350<br>H340<br>H372<br>H304 | | | P |

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|---|---|---|---|---|---|---|---|---|---|---|
| **649-405-00-X** | **Solvent naphtha (petroleum), medium aliph; [3]**<br><br>**Straight run kerosine;**<br>[A complex combination of hydrocarbons obtained from the distillation of crude oil or natural gasoline. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C9 through C12 and boiling in the range of approximately 140 oC to 220 oC (284 oF to 428 oF).] | **265-191-7** | **64742-88-7** | **STOT RE 1 (central nervous system) Asp. Tox. 1** | **H372 H304** | **GHS08 Dgr** | **H372 H304** | | | |

1) *USA term for white spirit, which corresponds to white spirit type 1*
2) *White spirit type 1*
3) *White spirit type 0*

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

| Index No | International Chemical Identification | EC No | CAS No | Classification | Labelling | Concentration Limits | Notes |
|---|---|---|---|---|---|---|---|
| 649-345-00-4 | **Stoddard solvent;**[1)]<br>**Low boiling point naphtha — unspecified;**<br>[A colourless, refined petroleum distillate that is free from rancid or objectionable odors and that boils in a range of approximately 300 oF to 400 oF.] | 232-489-3 | 8052-41-3 | Carc. Cat. 2; R45<br>Muta. Cat. 2; R46<br>Xn; R48/20-65 | T<br>R: 45-46-48/20-65<br>S: 53-45-46 | | P |
| 649-330-00-2 | **Naphtha (petroleum), hydrodesulphurized heavy;**<br>[2)] **Low boiling point hydrogen treated naphtha;**<br>[A complex combination of hydrocarbons obtained from a catalytic hydrodesulfurization process. It consists of hydrocarbons having carbon numbers predominantly in the range of C7 through C12 and boiling in the range of approximately 90 oC to 230 oC (194 oF to 446 oF).] | 265-185-4 | 64742-82-1 | Carc. Cat. 2; R45<br>Muta. Cat. 2; R46<br>Xn; R48/20-65 | T<br>R: 45-46-48/20-65<br>S: 53-45-46 | | P |
| 649-405-00-X | **Solvent naphtha (petroleum), medium aliph;** [3)]<br>**Straight run kerosine;**<br>[A complex combination of hydrocarbons obtained from the distillation of crude oil or natural gasoline. It consists predominantly of saturated hydrocarbons having carbon numbers predominantly in the range of C9 through C12 and boiling in the range of approximately 140 oC to 220 oC (284 oF to 428 oF).] | 265-191-7 | 64742-88-7 | Xn; R48/20-R65 | Xn<br>R: 48/20-65<br>S: (2-)23-24-62 | | |

1) *USA term for white spirit, which corresponds to white spirit type 1*
2) *White spirit type 1*
3) *White spirit type 0*

## 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 state-ment Code(s) | Pictogram, Signal Word Code(s) | Hazard state ment Code(s) | Suppl. Hazard statement Code(s) | | |
| 602-006-00-4 | chloroform<br>trichloromethane | 200-663-8 | 67-66-3 | Carc. 2<br>Repr. 2<br>Acute Tox. 3<br>Acute Tox. 4<br>STOT RE 1<br>Eye Irrit. 2<br>Skin Irrit. 2 | H351<br>H361d<br>H331<br>H302<br>H372[8]<br>H319<br>H315 | GHS06<br>GHS08<br>Dgr | H351<br>H361d<br>H331<br>H302<br>H372[8]<br>H319<br>H315 | | | |

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

| Index No | International Chemical Identification | EC No | CAS No | Classification | Labelling | Concentration Limits | Notes |
|---|---|---|---|---|---|---|---|
| 602-006-00-4 | chloroform<br>trichloromethane | 200-663-8 | 67-66-3 | Xn; R20/22<br>Xn; R48/20<br>Xi ; R36/38<br>Carc. Cat. 3; R40<br>Repr. Cat. 3; R63 | Xn<br>R:20/22-36/38-40-48/20-63<br>S: 2-36/37 | | |

[8] The following note will be added to the Main Conclusions and Action Points document for RAC16: This Classification was missing in the agreed action point document. The correction was introduced after the minutes were consulted with RAC.

**Classification & Labelling in accordance with the CLP Regulation**

| Index No | International Chemical Identification | EC No | CAS No | Classification | | Labelling | | | Specific Conc. Limits, M-factors | Notes |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Hazard Class and Category Code(s) | Hazard statement Code(s) | Pictogram, Signal Word Code(s) | Hazard statement Code(s) | Suppl. Hazard statement Code(s) | | |
| 607-023-00-0 | vinyl acetate | 203-545-4 | 108-05-4 | Carc. 2<br>Flam. Liq. 2 (currently in Annex VI)<br>Acute Tox. 4<br>STOT SE 3 | H351<br>H225<br>H332<br>H335 | GHS02<br>GHS07<br>GHS08<br>Dgr | H351<br>H225<br>H332<br>H335 | | | D (currently in Annex VI) |

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

| Index No | International Chemical Identification | EC No | CAS No | Classification | Labelling | Concentration Limits | Notes |
|---|---|---|---|---|---|---|---|
| 607-023-00-0 | vinyl acetate | 203-545-4 | 108-05-4 | Carc. Cat. 3; R40<br>F; R11 (currently in Annex VI)<br>Xn; R20<br>Xi; R37 | F; Xn<br>R: 11-20-37-40<br>S: (2-)36/37-46 | | D (currently in Annex VI) |

## 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 state-ment Code(s) | Pictogram, Signal Word Code(s) | Hazard state ment Code(s) | Suppl. Hazard stateme nt Code(s) | | |
| 030-012-00-1 | aluminium-magnesium-zinc-carbonate-hydroxide | 423-570-6 | 169314-88-9 | Aquatic Chronic 4 | H413 | | H413 | | | |

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

| Index No | International Chemical Identification | EC No | CAS No | Classification | Labelling | Concentration Limits | Notes |
|---|---|---|---|---|---|---|---|
| 030-012-00-1 | aluminium-magnesium-zinc-carbonate-hydroxide | 423-570-6 | 169314-88-9 | R53 | R: 53<br>S: 61 | | |

## 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) | | |
| | reaction mass of 2,4,4-Trimethylpent-1-ene and 2,4,4-Trimethylpent-2-ene | 246-690-9 | 25167-70-8 | Flam. Liq. 2<br>Asp. Tox. 1<br>STOT SE 3 | H225<br>H304<br>H336 | GHS02<br>GHS07<br>GHS08<br>Dgr | H225<br>H304<br>H336 | | - | Note D |

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

| Index No | International Chemical Identification | EC No | CAS No | Classification | Labelling | Concentration Limits | Notes |
|---|---|---|---|---|---|---|---|
| | reaction mass of 2,4,4-Trimethylpent-1-ene and 2,4,4-Trimethylpent-2-ene | 246-690-9 | 25167-70-8 | F; R11<br>Xn; R65<br>R67 | F; Xn<br>R: 11-65-67<br>S: (2-)46 | - | Note D |

**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 state-ment Code(s) | Pictogram, Signal Word Code(s) | Hazard state ment Code(s) | Suppl. Hazard stateme nt Code(s) | | |
| | Flufenoxuron | 417-680-3 | 101463-69-8 | Lact.<br>Aquatic Acute 1<br>Aquatic Chronic 1 | H362<br>H400<br>H410 | GHS09<br>Wng | H362<br>H410 | | Acute M = 10 000<br>Chronic M = 10 000 | |

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

| Index No | International Chemical Identification | EC No | CAS No | Classification | Labelling | Concentration Limits | Notes |
|---|---|---|---|---|---|---|---|
| | Flufenoxuron | 417-680-3 | 101463-69-8 | R64<br>R33<br>N; R50/53 | N<br>R: 33-64-50/53<br>S: 2-22-36-37-46- 60-61 | C≥0.0025%<br>N; R50/53<br>0.00025%≤C< 0.0025%<br>N; R51/53<br>0.000025%≤C<0.00025%<br>R52/53 | |

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

**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) | | |
| | Polyhexamethylene biguanide or Poly(hexamethylene) biguanide hydrochloride or PHMB | not allocated | 27083-27-8 or 32289-58-0 | Carc.2<br>Acute Tox. 1<br>STOT RE 1 (respiratory tract, inhalation)<br>Acute Tox 4<br>Eye damage 1<br>Skin sens 1B<br>Aquatic acute 1<br>Aquatic Chronic 1 | H351<br>H330<br>H372<br>H302<br>H318<br>H317<br>H400<br>H410 | GHS05; GHS06; GHS08; GHS09<br>Dgr | H351<br>H330<br>H372<br>H302<br>H318<br>H317<br>H410 | | Acute M = 10;<br>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 |
|---|---|---|---|---|---|---|---|
| | Polyhexamethylene biguanide or Poly(hexamethylene) biguanide hydrochloride or PHMB | Not allocated | 27083-27-8 or 32289-58-0 | Carc. Cat 3<br>Xn ; R 22[8]<br>T+; R26<br>T; R48/23<br>Xi; R41<br>Xi; R43<br>N; R50/53 | T+; N<br>R: 22-26-41-43-48/23-40-50/53<br>S: 22-26-36/37/39-45-60-61 | N; R50/53: C ≥ 2.5%<br>N, R51/53: 0.25% ≤ C ≤ 2.5<br>R52/53: 0.025% ≤ C ≤ 0.25% | |

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**Part III. List of Attendees of the RAC-16 meeting (7-10 June 2011)**

| **Members** | | **ECHA staff** |
|---|---|---|
| ANDERSSON Alicja | | ATLASON Palmi |
| BARANSKI Boguslaw | | ANFÄLT Lisa |
| MURRAY Brendan (replacing Barron Thomasina | | BARRUEL Philippe |
| BJØRGE Christine | | ERICSSON Gunilla |
| BORGES Teresa | | FUHRMANN Anna |
| BRANISTEANU Radu | | HONKANEN Jani |
| Di PROSPERO FANGHELLA Paola | | KOKKOLA Leila |
| DUNAUSKIENE Lina | | KULJUKKA-RABB Terhi |
| DUNGEY Stephen | | LEBSANFT Jörg |
| GREIM Helmut | | LEFEVRE Remi |
| GRUIZ Katalin | | LUOTAMO Marita |
| HALKOVA Zhivka | | LUSCHÜTZKY Evita |
| JENSEN Frank | | MAGGIORE Angelo |
| KADIKIS Normunds | | MALM Jukka |
| LARSEN Poul Bo | | MATTHES Jochen |
| LEINONEN Riitta | | MEGAW Peter |
| LOSERT Annemarie | | MERKOURAKIS Spyridon |
| LUND Bert-Ove | | MÜLLER Birgit |
| MULLOOLY Yvonne | | NYGREN Jonas |
| NUNES Maria do Céu | | PELTOLA Jukka |
| OLTEANU Maria | | RODRIGUEZ IGLESIAS Pilar |
| PARIS Pietro | | ROGGEMAN Maarten |
| PASQUIER Elodie | | RÖCKE Timo |
| PICHARD Annick | | SPJUTH Linda |
| PINA Benjamin | | TYNKKYNEN Sallamari |
| POLAKOVICOVA Helena | | VAINIO Matti |
| PRONK Marja | | Van HAELST Anniek |
| RUCKI Marian | | SCHÖNING Gabriele |
| RUPPRICH Norbert | | TARAZONA Jose |
| SCHLUETER Urs | | |
| SCHULTE Agnes | | **Stakeholder observers** |
| SMITH Andrew | | De POORTERE Michel (Cefic) |

| | | |
|---|---|---|
| SPETSERIS Nikolaos | | LAUBER Gertraud (EMCEF) |
| STOLZENBERG Hans-Christian | | McKINLAY Rebecca (EEB) |
| TADEO José L. | | MEISTERS Marie-Louise (ECETOC) |
| Van der HAGEN Marianne | | MUNARI Tomaso (EuCheMS) |
| Van MALDEREN Karen | | MUSU Tony (ETUC) |
| | | ROWE Rocky (ECPA) |
| **Advisers to the RAC members** | | SOBALLA Volker (BusinessEurope) |
| ALESSANDRELLI Maria (adviser to Paola Di Prospero Fanghella) | | VEROUGSTRAETE Violaine (Eurometaux) |
| ANDERSEN Trine (adviser to Frank Larsen) | | WAGNER Kristina (Eurogroup for Animals) |
| EKOKOSKI Elina (adviser to Riitta Leinonen) | | |
| ESPOSITO Dania (adviser to Pietro Paris) | | **Other observers** |
| HUSA Stine (adviser to Christine Bjørge) | | BARNS Emma (an observer accompanying the nominated ECPA observer for penconazole) |
| KORATI Safia (adviser to Karen van Malderen) | | COHEN Samuel (an observer acting as an expert to an observer representing CEFIC for PHMB) |
| Lindeman Birgitte (adviser to Marianne van der Hagen) and adviser supporting rapporteurs on 5 Gallium | | GAOU Isabelle (an observer acting as an expert to an observer representing CEFIC for chloroform) |
| PECZKOWSKA Beata (adviser to Boguslaw Baranski) and adviser to supporting rapporteurs on 6.2.f Anticoagulant) | | HARTNIK Thomas (Norwegian dossier submitter representative for Phenylmercury) |
| | | McKEE Richard (an observer acting as an expert to an observer representing CEFIC for white spirit) |
| **Invited Experts** | | |
| Le CURIEUX-BELFOND Olivier (RAC rapporteur for restricion dossier for phenylmercury compounds and CLH dossiers for FTOH, Propiconazole, Penconazole) | | **Remote participants** |
| VILANOVA Eugenio (RAC rapporteur for CLH dossiers for Benzoic acid, P-tert-butylphenol, Proquinazid) | | BAUMBUSH Angelika (a representative of the Norwegian CA following Phenylmercury (AP 7.1.a) |
| | | BRIGNON Jean-Marc (a SEAC rapporteur following restrictions (AP 7.1) |
| **Representatives of the Commission** | | CONWAY Louise (adviser to Yvonne Mullooly following CLH dossiers) |
| | | DOBEL Shima (adviser to Yvonne |

| | | |
|---|---|---|
| | | Mullooly following CLH dossiers) |
| BINTEIN Sylvain (DG ENV) | | FANKHAUSER Simone (a SEAC rapporteur following restrictions (AP 7.1) |
| Bouvier d´Yvoire Michel (DG ENTR) | | FIORE Karin (a SEAC rapporteur following restrictions (AP 7.1) |
| | | HERBST Uta (a representative of the German CA following Vinyl acetate (AP 6.1.f) |
| SCAZZOLA Roberto (DG ENTR) | | HERZLER Matthias (a representative of the German CA following Vinyl acetate (AP 6.1.f) |
| WISTUBA Christine (DG ENV) | | KOPANGEN Marit (a representative of the Norwegian CA following Phenylmercury (AP 7.1.a) |
| | | LANGTVET Espen (a representative of the Norwegian CA following Phenylmercury (AP 7.1.a) |
| | | LUTTIKHUIZEN Cees (a SEAC rapporteur following restrictions (AP 7.1) |
| | | MORKA Heidi (a representative of the Norwegian CA following Phenylmercury (AP 7.1.a) |
| | | SMITH Colin (adviser to Yvonne Mullooly following CLH dossiers) |
| | | THIELE Karen (a SEAC rapporteur following restrictions (AP 7.1) |

## Part IV. LIST OF ANNEXES

**ANNEX I** Final Agenda of the RAC-16 meeting

**ANNEX II** List of documents submitted to the Members of the Committee for Risk Assessment for the RAC-16 meeting

06 June 2011
**RAC/A/16/2011**

# Final Agenda

## 16th meeting of the Committee for Risk Assessment

## 07 – 10 June 2011
## Helsinki, Finland

**07 June: starts at 9:00**
**10 June: ends at 13:00**

**Item 1 – Welcome & Apologies**

**Item 2 – Adoption of the Agenda**

***RAC/A/16/2011***
***For adoption***

**Item 3 – Declarations of conflicts of interest to the Agenda**

**Item 4 – Administrative issues and information items**

a. Status report on the RAC-15 action points
b. Outcome of written procedures
c. Report from other ECHA bodies and activities

***RAC/16/2011/13***
***ROOM DOCUMENT***
***For information***

**Item 5 – Requests under Article 77 (3)(c)**

- Gallium arsenide

***For discussion***

**Item 6 – CLH**

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

a. White spirit dossiers

***For adoption***

b. PHMB (poly(iminoimidocarbonyl)iminohexamethylene hydrochloride)

***For adoption***

c. Chloroform

***For adoption***

d. Reaction mass of 2,4,4-trimethylpent-1-ene and 2,4,4-trimethylpent-2-ene

***For adoption***

e. Aluminium-magnesium-zinc-carbonate-hydroxide

***For adoption***

f. Vinyl acetate

***For adoption***

g. Flufenoxuron

***For adoption***

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

a. Penconazole

***For first discussion***

b.

c. Di-n-hexyl phthalate

***For first discussion***

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

***For first discussion***

e. MMTC (trichloride of methyltin) and EHMA (methyltin tri(2-ethylhexyl-mercaptoacetate MMT)

***For first discussion***

f. Fenamiphos

***For information***

g. Anticoagulant rodenticides (brodifacoum; bromadiolone; chlorophacinone; coumatetralyl; difenacoum; difethialone; flocoumafen and warfarin) – outcome of accordance checks and follow-up

***For information***

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

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

***RAC/16/2011/14***
***ROOM DOCUMENT***
***For agreement***

**6.4 General CLH issues**

a. State of play of the submitted CLH dossiers

***RAC/16/2011/10***
***For information***

- Ammoniumpentadecafluorooctanoate (APFO); perfluorooctanic acid (PFOA) and its salts

- FTOH (1,1,2,2.tetrahydroperfluoror-1-decanol)

***For information***

b. Outcome of the workshop on the classification and labelling of active substances in PPP taken place in April 2011

***For information***

c. Framework for the accordance check

***RAC/16/2011/11***
***For agreement***

d. Review of the process for developing CLH opinions
   - Model for the CLH opinion

***RAC/16/2011/16***
***ROOM DOCUMENT***
***For information***

**Item 7 – Restrictions**

**7.1 Restriction Annex XV dossiers**

a. Phenylmercury compounds – fourth draft opinion

***For adoption***

b. Mercury in measuring devices – fourth draft opinion

***For adoption***

c. Phthalates – outcome of the conformity check

***For agreement***

**7.2 General restriction issues (if relevant)**

a. Update on intended restriction dossiers

***For information***

b. Other general issues

***RAC/16/2011/17***
***ROOM DOCUMENT***
***For information***

**Item 8 – Authorisation**

**8.1 Formulation of RAC opinions on authorisation applications**

a. Risk assessment of non-threshold substances
   - o - Carcinogenic substances
   - o - PBT substances

***For discussion***

b. Format of the opinion (if time allows)

**SEAC documents distributed for information**
***For discussion***

**8.2 Appointment of RAC rapporteurs for substances listed in Annex XIV**

***RAC/16/2011/15***
***ROOM DOCUMENT***
***For agreement***

**8.3 Preparation of structure of RAC opinions on authorisation applications (Closed Session)**

a. musk xylene
b. MDA
c. HBCDD
d. DEHP
e. BBP
f. DBP

***For information***

**Item 9 – Guidance issues**

a. Update on the guidance on the application of the CLP criteria

b. Report on other guidance activities

***RAC/16/2011/12***
***For information***

**Item 10 – Any other business**

a. Role of RAC STOs (Closed session)
b. Cooperation with other Scientific Committees and Panels

***For information***

**Item 11 – Main conclusions and Action Points of RAC-16**

- Table with main conclusions and action points from RAC- 16

***For adoption***

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ANNEX II

**Documents submitted to the members of the Committee for Risk Assessment for the RAC-16 meeting.**

| | |
|---|---|
| RAC/A/16/2011 | Final Draft Agenda |
| RAC/16/2011/10 | State of play of the submitted CLH dossiers |
| RAC/16/2011/11 | Framework for the accordance check |
| RAC/16/2011/12 | Report on other guidance activities |
| RAC/16/2011/13 room doc | Administrative issues and information items |
| RAC/16/2011/14 room doc | Appointment of CLH rapporteurs intentions |
| RAC/16/2011/15 room doc | Appointment of RAC rapporteurs for substances listed in Annex XIV |
| RAC/16/2011/16 room doc | Review of the process for developing CLH opinions |
| RAC/16/2011/17 room doc | General restriction issues |

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